SP1010 – Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination

Final Project Report (Revision 2)

FINAL

Contaminated Land: Applications in Real Environments (CL:AIRE)

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CONTENTS

ABBREVIATIONS

AC	Assessment Criterion / Criteria
ADE	Average Daily Exposure
ADI	Acceptable Daily Intake
AGAC	Acute Generic Assessment Criterion
AGS	Association of Geotechnical and Geoenvironmental Specialists
AIC	Akaike Information Criteria
ALARP	As Low As Reasonably Practicable
AQO	Air Quality Objective
ATSDR	Agency for Toxic Substances and Disease Registry
BGS	British Geological Survey
BMD	Benchmark Dose
BMDL	Lower Confidence Limit of BMD
BMDS	Benchmark Dose Software
BMR	Benchmark Response
BLRS	British Land Reclamation Society
BSI	British Standards Institution
BTS	British Toxicological Society
BW	Body Weight
C4SL	Category 4 Screening Level
CCA	Copper Chrome Arsenate
CCME	Canadian Council of Ministers of the Environment
CECA	Civil Engineering Contractors Association
CF	Concentration Factor
CIA	Chemical Industries Association
CIEH	Chartered Institute of Environmental Health
CIWEM	Chartered Institute of Environmental and Water Management
CLEA	Contaminated Land Exposure Assessment
CLIS	Contaminated Land information Sheet
COC	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
CR	Consumption Rate
CSAF	Chemical Specific Adjustment Factor
CSM	Chemical Specific Margin
DBaIP	Dibenzo[a,l]pyrene
DCLG	Department for Communities and Local Government
Defra	Department for Environment, Food and Rural Affairs
DL	Dust Loading Factor
DNA	Deoxyribonucleic acid
DQRA	Detailed Quantitative Risk Assessment
dw	dry weight
EA	Environment Agency
EAW	Environment Agency Wales
EF	Exposure Frequency
EFSA	European Food Safety Authority
EIC	Environmental Industries Commission
ELCR	Excess Lifetime Cancer Risk
EPUK	Environmental Protection UK
FERA	Food and Environment Protection Agency
FSA	Food Standards Agency

fw	fresh weight
GAC	Generic Assessment Criteria / Criterion
GQRA	Generic Quantitative Risk Assessment
HBGV	Health Based Guidance Value
HBF	Home Builders Federation
HCA	Homes and Communities Agency
HCV	Health Criteria Value
HF	Homegrown Fraction
HPA	Health Protection Agency
HSL	Health and Safety Laboratory
HTDS	Human Toxicological Data Sheet
IA	Impact Assessment
IARC	International Agency for Research on Cancer
ICE	Institution of Civil Engineers
ID	Index Dose
IES	Institution of Environmental Sciences
IGHRC	Interdepartmental Group on the Health Risks from Chemicals
IPCS	International Programme on Chemical Safety
IR	Intake Rate
JECFA	Joint Expert Committee on Food Additives
LCD	Lifetime Cumulative Dose
LLTC	Low Level of Toxicological Concern
LMWP	Low Molecular Weight Proteins
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
MDI	Mean Daily Intake
MOE	Margin of Exposure
MRL	Minimal risk Level
NBC	Normal Background Concentration
NCB	National Childrens Bureau
NHBC	National House Building Council
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NRW	Natural Resources Wales
NWBRF	Northwest Brownfield Remediation Forum
OECD	Organisation for Economic Co-operation and Development
pC4SL	Provisional Category 4 Screening Level
PDF	Probability Density Function
PHE	Public Health England
PMTDI	Provisional Maximum Tolerable Daily Intake
POD	Point of Departure
POS_{park}	Public Open Space - Park
POS_{resi}	Public Open Space - Residential
PRA	Preliminary Risk Assessment
PTWI	Provisional Tolerable Weekly Intake
RBA	Relative Bioavailability
RCF	Reverse Cumulative Frequency
RfC	Reference Concentration
RfD	Reference Dose
RICS	Royal Institution of Chartered Surveyors
RoGEP	Register of Ground Engineering Professionals
RSC	Royal Society of Chemistry

RTPI	Royal Town Planning Institute
SAGTA	Soil and Groundwater Technology Association
SCI	Society of Chemical Industry
SCL	Significant Contaminant Linkage
SEGH	Society for Environmental Geochemistry and Health
SG	Statutory Guidance
SGV	Soil Guideline Value
SILC	Specialist in Land Condition
SOM	Soil Organic Matter
SM	Surrogate Marker
SoBRA	Society for Brownfield Risk Assessment
SPOSH	Significant Possibility of Significant Harm
SR	Science Report
SSAC	Site-Specific Assessment Criterion / Criteria
TCA	Tolerable Concentration in Air
TDI	Tolerable Daily Intake
TEF	Toxic Equivalency Factor
TEQ	Toxic Equivalences
TF	Transport Factor
UCD	Urinary Cadmium Dose
UCDL	Urinary Cadmium Dose Lower Confidence Limit
UCL	Upper Confidence Limit
UF	Uncertainty Factor
UKCG	UK Contractors Group
UKELA	UK Environmental Law Association
USEPA	United States Environmental Protection Agency
WG	Welsh Government
WHO	World Health Organisation
WRAP	Waste and Resources Action Programme

TABLES

FIGURES

APPENDICES

1. INTRODUCTION

This report presents a suggested methodology for the development of Category 4 Screening Levels (C4SLs). It constitutes the primary output of Defra research project SP1010, and it incorporates feedback from both the project's Steering Group and the wider contaminated land community, via meetings, workshops and correspondence.

The project's Steering Group comprised individuals from the following organisations:

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

Engagement with the wider contaminated land community primarily took the form of three stakeholder workshops, which took place at regular intervals during the project. Attendees at the stakeholder workshops included individuals and representatives from a variety of trade and professional organisations involved in the management of land contamination, as well as local authorities, learned societies and university departments. Individuals and organisations invited to send representatives to the workshops included the following:

Association of Geotechnical and Geoenvironmental Specialists (AGS)

British Geological Survey (BGS)

British Land Reclamation Society (BLRS)

British Property Federation

British Standards Institution (BSI) - EH/4 Soil Quality Committee

British Toxicology Society (BTS)

Chartered Institute of Environmental and Water Management (CIWEM)

Chartered Institute of Environmental Health (CIEH)

Chemical Industries Association (CIA)

City of London Law Society

Civil Engineering Contractors Association (CECA)

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)

Cranfield University

Energy Institute

Environmental Industries Commission (EIC) – Contaminated Land Working Group

Environmental Protection UK (EPUK) – Land Quality Group

Geological Society of London (GeolSoc)

Greater Manchester Contaminated Land Officers Group

Health and Safety Laboratory (HSL)

Home Builders Federation (HBF)

Institution of Civil Engineers (ICE)

Institution of Environmental Sciences (IES)

Local Authorities - East Midlands Region

Local Authorities - East of England Region

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

An interim version of the methodology was published by Defra in February 2013 (Defra, 2013) and an initial final version, dated December 2014, was published in March, 2014, along with a Policy Companion Document and, more recently, two sets of peer review comments. This revised version of the final report corrects a number of minor errors which recently came to light, as detailed in the associated Erratum.

At the request of the Steering Group, this report stops short of providing "final C4SLs" for any substances but, instead, presents "provisional" values for certain test substances upon which finalised C4SLs could be based.

1.1 BACKGROUND AND OBJECTIVES

The overall objective of the C4SLs research project has been to assist the provision of technical guidance in support of Defra's revised Statutory Guidance (SG) for Part 2A of the Environmental Protection Act 1990 (Part 2A) (Defra, 2012a). Specifically, the project aimed to deliver:

- A methodology for deriving C4SLs for four generic land-uses comprising residential, commercial, allotments and public open space; and
- A demonstration of the methodology, via the derivation of C4SLs for six substances – arsenic, benzene, benzo(a)pyrene, cadmium, chromium (VI) and lead.

Part 2A was originally introduced to ensure that significant risks from land contamination to human health, property and the environment were identified and managed appropriately, with the revised SG being designed to address concerns

regarding the effectiveness and efficiency of its real-world application. Details of some of these concerns and the importance of striking the right balance between the benefits and impacts of regulatory action under Part 2A were provided in the consultation document issued by Defra in connection with the planned revisions to the SG in 2010 (Defra, 2010a). The resulting revisions to the SG were believed to address them, as described in the Ministerial foreword to the revised SG:

> *"It has been refined in order to give greater clarity to regulators as to how to decide when land is and is not actually contaminated land. It is shorter, simpler and more focused towards achieving optimum results in terms of dealing with sites most in need of remediation. Also included are various other improvements, reflecting the experience accumulated after eleven years of operating the regime and the progress in research and technology that we have seen in that time. They enable local authorities to take a more targeted approach which remains precautionary rather than a blanket approach which is over cautious."*

To help achieve a more targeted approach to identifying and managing contaminated land in relation to the risk (or possibility) of harm to human health, the revised SG presented a new four category system for considering land under Part 2A, ranging from Category 4, where there is no risk that land poses a significant possibility of significant harm (SPOSH), or the level of risk is low, to Category 1, where the risk that land poses a significant possibility of significant harm (SPOSH) is unacceptably high. More specific guidance on what type of land should be considered as Category 4 (Human Health) is provided in Paragraphs 4.21 and 4.22 of the revised SG, as follows:

"4.21 The local authority should consider that the following types of land should be placed into Category 4: Human Health:

(a) Land where no relevant contaminant linkage has been established.

(b) Land where there are only normal levels of contaminants in soil, as explained in Section 3 of this Guidance.

(c) Land that has been excluded from the need for further inspection and assessment because contaminant levels do not exceed relevant generic assessment criteria in accordance with Section 3 of this Guidance, or relevant technical tools or advice that may be developed in accordance with paragraph 3.30 of this Guidance.

(d) Land where estimated levels of exposure to contaminants in soil are likely to form only a small proportion of what a receptor might be exposed to anyway through other sources of environmental exposure (e.g. in relation to average estimated national levels of exposure to substances commonly found in the environment, to which receptors are likely to be exposed in the normal course of their lives).

4.22 The local authority may consider that land other than the types described in paragraph 4.21 should be placed into Category 4: Human Health if following a detailed quantitative risk assessment it is satisfied that the level of risk posed is sufficiently low."

The C4SLs are intended as "relevant technical tools" (in relation to Paragraph 4.21(c)) to help local authorities and others when deciding to stop further assessment of a site, on the grounds that it falls within Category 4 (Human Health).

The Impact Assessment (IA), which accompanied the revised SG (Defra, 2012b) provides further information on the nature and potential role of the C4SLs. Paragraph 47(h) of the IA states that:

"The new statutory guidance will bring about a situation where the current SGVs/GACs are replaced with more pragmatic (but still strongly precautionary) Category 4 screening levels (C4SLs) which will provide a higher simple test for deciding that land is suitable for use and definitely not contaminated land."

A key distinction between the Soil Guideline Values (SGVs) and the C4SLs is the level of risk that they describe. As described by the Environment Agency (2009a):

"SGVs are guidelines on the level of long-term human exposure to individual chemicals in soil that, unless stated otherwise, are tolerable or pose a minimal risk to human health."

The implication of Paragraph 47(h) of the IA (see above) is that minimal risk is well within Category 4 and that the C4SLs should describe a higher level of risk which, whilst not minimal, can still be considered low enough to allow a judgement to be made that land containing substances at, or below, the C4SLs would typically fall within Category 4. This reflects Paragraph 4.20 of the revised SG, which states:

"4.20 The local authority should not assume that land poses a significant possibility of significant harm if it considers that there is no risk or that the level of risk posed is low. For the purposes of this Guidance, such land is referred to as a "Category 4: Human Health" case. The authority may decide that the land is a Category 4: Human Health case as soon as it considers it has evidence to this effect, and this may happen at any stage during risk assessment including the early stages."

C4SLs, therefore, should not be viewed as "SPOSH levels" and they should not be used as a legal trigger for the determination of land under Part 2A.

1.2 UK APPROACH TO CONTAMINATED LAND RISK ASSESSMENT

As outlined in the revised SG and Defra and the Environment Agency's CLR 11 document (Defra & EA, 2004), a "staged" or "tiered" approach is recommended for assessing risks from land contamination in the UK. After each tier of assessment, a decision is made as to whether further action is required, and whether this should entail further assessment (such as gathering more data or proceeding to the next tier) or risk mitigation (such as remediation or the implementation of risk control measures).

The revised SG and CLR 11 describe three tiers of assessment:

- **Preliminary Risk Assessment (PRA).** A primary objective of a PRA is to gather as much information as possible about a site so that a *conceptual model* can be developed that represents site characteristics and shows the possible relationships between contaminants, pathways and receptors. Any possible requirement for further assessment (e.g. intrusive investigation) or remediation can then be considered on the basis of the conceptual model.

- **Generic Quantitative Risk Assessment (GQRA).** In the event that the PRA indicates the existence of *plausibly significant contaminant linkages* (and remediation is not otherwise planned), GQRA is then carried out by comparison of measured concentrations (in, for example, soil, water or soil vapour) with generic screening values appropriate for the conceptual model and pollutant linkage(s) being assessed. In simple terms, provided the measured concentrations are below appropriate generic screening criteria, the risk from the pollutant linkages(s) being assessed are unlikely to be significant. Note that GQRA often involves the application of statistical methods to estimate a representative exposure concentration for comparison against the generic screening criteria.

- **Detailed Quantitative Risk Assessment (DQRA).** If contaminant levels exceed the generic screening criteria, or if use of generic screening criteria are not appropriate for a particular site, then DQRA may be carried out and site-specific assessment criteria (SSAC) developed. The outcome of the DQRA is a final assessment regarding which, if any, of the plausible contaminant linkages identified in the PRA and GQRA should be considered significant. If any pollution linkages are considered to be significant, then consideration of remedial options, or other corrective action can take place. In the event that no significant contaminant linkages (SCLs) are identified, then no further action is normally required.

The generic screening values referred to above usually take the form of risk-based Soil Guideline Values (SGVs) or other Generic Assessment Criteria (GACs) that are most typically derived using the Environment Agency's Contaminated Land Exposure Assessment (CLEA) model, as described in the Environment Agency's SR2, SR3 and SR7 reports (EA, 2009b & c; EA, 2008). It is anticipated that C4SLs will be used in a similar manner; as generic screening criteria that can be used within a GQRA, albeit describing a higher level of risk than the SGVs.

1.3 SUMMARY OF SUGGESTED APPROACH FOR DERIVING C4SLs

The suggested approach to the development of C4SLs described herein consists of the retention and use of the CLEA framework, modified according to considerations of the underlying science within the context of Defra's policy objectives relating to the revised SG (as outlined above). Within this context, it is suggested that the development of C4SLs may be achieved in one of three ways, namely:

- By modifying the toxicological parameters used within CLEA (while maintaining current exposure parameters);
- By modifying the exposure parameters embedded within CLEA (while maintaining current toxicological "minimal risk" interpretations); and
- By modifying both toxicological and exposure parameters.

There is also a suggested check on "other considerations" (e.g., background levels, epidemiological data, sources of uncertainty) within the approach, applicable to all three options.

1.4 REPORT FORMAT

The sections that follow describe the CLEA framework and the suggested modifications that could be made to it to derive C4SLs and incorporate feedback received from the Steering Group and stakeholders. They also discuss how "other considerations" should be factored into the overall C4SL methodology while a final section summarises relevant considerations regarding the potential use of C4SLs in assessing land contamination.

The report also presents details of sensitivity and probabilistic analyses that have been undertaken as part of the research, in order to help elucidate some of the uncertainty present in the exposure modelling. These are described in more detail in Appendices A and B, with other appendices comprising:

- Substance-specific reports, providing provisional C4SLs (pC4SLs) for arsenic, benzene, benzo(a)pyrene, cadmium, chromium (VI) and lead; and
- Review of the CIEH/CL:AIRE statistical guidance.

It is important to note that the methodology and provisional values presented herein represent the outcome of a research project and they do not, in any way, constitute formal guidance from Defra (or the consortium, or any other party). As indicated

above, further policy inputs are expected to be required in order to finalise the methodology and C4SLs (as noted in the text) and the report's findings have been designed more for discussion purposes than immediate application.

2. TOXICOLOGICAL ASSESSMENT

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

This section outlines the process of toxicological assessment for the purposes of land contamination risk assessment. It begins with a summary of the requirements of such assessments under Part 2A (in terms of the toxicological effects that are potentially relevant) and continues with a review of existing guidance to derive "minimal risk" Health Criteria Values (HCVs) under the CLEA framework (as outlined in SR2). It concludes with suggestions on how this framework could be adapted for the purpose of the development of C4SLs, presenting decisions on how such minimal risk values could be refined with further chemical-specific knowledge, to generate a new guidance value that can be regarded as meeting the requirements of the C4SLs.

Such an explicit deviation from the use of "minimal risk" levels is considered necessary in order that C4SLs can meet Defra's policy objectives outlined above. With this in mind, it should be noted that the adoption of "minimal risk" considerations is not a requirement of existing legislation or statutory guidance relating to the setting of screening criteria for use under Part 2A. Indeed, the potential usefulness of toxicological tools to derive substance-specific doses equivalent to different orders of risk, in relation to Part 2A, has been highlighted by the Royal Society of Chemistry (RSC, 2009).

It is suggested that a new term is defined for the toxicological guidance values associated with the derivation of C4SLs – a Low Level of Toxicological Concern (LLTC). An LLTC should represent an intake of low concern that remains suitably protective of health, and definitely does not approach an intake level that could be defined as SPOSH.

2.1 SIGNIFICANT HARM

When selecting critical study endpoints on which to base toxicological risk assessment for land contamination, it is important to consider whether such endpoints are relevant to assessing significant harm under Part 2A. The new Part 2A statutory guidance (April 2012) describes what types of harm to human health should be considered "significant" in relation to land contamination, as summarised in Table 2.1 below.

Table 2.1: Part 2A Statutory Guidance Definition of Harm to Human Health

	Part 2A Environmental Protection Act 1990 New Statutory Guidance 2012
Always considered as significant harm	Death
	Life threatening diseases (cancers)
	Serious injury caused by the chemical or biochemical properties of the substance, such as injury resulting from explosive or asphyxiating properties of gases
	Birth defects
	Impairment of reproductive functions
	Other diseases likely to have serious impacts on health
May or may not constitute significant harm	Physical injury
	Gastrointestinal disturbances
	Respiratory tract effects
	Cardiovascular effects
	Central nervous system effects
	Skin ailments
	Effects on organs such as kidney or liver
	Wide range of other health impacts

2.2 EXISTING GUIDANCE ON DERIVING HEALTH-BASED GUIDANCE VALUES

This section describes the current guidance for deriving Health-Based Guidance Values (HBGV) that are defined as the estimated dose in humans that is without appreciable risk over a lifetime. Examples of HBGVs include a tolerable daily intake (TDI) used for environmental contaminants or an acceptable daily intake (ADI) used for additives or residues in food.

Similarly, the term HCV has been used to describe the level of long-term human exposure to chemicals *in soil* that is tolerable or poses a minimal risk to health. It is an umbrella term that encompasses a TDI for thresholded compounds (i.e. compounds where there is a dose below which adverse effects are not discernible in experimental studies) and index dose (ID) for non-thresholded chemicals (i.e. chemicals where there is no dose under which effects do not occur in experimental studies). HCVs represent a baseline and health protective position to minimise risks of significant harm for all people exposed (including children); *they do not represent thresholds above which an intake would be unacceptable* (EA, 2009b; Defra, 2008).

The methods used to derive HBGVs differ depending on, amongst other things, whether or not a given chemical exhibits a threshold for its critical toxicological effects and the criteria that are applied by different worldwide authorities. The remainder of this section describes the derivation of HBGVs for both threshold and non-threshold chemicals.

2.2.1 SELECTION OF THE PIVOTAL STUDY AND IDENTIFICATION OF CRITICAL ENDPOINT

The first step in the derivation of a HBGV is the selection of the pivotal study and identification of the critical endpoint from an array of toxicity studies. This is done by reviewing all available toxicology data and identifying suitable Points of Departure (PODs) in the form of No Observed Adverse Effect Levels (NOAELs), Lowest Observed Adverse Effect Levels (LOAELs) or Benchmark Doses (BMDs). The NOAEL is the highest dose at which no adverse effects are seen in the toxicity study. If a NOAEL cannot be determined from the data, due to effects being seen at even the lowest dose tested, a LOAEL is determined i.e. the lowest dose at which some adverse effects are seen. A NOAEL (or LOAEL) is determined for all good quality studies and for all endpoints, and the study with the lowest (most sensitive) value is considered to be the pivotal study. If there is more than one good study for the most

sensitive effect, the highest NOAEL (or lowest LOAEL) is selected. Care should be taken in selecting the most sensitive NOAEL and it will depend on careful consideration of relevant studies, and factors such as dose-spacing and consistency between studies. This NOAEL (or LOAEL) represents the most sensitive endpoint of toxicity and can be used as a POD to form the basis of the HBGV derivation.

It should be noted that the magnitude of a NOAEL or LOAEL is highly dependent on the dosing regimen used and endpoints measured in the original toxicity study. As a consequence, the true "no effect level" could conceivably be higher or lower than the experimental NOAEL, depending on the sensitivity of the study and the choice of endpoint. Similarly, the true dose at which effects begin to occur could be lower than the experimental LOAEL. This makes a NOAEL or LOAEL a highly uncertain value in some studies.

As an alternative approach to qualifying hazard, a BMD may be derived. This is the dose that produces a predetermined change in response, the Benchmark Response (BMR), for a given toxicological effect. For risk assessment purposes, the 95% lower confidence limit of the BMD (BMDL) is often used as the POD.

The concept of the benchmark dose is illustrated below in Figure 2.1.

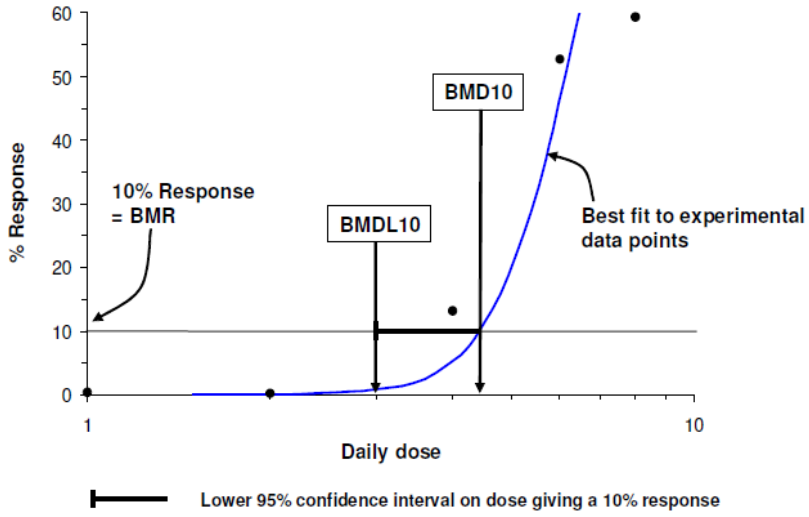


Figure 2.1: Hypothetical dose-response curve to illustrate the concepts of BMR, BMD and BMDL, for a 10% incidence response above control (taken from EFSA 2005)

The use of the BMD is beneficial as it is based on all available data of the dose response, and is on the scale of observable effects, rather than being based on one uncertain data point e.g. a NOAEL (EFSA, 2005, 2009a). However, there may be some endpoints not amenable for BMD modeling (e.g. in a study where no response is seen at any dose) for which a NOAEL approach should still be used (USEPA, 2012).

BMD modelling is being used more widely for dose-response modelling (USEPA, 1995 & 1996). In the EU, EFSA (2005) recommended the use of BMD modelling for genotoxic carcinogens, as well as other toxicity endpoints, as the method of choice to derive a quantitative POD. A citation from EFSA (2005) indicates the main scientific rationale as to why a BMD is considered a better choice than a NOAEL for quantitative risk assessment, as follows:

> *"…..the Scientific Committee concludes that the BMD approach is a scientifically more advanced method to the NO(A)EL …..it makes extended*

use of available dose-response data and it provides a quantification of the uncertainties in the dose-response data."

The UK COC also recommends the use of the BMD approach for the interpretation of carcinogenicity dose-response data (COC, 2012). The BMD refers to central estimates for continuous and dichotomous endpoints, based on a predefined level of response above background (the BMR). For dichotomous endpoints e.g. incidence data such as carcinogenic endpoints, an incidence of 10% is commonly used largely due to the 10% response being at or near the limit of sensitivity in most cancer bioassays (Benford *et al*., 2010). A default BMR of 5% is recommended by EFSA for continuous data e.g. an increase in kidney/liver enzymes (EFSA, 2009). A lower BMR for either dichotomous or quantal data could be used if the study has greater sensitivity or is considered biologically relevant (eg. for lead, a BMR of 1% has been selected by EFSA, 2010 and for arsenic a BMR of 0.5% has been able to be calculated for lung carcinogenicity effects (WHO, 2011)). It is also possible to calculate a higher BMR value that represents an incidence rate of effect higher than 10%. A quantitative selection for the incidence rate that can be determined from the sensitivity and quality of the dataset is a scientific judgment based on the data. To date, toxicology data for only a few land contaminants have been interpreted using BMD modeling, and this approach has not formed the basis of any published HCVs (although the HPA's Contaminated Land Information Sheet publication on benzo[a]pyrene/PAHs adopts this approach).

2.2.2 DEALING WITH UNCERTAINTY

In order to derive a HBGV for a given substance, the selected POD is divided by a measure of uncertainty in order to derive an estimated intake for humans that is judged to be protective of public health. The Uncertainty Factors (UFs) or margin (i.e. the difference between the POD and exposure intake) selected depend upon the quality and type of toxicity study, the species used in the pivotal study and the nature of the critical endpoint. The incorporated uncertainty aims to account for potential differences in the human response to the chemical compared to the species used in the toxicity study, and also variability in human responses due to age, genetic factors and health status.

Threshold chemicals

For all thresholded chemicals, an UF approach is recommended (COT, 2007). The recent COC (2012) guidance also advocates the use of such an approach, which has not changed from the COC guidance of 2004 on which SR2 is based. The choice of UFs depends on the quality of the animal data and the uncertainties in the evaluation of the toxicological data (COT, 2007; COC, 2012).

When basing a HBGV on a NOAEL from a chronic animal study, a default UF of 100 is typically used, consisting of a factor of 10 for interspecies variability (4 for toxicokinetics[1] and 2.5 for toxicodynamics[2]) and 10 to account for intraspecies differences (3.2 for toxicokinetics and 3.2 for toxicodynamics) (EFSA, 2012a; IPCS, 2005). Put another way, the first factor of 10 is assumed to move the dose response curve in the test species to an exposure value for the average human (taking account of the fact that the true no effect level in average humans could actually be 10-fold less than the animal NOAEL, given toxicokinetic and toxicodynamic differences); and the second factor of 10 is assumed to move an exposure value in the average human to a value that will cover the whole population, including sensitive sub-groups (Walton *et al*., 2001).

[1] Toxicokinetics - the rates that chemicals pass into, through and out of the body's organs.

[2] Toxicodynamics - the interactions the chemicals have with molecules, cells and organs of the body.

In many cases, the use of default UFs that are generic and not chemical- or species-specific will result in conservative HBGVs being derived, as the underlying data supporting them are generic and show wide variability. Default UFs may not take into consideration the sensitivity of the animal used in the toxicity study, the number of doses used, the interval between doses, the number of animals per dose group and the choice of toxicological endpoint (Health Council of the Netherlands, 2008). An alternative approach may therefore be to define chemical specific adjustment factors (CSAFs) on a case by case basis, making each uncertainty and its associated factor transparent. For example, the CSAF will replace the default UF if suitable data are available showing differences in target organ exposure in animals and humans, therefore enabling the toxicokinetic factor to be amended (IPCS, 2005). As indicated above, evidence suggests that a distinction should be made between toxicokinetic and toxicodynamic components, as both can contribute to species differences, although variations between animals and humans are often due to absorption, distribution, metabolism and excretion (toxicokinetic factors) (Health Council of the Netherlands, 2008).

SR2 already supports the use of CSAFs for thresholded substances and states the following in relation to this issue:

Box 2.4 Uncertainty factors

Uncertainty factor is the generic term used in the UK for the numerical factors applied to toxicity data (points of departure) to take into account the uncertainty in extrapolating the data to derive HCVs for humans. Various terms are used by different organisations to denote such factors, including **safety factor**, **variability factor**, **assessment factor** and others. These terms are generally interchangeable. In some cases, however, it may not be uncertainty that dictates the application of the factor, but rather evidence that humans or a human subpopulation are more sensitive than the subjects (either animal or human) of the critical study. Similarly, there may be evidence of decreased sensitivity of the target population relative to the test population, in which case a smaller than usual factor may be applied. Where the difference in sensitivity of the test and target populations to a particular chemical is known and can be quantified or estimated, a **chemical-specific adjustment factor** is applied (see IPCS, 2005).

Moreover, for non-genotoxic carcinogens, the COC also advocates that default factors could be replaced in part or in full by CSAFs if the available data provide adequate information on interspecies or human variability (COC, 2012; Meek *et al.*, 2002).

Non-threshold chemicals

Some chemicals exhibit an effect that does not have an observable threshold (i.e. there is no dose under which effects do not occur in experimental studies). This is often a cancer related effect but may also include other endpoints (e.g. neurobehavioural toxicity for lead also shows no threshold in human epidemiological studies). Specifically, 'genotoxic carcinogens' that are seen to damage DNA in genotoxicity assays are chemicals that are considered to have no threshold dose. For these substances, all doses however small, may carry a risk of effect, even at the level of minimal risk described in SR2.

The principle of "As Low As Reasonably Practicable" (ALARP) automatically applies to the regulation and management of non-threshold chemicals in the UK. It is important to note that ALARP remains the overriding principle even when a margin of exposure or minimal risk level suggests there is unlikely to be a concern for human health (COC 2012; EA 2009b). What is considered practicable is a remediation/risk management decision.

SR2 is based on guidance from the COC in 2004. This has now been superseded as of October 2012, as the Committee on Carcinogenicity (COC) published a new guidance document (G06) for the risk assessment of chemical carcinogens (COC, 2012). However, the basic principles for defining 'minimal risk' as described in SR2

remain valid and hence that document can still be referred to for 'minimal risk' guidance. For circumstances where exposure to non-thresholded chemicals is unavoidable, COC (2012) states:

> 'For carcinogens which do not show a threshold for effect, exposure should be as low as reasonably practicable (ALARP). In addition, the Committee recommends that the Margin of Exposure (MOE) approach be adopted as a tool *to indicate the level of concern* in situations where exposure is unavoidable. When it is necessary to set a standard or guideline value for a genotoxic contaminant, identification of a minimal risk level may be appropriate.'
>
> It continues: 'The derivation of a minimal risk level for a genotoxic and carcinogenic contaminant or impurity involves assessment of all available dose-response data for carcinogenicity to determine an appropriate point of departure and *use of expert judgement to identify a suitable margin between this point of departure and a level of exposure which would result in a minimal risk*. One proposal is that a suitable margin might be 10,000 (Gaylor, 1994; Gold *et al*, 2003), which parallels the margin of exposure approach, where an MOE of 10,000 is considered to be *unlikely to be of concern* when based on a BMDL10 from an animal study. For a genotoxic and carcinogenic contaminant or impurity, a comparison of the minimal risk level with estimated exposure can be informative to risk managers.'

The usual way of implementing a 'margin of exposure' approach is to divide the POD by an exposure intake value estimated using a model of the exposure scenario (e.g. that would mean to use CLEA in 'forward mode' to derive an average daily exposure (ADE) for each site assessed and compare with the POD to arrive at an MOE). One would then decide in the context of risk management as to whether the MoE was 'acceptable' or 'unacceptable'. The exposure used to calculate the MOE for a genotoxic carcinogen should be chosen carefully, and adequately justified. MoE approaches to risk characterisation are being used more widely and in particular, for the risk characterisation of genotoxic carcinogens in foods (EFSA, 2005; IPCS-WHO, 2009; EFSA, 2009a & USEPA, 1995). A joint EFSA, ILSI and WHO workshop was held in 2005, and a comprehensive list of the advantages and limitations of adopting an MOE approach was produced afterwards (EFSA, 2005).

EFSA (2005 & 2012b) have indicated that for genotoxic and carcinogenic contaminants, in general, an MOE of ≥10,000 is of low public health concern when based on a $BMDL_{10}$ from an animal study. The exact recommendations from the EFSA statement in 2012 are as follows:

> *'In the 2005 opinion, the Scientific Committee gave some guidance on how to interpret the MOE. It was stated that "The Scientific Committee is of the view that in general a margin of exposure of 10,000 or higher, if it is based on the BMDL10 from an animal carcinogenicity study, and taking into account overall uncertainties in the interpretation, would be of low concern from a public health point of view and might be reasonably considered as a low priority for risk management actions. However, such a judgment is ultimately a matter for the risk managers. Moreover an MOE of that magnitude should not preclude the application of risk management measures to reduce human exposure".*
>
> *The Scientific Committee is aware that the magnitude of an MOE only indicates a level of concern and does not quantify risk. Moreover, the implications of any MOE need to be considered case-by-case, looking at both its magnitude and the uncertainties regarding its derivation. The Scientific Committee reiterates that an MOE of 10,000 or higher is considered of low concern from a public health point of view with respect to the carcinogenic effect. As a small MOE represents a higher risk than a larger MOE, it follows that a very high MOE would be very unlikely to be of safety concern.*
>
> *However, there is at present no international consensus on banding of MOEs and corresponding descriptive terminology. When using the MOE approach for assessing impurities, EFSA Scientific Committee and Panels should describe the derivation of the MOE, its magnitude, and the associated uncertainties regarding its derivation. They should also give their view on whether the MOE is of high concern, low concern, or unlikely to be of safety concern. It will then be*

the role of the risk managers to decide whether the substance containing the impurities should be authorised.'

The UK Committee on Carcinogenicity (2007) have agreed MOE bandings for genotoxic carcinogens, for use in risk management and communication, as follows:

Table 2.2: MOE bands (as agreed by COC, 2007)

MOE band	Interpretation
< 10,000	May be a concern
10,000 – 1,000,000	Unlikely to be a concern
>1,000,000	Highly unlikely to be a concern

An MOE of 10,000 represents a default 100-fold difference between the point of departure and human exposures to allow for general differences between species and for human variability and an additional 100-fold difference has been suggested to allow for the additional uncertainties due to using a BMDL and due to the inter-individual variability in carcinogenic processes. Therefore, a MOE of 10,000 or higher when used with a $BMDL_{10}$ would be unlikely to be a concern from a public health point of view, whereas a MOE of less than 10,000 indicates that exposure 'may be of concern' (EFSA, 2005). Proposals on interpreting the magnitude of the MOE were adopted and expanded by COC and a system for banding MOE values was proposed, as above. There is no precedent set for what margin may constitute *low concern*. One suggestion proposed here for the first time, is that a generic margin of 5000 could constitute 'low concern' when using a $BMDL_{10}$. This would lead to a notional risk level of 1 in 50,000, as compared to the risk level of 1 in 100,000 used currently to represent minimal risk in contaminated land risk assessment and the derivation of SGVs. However, the choice of margin and level of concern is not a purely scientific matter, but a matter of risk management that must be agreed by a broad range of stakeholders and policy makers. Other margins could constitute low concern when used with other BMDs relating to lower BMRs (see Table 5.5).

However, it should be noted that, whilst the MOE is a usefully flexible approach for risk characterisation, the MOE approach does not lead to a HBGV as needed for input into the CLEA model . The conceptual difference between the use of guideline values versus the margin of exposure approaches in risk characterisation is well described in Figure 2 of the IGHRC CR9 (2003). In general, hazard assessment often leads to a health based guidance value such as a TDI, or in this case an LLTC. Risk characterisation is then conducted by comparing the standard with the estimated exposure. Alternatively, a comparison between the hazard assessment (i.e. the point of departure) and the exposure assessment can be made, leading to a ratio (the MOE), which can be interpreted in terms of potential risk of adverse effects. Notwithstanding this, a 'margin' approach, which parallels the MOE approach, can be implemented when setting guideline values, as described below (Section 2.2.4).

2.2.3 HCVs FOR THRESHOLD SUBSTANCES

As mentioned above, according to SR2, HCVs for threshold substances are typically referred to as TDI values in the UK. A TDI is defined as 'the estimated amount of a chemical (expressed on a body weight basis) that can be ingested daily over a lifetime without appreciable risk to health' and it is typically calculated by dividing a POD by a UF. For inhalation exposure, a tolerable concentration in air (TCA) can instead be defined, as the estimated amount of a chemical (expressed as an atmospheric concentration) that can be inhaled over a lifetime without appreciable risk. The TDIs and TCAs used in the UK are equivalent to many of the toxicological criteria used in other countries, such as JECFA's provisional maximum tolerable daily intakes

(PMTDI) and USEPA's Reference Doses (RfDs), Reference Concentrations (RfCs) and US ATSDR's Minimal risk Levels (MRLs). All of these criteria take data from a pivotal toxicology study and incorporate a value (an uncertainty or assessment factor) to account for uncertainties in the data. Differences in the choice of pivotal toxicology study and POD should be appreciated when comparing HCVs from different jurisdictions as well as their conservatism, highlighted in their choice of uncertainty factors (EA, 2009b).

2.2.4 HCVs FOR NON-THRESHOLD SUBSTANCES

According to SR2, HCVs for non-threshold effects (i.e. those chemicals whose toxic effects do not exhibit a threshold) should take the form of an ID. An ID is defined as 'a daily dose, derived for a non-threshold carcinogen, which is expected to be associated with a minimum excess risk of cancer'. IDs can be derived using two approaches, referred to in SR2 as "quantitative dose-response modeling" and "non-quantitative extrapolation". The selection of which approach to use is largely dependent on the extent and quality of data available (EA, 2009b).

Non-quantitative extrapolation has been used in SR2 to set IDs for non-threshold carcinogens using an approach which is similar to that used for threshold chemicals (i.e. a POD divided by a default UF). The POD, in the form of a BMD, is identified from relevant carcinogenicity data as the dose where effects may be observed.. As with threshold effects, the consideration of uncertainty needs to account for potential inter and intraspecies differences. However, additional factors are also included to reflect the additional uncertainties for substances that are genotoxic and carcinogenic; due to human variability in cell cycle control and DNA repair,for example, as well as the uncertainties surrounding using a reference point that is not equivalent to a NO(A)EL.

The EFSA Scientific Committee considered the application of additional measures of uncertainty to allow for the severity of an effect. Whilst this is not routinely used, it should be considered on a case by case basis as there are some examples where the toxicological effects are judged to be irreversible or particularly severe (EFSA, 2012a). The Guidelines for Drinking Water Quality (WHO, 2011), suggested that additional uncertainty may be needed for endpoints such as foetal malformations, or carcinogenicity with a non-thresholded mode of action.

For deriving guideline values for non-thresholded carcinogens, there is now strong support in COC (2012) for adopting an approach that parallels the 'margin of exposure' approach described above in section 2.2.2. The 'margin' applied to the POD is a value derived to represent a specified level of concern and is arrived at by reviewing the toxicological evidence, reviewing the uncertainties in the data (similar in approach to that above for thresholded chemicals) using expert judgment (the basis for which should be well documented) and also with good knowledge of the exposure model context and uncertainties within the exposure parameters.

The default margin of 10,000 between human exposure and a $BMDL_{10}$ from an animal study is considered to be 'unlikely to be a concern' (COC, 2007 & 2012), and echoes the way of defining minimal risk as per SR2 (EA, 2009b), DEFRA (2008) and COC (2004). Using a $BMDL_{10}$ for non-threshold carcinogenic effects divided by a default UF of 10,000 has been equated to a minimal risk level of 1 in 100,000 (EA, 2009b). If scientific evidence is available to refine the degree of uncertainty required in a chemical specific manner, lower margins than 10,000 may describe 'low' concern scenarios (EFSA 2012b).

In *quantitative dose-response modeling*, numerical approaches are used to derive an estimate of dose that corresponds to an excess lifetime cancer risk (ELCR) (EA, 2009b; DEFRA, 2008). Although this approach is used in some parts of the world (e.g. by USEPA, WHO) with data obtained from high dose animal studies, the Committee on Carcinogenicity does not recommend its use for routine risk assessment, as the models used to extrapolate data do not adequately simulate carcinogenic processes and can lead to highly variable outcomes (COC, 2004; COC, 2012). As a consequence, it is only recommended for use in the UK where there are human data,

and even then, if BMD modeling can be carried out against the dataset this should be done in preference over using an ELCR. Defra has considered that an ELCR of 1 in 100,000 (10^{-5}) based on suitable human cancer data is appropriate to represent "minimal risk" (EA, 2009b; DEFRA, 2008). Given that C4SLs are designed to represent risks which are 'low', consideration could be given to defining an ELCR that represents a 'low level of concern' in the derivation of toxicological criteria using this approach.

For non-thresholded chemicals, as explained above, the concept of ALARP automatically applies in the UK, as per the guidance in SR2, which states "The ALARP principle ensures that, irrespective of whether a health-based guideline is being breached or not, exposures are kept 'as low as reasonably practicable". What is considered practicable is a risk management decision.

2.2.5 LIFE-TIME AVERAGING

CLEA currently does not allow the user to select an averaging time greater than exposure duration but the user is able to select the age classes considered in the ADE calculations and thus can base the ADE calculations on exposure over a lifetime. As indicated in Section 3.5.1.2, averaging exposure over a lifetime can have a large influence on the ADE estimates derived by CLEA and, therefore, any guideline values derived.

Lifetime averaging as a concept arises from Haber's rule in the context of acute inhalation toxicity and is described as the concentration/dose x time of exposure = toxic effect (C x t = k). The USEPA (and others) assume that the lifetime cumulative dose (LCD) is appropriate for cancer risk assessment. When assessing less than lifetime exposure periods, it is assumed that a high dose over a shorter periods is equivalent to a low dose over a longer (lifetime) period. However, for shorter exposure periods a dose rate correction factor may be needed to correct for dose-related toxic effects and it is important that toxicokinetic factors are also taken into account (Felter *et al.*, 2011). Other authors have suggested that the risk attributable to early-life exposure often appears modest compared with the risk from lifetime exposure, but it can be about 10-fold higher than the risk from an exposure of similar duration occurring later in life (Ginsberg, 2003).

A key consideration in regards to lifetime averaging is whether there are differences in susceptibility to the chemical between children and adults. As mentioned in Section 2.2.2, the default UF of 10 for intraspecies differences already allows for variation within the human population, including specific subgroups such as children (COT, 2007). The US Food Quality Protection Act (USA, 1996) proposed the need for additional UFs to calculate HBGVs of pesticides for infants and children. Such a need is based on whether the 10-fold intraspecies UF is sufficiently protective of pregnant women, embryo/foetuses, infants and children. It has been proposed that elimination/clearance of some xenobiotics is higher in children than in adults hence in that instance children could be less sensitive as they could have lower body burden than adults for the same daily intake, when expressed on a body weight basis, and in fact, the higher elimination of the chemical may in part compensate for increased organ sensitivities during child development (Renwick, 1998). Therefore it has been suggested that an additional UF to account for infants and children is not required in relation to age-related toxicokinetics (Renwick, 1998; Renwick *et al*., 2000). Moreover, Renwick *et al*. (2003) also suggested that additional UFs would not be required if age-related differences are tested for in animal toxicology studies. The scientific evidence for making these arguments in risk assessment is not extensive however.

The current understanding of the biological processes of carcinogenesis is that young animals or children are more susceptible to many carcinogens compared to mature animals or adults (McConnell, 1992; Anderson *et al*., 2000; Birnbaum and Fenton, 2003; Ginsberg, 2003; Miller *et al*., 2002; Scheuplein *et al*., 2002). Studies in rodents being exposed to chemicals with a mutagenic mode of action suggest a decline in cancer risk with age at exposure, as the earliest two or three postnatal weeks in

rodents appear to be most susceptible (USEPA, 2005 a & b). This is due to a variety of biological mechanisms:

- There can be differences in the capacity to metabolize and eliminate chemicals, resulting in different internal doses of the active agent(s), depending on whether the parent compound or metabolite is the active agent.
- More frequent cell division during development can result in enhanced expression of mutations due to the reduced time available for DNA repair (Slikker *et al*., 2004).
- More frequent cell division during development can result in clonal expansion of cells with mutations from prior unrepaired DNA damage (Slikker *et al*., 2004).
- Key DNA repair enzymes are sometimes lacking in embryonic cells, such as brain cells.
- Some components of the immune system are not fully functional during development (Holladay and Smialowicz, 2000; Holsapple *et al*., 2003).
- Hormonal systems operate at different levels during different lifestages.
- Induction of developmental abnormalities can result in a predisposition to carcinogenic effects later in life (Anderson *et al*., 2000; Birnbaum and Fenton, 2003; Fenton and Davis, 2002).

Understanding the mode of action of the compound where a key event is likely to occur in children, as well as understanding the toxicokinetics in different life stages that may predict a sufficiently large internal dose in children, are critical in the understanding of whether children are in fact more susceptible than adults. For example, pro-carcinogens may require metabolic activation by hepatic enzymes (cytochrome P450) to exert their carcinogenic effect. The expression and activity of some cytochrome P450 isoforms in some cases has been shown to be lower in neonates and children compared to adults (Faustmann *et al.*, 2000). Therefore, in terms of pro-carcinogens, children may effectively be protected against carcinogenic metabolites due to their lower metabolic capacity. Conversely, if the parent compound exerts the toxicological effects then a reduced metabolism and elimination could result in higher body burden. Moreover, exposures to chemicals acting through a mutagenic, as well as through other modes of action could result in a greater susceptibility for the development of tumours when the exposures occur in early life stages (USEPA 2005 a & b). The COC have recently discussed the US EPA document on life stage sensitivity to carcinogens (July 2006; http://www.iacoc.org.uk/meetings/Minutes13.07.2006.htm) and concluded that at this time "there was insufficient evidence at this stage to adopt adjustment factors for genotoxic carcinogens for different life stages".

The decision to perform lifetime averaging when using CLEA is therefore not trivial, and it should be taken at the toxicology-exposure interface, with the question being considered on a chemical-by-chemical basis, where evidence permits. If there is evidence to suggest that a child could be more susceptible than an adult to a chemical's toxic effect, based on the mode of action of the chemical for the critical toxicity endpoint and child specific toxicokinetic/toxicodynamic factors, then averaging exposure over a lifetime would not be considered appropriate. Where there is an absence of evidence either way regarding the mode of action and the sensitivity of children, a precautionary position could be adopted i.e. that a child *could* be more sensitive and therefore lifetime averaging is not applied, or alternatively, lifetime averaging is adopted as there is no evidence to suggest children are more sensitive than adults. Within CLEA, the current position is the former conservative position for most chemicals, with the exception of cadmium where lifetime averaging was considered to be appropriate.

It should also be noted that the fact that children often have higher exposure to soil than adults, due to their assumed behaviour and lower body weight, is accounted for in the parameters and modeling of the CLEA model.

2.2.6 USE OF DEFAULT VALUES FOR PHYSIOLOGICAL PARAMETERS

During the derivation of toxicological criteria, it is sometimes necessary to calculate human dose estimates from chemical concentrations in water or air (e.g. drinking water standards and air quality standards/objectives). Default values for physiological parameters such as body weight, inhalation rate and drinking water consumption are used for this purpose. The body weight parameter used for derivation of a HCV in the UK is based on a 70 kg adult drinking 2 litres per day (EA, 2009b). This correlates with new guidance recently published by EFSA who stated that a body weight of 70 kg should be used as a default for the European adult population. Moreover, a 2L default value for chronic daily total liquid intake was also recommended (EFSA, 2012a).

The inhalation rate is also based on a 70 kg adult breathing 20 cubic metres of air per day (EA, 2009b).

There are deviations from these values in other parts of the world. For example, other authoritative bodies such as the World Health Organisation (WHO) use a default body weight of 60 kg (WHO, 2011).

2.3 DEFINITION OF A LOW LEVEL OF TOXICOLOGICAL CONCERN (LLTC)

As indicated above, for the purposes of defining a C4SL, it is suggested that a new term is defined – a Low Level of Toxicological Concern (LLTC) – which would correspond to a pragmatic intake level that remains sufficiently protective of health but represents a level of concern that is low. The units of the LLTC will be the same as those of the HCVs - mg kg^{-1} bw day^{-1} (unless judged otherwise) and they will be used to provide information on the toxicological aspects of a substance, as part of a range of factors to be considered in deriving a C4SL.

It could be argued that it might be simple and effective to adopt a policy decision to derive LLTCs and simply multiply the minimal risk HCVs by a factor of, say, 10. The advantage of this approach is that it would, in theory, be easy to implement, as risk assessors would not have to review the toxicology data and simply multiply the existing HCVs/GACs by a fold factor (assuming linearity and that all substances are the same). However, significant differences between substances exist in reality and there are serious downsides with this approach. If a generic fold increase were employed the resulting modified HCV for one substance may still lie within a low risk/low level of concern range but for another substance it may represent a level of concern that could be SPOSH i.e. if the dose-effects curve is steep. Also, if a small uncertainty factor was used in the derivation of the HCV e.g. 10, then applying a generic fold increase to the HCV of 10 would result in the LLTC being the same as the POD with no aspect of uncertainty being accounted for. Also, in setting the HCV, the most sensitive effect has been looked at quantitatively. Multiplying the HCV by a fold factor may then encroach on a different health effect where the dose-response curves overlap. Hence, there could be a risk of significant harm occurring, if a generic and purely numerical approach to raising the HCV to an LLTC were taken. The same would be true if increases in exposure were advocated without knowing where those exposures lie on the toxicological dose-response curve. Hence interpretation of dose response information is critical, especially when going above minimal risk. Therefore, a scientific approach to define LLTCs is recommended as described in Section 2.4 below.

2.4 SUGGESTED FRAMEWORK FOR DEFINING A LOW LEVEL OF TOXICOLOGICAL CONCERN (LLTC)

A framework for evaluating chemical-specific toxicology data for the purposes of C4SL derivation is presented in the form of a flowchart in Figure 2.2. The remainder of this section is structured to guide the reader through the flowchart by referring to, and providing further information on, its numbered elements. It is recommended that a suitably qualified individual who sufficiently understands the nature of toxicological data, collates the evidence and produces a document for each substance being considered, that works through the steps of the framework for each route of exposure.

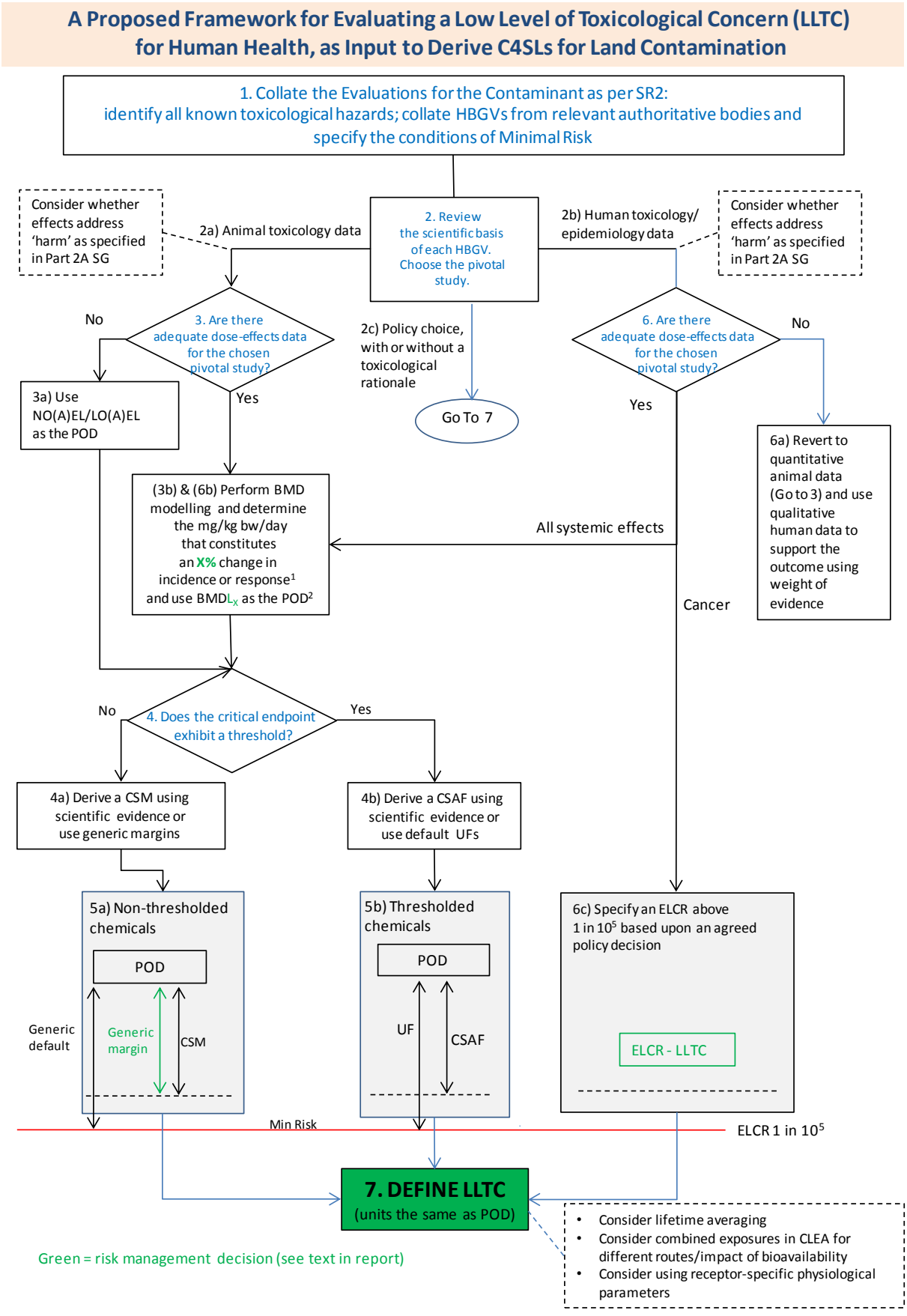


Figure 2.2: Toxicological Framework for Defining LLTCs

2.4.1 FLOWCHART ELEMENT 1: COLLATE THE EVALUATIONS FOR THE CONTAMINANT AS PER SR2: IDENTIFY ALL KNOWN TOXICOLOGICAL HAZARDS; COLLATE HBGVS FROM RELEVANT AUTHORITATIVE BODIES AND SPECIFY THE CONDITIONS OF MINIMAL RISK

The general principles described in the section above, together with the detailed methods published in SR2 and the COC guidance (2012) form the basis of defining a minimal risk HBGV that is unlikely to represent a health concern. Since the purpose of deriving an LLTC is to underpin the definition of C4SLs representing a low level of risk (at a "more pragmatic but still strongly precautionary" level above minimal risk), it is recommended that, for any substance, the minimal risk HBGV position is understood and mapped first, before attempting to derive an LLTC. This is the purpose of flowchart element 1.

It is simplest to collate a record of the information initially in spreadsheet form (for example by following the Human Toxicological Data Sheet (HTDS) template used in Appendices C to H) to provide an overview of the various existing HBGVs derived for each substance and note the underpinning basis for each HBGV. A repository of the original publically available reports, reviews and relevant data from authoritative bodies should be gathered in a data repository file electronically, as a record of all relevant publically available information for each substance. All of the identified human health hazards by the oral, inhalation and dermal routes should be noted, and where possible a POD determined from the pivotal study for the endpoint and exposure route. All of the authoritative evaluations of the substance, by worldwide organisations (as mentioned in SR2) are tabulated in descending order of the HBGV derived (as in section II of the HTDS). It should be noted that the HBGVs have not necessarily been calculated for the purposes of assessing land contamination and that they may have been derived in the context of specific accompanying exposure scenarios.

2.4.2 FLOWCHART ELEMENT 2: REVIEW THE SCIENTIFIC BASIS OF EACH HBGV. CHOOSE THE PIVOTAL STUDY.

Flowchart element 2 requires a suitably qualified individual who sufficiently understands the nature of toxicological data to review the scientific basis of all existing HBGVs and choose the pivotal toxicology study for the LLTC calculation. This should be a study that has been reviewed and recommended as good quality by an authoritative body.

Three possible options are provided for the type of pivotal study that could be chosen at this point, i.e. in the form of: 1) animal toxicology data; 2) human toxicology/epidemiology data; and 3) a policy choice (i.e. based on an existing guideline from another regime, with or without a toxicological rationale). Good quality human data should predominate as the pivotal study over animal data evaluations where both exist. Each of the three options is described in more detail below.

2a) Animal Toxicology Data

Many *in vivo* toxicological studies are available to study the effects of chemicals, including acute, sub-acute, sub-chronic and chronic toxicity tests, as well as one- and two-generational reproductive studies. For the purposes of deriving HBGVs, data from chronic toxicity tests, carcinogenicity tests, as well as reproductive studies are predominantly used, if available, as these better simulate the chronic exposure of humans to contaminants in soil. In general, *in vivo* studies should be performed in accordance with internationally accepted guidelines (e.g. OECD guidelines).

Chronic toxicity studies are used to characterise the profile of the chemical in a mammalian species (usually rodents), and to determine the dose-response relationships, following prolonged and repeated exposure to defined doses of chemical. Carcinogenicity studies are carried out to observe test animals for the majority of their life span for the development of neoplastic lesions during or after exposure to a chemical via various routes of exposure.

One-generation studies are designed to evaluate the reproductive and developmental effects that may occur following pre- and postnatal chemical exposure, as well as to assess systemic toxicity in pregnant and lactating females, and young and adult offspring. Pups are assessed for reproductive and developmental effects, developmental neurotoxicity and developmental immunotoxicity (OECD, 2012).

Two-generation studies are designed to provide general information on the effects of a chemical on the integrity and performance of male and female reproductive systems, as well as on the growth and development of offspring. Data from such a study should provide an estimation of the no-effect level and an understanding of the adverse effects on reproduction, parturition, lactation, postnatal development, growth and sexual development (OECD, 2001).

2b) Human Toxicology/Epidemiology Data

It is clearly not ethical to perform toxicology studies in humans. Therefore, much of the human dose-response data comes from epidemiology studies carried out following unavoidable chemical exposure, where humans have suffered adverse effects. Such studies are often in worker populations, where exposure to a substance has occurred within a given exposure scenario, and in population studies where people were exposed to chemicals inadvertently or in an unregulated context. It can be difficult to gain good quantitative dose-effects information from human data, but evidence of effects in man can corroborate the findings from animal studies in a weight-of-evidence approach. The most useful epidemiological data for the purposes of setting an LLTC are obtained from observational studies, such as cohort and case-control studies, in an occupational setting.

A cohort study looks at the effects that arise following exposure to a chemical. Subjects are defined according to their exposure status and followed over a period of time to assess the prevalence of health outcomes. In contrast, case-control studies select subjects on the basis of their disease status. Their potential chemical exposures are then compared with a control, non diseased group. Data from both types of study may be used as the basis of an LLTC, although in most cases, cohort studies are most relevant. If epidemiology or other human data are available, they will often take precedence over animal data, although this is largely dependent on the quality of the human data (EA, 2009b).

2c) Policy choice, with or without a toxicological rationale

Where there is not a toxicological basis on which to base the derivation of an LLTC, in the absence of evidence, a value could be based on policy decisions alone. For instance, where there are insufficient scientifically robust toxicity data to derive a POD. In such cases it would be a policy decision if and whether to go forward with stating an LLTC for the substance.

A policy driven approach may also be used in cases where the C4SL that would reflect low risk is considered unachievable in practical terms, or if it would disproportionately target exposures from soil compared with other media such as water or air. In such cases, a toxicologically-based LLTC could be derived which would then be over-ridden by a policy based LLTC that would be recommended centrally by UK government. It is advisable that the scientific evaluation is performed and communicated, such that there is transparency in providing information of the level of toxicological concern the policy-based LLTC represents.

2.4.3 FLOWCHART ELEMENT 3: ARE THERE ADEQUATE DOSE-EFFECTS DATA FOR THE CHOSEN PIVOTAL STUDY – ANIMAL DATA?

This element of the flowchart relates to the use of animal toxicology data to derive an LLTC. More specifically, it requires a suitably qualified individual who sufficiently understands the nature of toxicological data to consider whether there are adequate data from the chosen pivotal study to perform BMD modelling.

If the answer is “no”, then a NO(A)EL/LO(A)EL should be used as the POD (3a). In this case, the process would be the same as described in SR2 and COC guidance (2012).

If the answer is “yes”, then BMD modelling should be performed (3b) in order to provide a more quantitative interpretation of the data. A chemical-specific decision regarding what % increased incidence of effect i.e. the BMR is necessary.

(3a) If the answer is “no”, then the assessor should use a NOAEL/LOAEL as the POD. In this case, the process would be the same as described in SR2 (EA, 2009b) and COC guidance (2012), as the information provided in the study would be considered too weak to draw good quantitative conclusions about the dose response, or to provide robust scientific evidence of the level of risk/concern at doses higher than a single POD. Depending upon the substance and the nature of the data in the pivotal toxicology study, it may be possible to use a NO(A)EL to define minimal risk, and a LO(A)EL to define the LLTC. However, this would need to be judged on a substance by substance basis, looking at the dosing regimen used in the study. One could also consider using an value in between the NO(A)EL and the LO(A)EL (e.g. the median point).

(3b) If the answer is “yes”, then BMD modelling should be performed. As explained above, BMD modelling provides a more quantitative way of interpreting toxicology data, such that incremental increases in exposure can be aligned to an increase or decrease in continuous data as well as to an increased incidence of an effect. Therefore, if data are available, that are suitable for BMD modelling, then such modelling should indeed be carried out in order to provide a more quantitative interpretation of the data. If BMD modelling has been performed under the auspices of an authoritative body, this should be used in preference to an evaluation from the open peer review literature or performed afresh.

Benchmark dose software (BMDS) is freely available from the USEPA, as well as PROAST software developed by the Netherlands National Institute for Public Health and the Environment (RIVM) (EFSA, 2011; USEPA, 2012). Additional commercially available resources include the Excel-based Wizard and DRAGON software products developed by ICF international (USEPA, 2012). Whilst it is mathematically straightforward to use the software, accompanying technical guidance should be closely followed and care taken in modelling the data appropriately and transparently. The output is a curve from which various BMRs and their associated BMDs can be calculated as options from which to choose the POD for an LLTC calculation.

As discussed in Section 2.2.1, a decision is necessary as to what % increased incidence of effect (i.e. the BMR and associated BMD or BMDL) is considered appropriate to represent low concern for each substance. The shape of the dose-response curve may influence this choice, and advice should be sought from a person who understands the nature of the toxicology data and health effect of pivotal concern.

For the purposes of LLTC derivation, it may be considered pragmatic and precautionary from a risk management perspective to use the same BMR as used in minimal risk calculations (i.e. in most cases 10% BMR is proposed for carcinogenicity studies and 5% as a default BMR for continuous data, although this could be smaller for incidence data in epidemiology studies with large populations (EFSA 2009)). This would mean, in scientific terms, that when the BMDL (representing the lower 95th percentile confidence limit of the BMD) defines minimal risk, the BMD of the same BMR would be used as the POD for LLTC derivation wherever possible, unless there are justifiable reasons to choose otherwise. Maximally for an LLTC, based upon a widely held view in stakeholder feedback, it is also suggested that the BMR chosen should not be above 10% incidence for any effect that is chosen as a measure of low concern. However, the final choice of what level of BMR represents 'low concern' for the purposes of deriving a C4SL is a risk management choice.

2.4.4 FLOWCHART ELEMENT 4: DOES THE CRITICAL ENDPOINT EXHIBIT A THRESHOLD?

If the answer is “no”, i.e. for non-thresholded chemicals, then the assessor should look to use either a generic margin or a chemical-specific margin (CSM) if robust data are available.

If the answer is “yes” i.e. for thresholded chemicals, then the assessor should look to derive a chemical-specific adjustment factor (CSAF), if robust data are available.

The identification of whether the chemical in question exhibits a threshold for the critical toxicity endpoint is a key decision in the framework and should be made by a suitably qualified individual who understands the nature of the toxicology data.

(4a) If the answer is “no”, i.e. for non-thresholded chemicals, then a chemical-specific margin should be defined based on a scientifically defensible rationale around the uncertainties in the toxicological data and with the use of expert judgement.

A margin that would constitute ‘low concern’ for the C4SL policy objectives may be derived either generically (e.g. a set default margin to be applied to all genotoxic carcinogens) or in a chemical specific way using scientific information in the assessment of uncertainty that is specific for the chemical being evaluated in each case.**Generic margins** to be applied to all non-thresholded genotoxic carcinogens, are dependent upon the BMR and BMD(L) chosen for the POD and should be chosen on the basis of scientific knowledge. As mentioned above in Section 2.2.2, the COC (2012) propose that a suitable margin might be 10,000 as applied to a $BMDL_{10}$, for minimal risk or is ‘unlikely to be of concern’ (COC 2012). The EFSA Scientific Committee (2005) also considered this generic figure of 10,000 for a MOE with a $BMDL_{10}$ from an animal study (which parallels the COC-proposed margin approach) (EFSA 2005). Similarly, SR2 mentioned the application of a factor of 10,000 to a $BMDL_{10}$ as representing minimal risk (EA, 2009b).

A different margin representing ‘low concern’ may be chosen to apply to a BMD_{10} or $BMDL_{10}$ from animal data. For the purpose of deriving LLTCs, a generic margin of 5,000 is proposed, when a BMD_{10} is used as the POD. This leads to a notional risk level of 1 in 50,000. Other margins would need to be chosen and developed for use with BMRs lower than a 10% increased incidence of effect in order to achieve a similar notional risk level across different substance (see table 5.5), or a transparent explanation given if the resulting risk level is different across different substances.Alternatively, a **Chemical Specific Margin** (CSM) may be based on a scientifically defensible rationale around the uncertainties in the toxicological data and with the use of expert judgement. EFSA (2005) suggest the following uncertainties be considered in setting a margin of exposure.

- Intraspecies differences (human variability factors) – range 1-10
- Interspecies differences (animal to human factors) – range 1-10
- Additional uncertainties – range 1-100

Such an approach could be adopted in setting a CSM. Differences in fate and behaviour between animals and human could be amended if there are toxicokinetics/dynamic data that show there is <10-fold difference between animals and humans. Similarly, toxicokinetic/dynamic data may indicate that there is <10-fold difference between individuals. The factor of 100 covers additional uncertainties including inter-individual variability in cell cycle control and DNA repair as well as the uncertainties surrounding the use of a point of departure that does not represent a no effect level. Quality of the database/study should also be considered. Again such factors could be amended as appropriate. This approach to set a CSM would have to be carried out on a chemical specific basis. In practical terms, there is currently no guidance on how the 100-fold factor for additional uncertainties would be modified if

one had data on DNA repair or cell cycle control etc. though in qualitative ways these aspects can vary between individuals and should be accounted for, therefore it should be regarded that this application of a 100-fold assessment factor is a pragmatically applied tool to represent such uncertainty at this time.

An example of a breakdown of factors that can be used to account for specified uncertainties in a dataset, that have been used in UK Government chemical risk assessment, are shown in Table 2.3, as presented by the Interdepartmental Group on Health Risks from Chemicals (IGHRC, CR9, 2003). As shown in the table, various factors in considering the toxicology data could be amended and used to derive CSMs.

Table 2.3: Example of default factors used in UK Government risk assessment (IGHRC, 2003)

Chemical sector	Animal to human factor	Human variability factor	Quality or quantity of data factor	Severity of effect factor
Food additives and contaminants	10	10	2-10	2-10
Agricultural pesticides	10	10	2-10	2-10
Veterinary products	10	10	2-5	2-10
Air pollutants	10	10	-	-
Consumer products	10	10	2 or greater	2 or greater
Drinking water contaminants	1-10	1-10	1-10	1-10
Soil contaminants	1-10	1-10	1-10	1-10
Human medicines	1-10	1-10	1-100	-

If robust data are not available on which to make an informed decision on how to derive a CSM, then a default generic margin should be used.

(4b) If the answer is “yes” i.e. for thresholded chemicals, then the assessor should look to derive a CSAF if robust data are available. As described above, chemical specific toxicokinetic or toxicodynamic data may be used, if available, to help identify more specifically the differences in sensitivity between humans and the animals used in the toxicity study, and between different human populations (i.e. adults and children). Hence more specific factors for toxicokinetics and toxicodynamics could be used rather than the default factors of 10 (IPCS, 2005).

This is not a new concept as it was described in SR2 (EA, 2009b) as a potential methodology for deriving HCVs and has also been used by other authoritative bodies. For example, the European Food Safety Authority (EFSA) used a CSAF of 3.9 to a $BMDL_5$ to derive a urinary cadmium concentration (see Appendix F). The EA suggests that where differences in sensitivity of the test and target population to a chemical are known and can be quantified or estimated, then a CSAF may be applied i.e. humans may be more or less sensitive than the test population hence a larger or smaller factor may be applied (EA, 2009b).

If there is no additional information available that could be used, or if the available data are not considered to be robust and scientifically defensible, then default UFs should be used. For thresholded systemic toxicity, such a default factor is usually 100. There may be some cases where the UF needs to be higher than the default, if a special consideration needs to be taken into account, e.g. for sensitive subgroups.

For both threshold and non-threshold chemicals, factors for all of the individual uncertainties are simply multiplied together to contribute to an overall value for a CSM (for non-threshold chemicals) or a CSAF (for threshold chemicals), that is then applied to the POD.

2.4.5 FLOWCHART ELEMENT 5: CALCULATING THE LLTC

For non-thresholded chemicals, the LLTC is calculated by dividing the POD by the margin (either a generic margin or a CSM)

POD/margin = LLTC (units as per POD)

For thresholded chemicals, the POD is divided by a CSAF (or default UF);

POD/(CSAF or default UF) = LLTC (units as per POD)

Flowchart element 5 requires the derivation of the LLTC by performing the calculation shown above using the POD and the appropriate measure of uncertainty in the form of a margin or CSAF.

These calculations yield a fixed value based upon the uncertainties in the toxicology data for the pivotal study on which the POD is based.

2.4.6 FLOWCHART ELEMENT 6: ARE THERE ADEQUATE DOSE-EFFECTS DATA FOR THE CHOSEN PIVOTAL STUDY – HUMAN DATA?

If the answer is "no", then the assessor should revert if possible to quantitative data from animal studies. If the answer is "yes" then BMD modelling can be performed on the human data or an excess lifetime cancer risk (ELCR) can be defined.

This element of the flowchart relates to the use of human toxicological/epidemiological data to derive an LLTC. More specifically, it requires a suitably qualified individual who understands the nature of the toxicology or epidemiology data to assess whether there are adequate quantitative data from the chosen pivotal human study. If "no", then the assessor should revert to quantitative data from animal studies (6a). If the answer is "yes" then BMD modelling can be performed on the human data (6b) or an excess lifetime cancer risk (ELCR) can be defined (6c). If both have been performed, the BMD modelling route should carry more weight over an ELCR calculation, the latter of which is only a rough estimation of risk. However, worldwide authoritative bodies do use the concept of ELCR and it is useful as a comparator alongside the BMD approach.

(6b) In circumstances where there are good dose-effects relationships in human epidemiology data, they can be modelled using BMD approaches, as with animal data (see above). In such cases, as with animal data, a CSAF or margin may also be derived, which conceivably may be lower as interspecies differences do not need to be accounted for, and an LLTC may be derived. Good human data tend to carry more weight than animal data, where both are available.

(6c) As indicated above, quantitative dose-response modelling of cancer data involves the concept of ELCR, defined as:

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

From such quantitative risk estimations, relevant guidance has stated that an ELCR of 1 in 100,000 (10^{-5}) should constitute minimal risk (EA, 2009a; DEFRA, 2008). However, it is also considered in previous guidance that ELCR calculations are approximations of risk (i.e. what could be considered a rough estimate rather than an accurate prediction of risk). For the purposes of C4SL derivation, a risk estimate of 1

in 10,000 – 1 in 50,000 could be specified as 'low risk' and this would be a generic level used for all human carcinogens, irrespective of mode of action.

2.4.7 FLOWCHART ELEMENT 7: DERIVE LLTC

The definition of the LLTC has been described previously. Overall, there are 3 routes to deriving an LLTC:

- For thresholded chemicals: derivation of a human intake using POD divided by CSAFs (or default UFs). The POD can be derived from animal or human data.
- For non-thresholded chemicals: derivation of a human intake using POD divided by a recommended CSM (or default generic margin). The POD can be derived from animal or human data.
- For human carcinogens (with quantitative data): Recommendation of an intake dose based on human data that equals a specified ELCR that is considered low risk.

2.4.8 CALCULATION OF A CHILD-SPECIFIC LLTC

The use of default values for physiological parameters when deriving HBGV (in units of µg kg $bw^{-1}.day^{-1}$) from drinking water guidelines or air quality standards/objectives has been discussed in Section 2.2.6. Typically default values based on adult exposure are used, but this can introduce unnecessary conservatism where the HBGVs are compared to exposure estimates for children. For example, inhalation HBGVs ($HBGV_{inh}$) for volatile contaminants are recommended as intake values (µg kg^{-1} bw day^{-1}) for use in CLEA, and have often been based on airborne contaminant concentrations (mg m^{-3}) such as reference concentrations taken from toxicology studies (e.g. USEPA RfCs) or Air Quality Objectives AQOs/Standards. These RfCs and AQOs/Standards are generally recommended for long-term or lifetime exposure with minimal risk. The conversion from an airborne concentration to a $HBGV_{inh}$ is based on adult receptor characteristics (i.e. daily inhalation rate of 20 m^3 and 70 kg body weight) whereas the calculation of exposure for the residential land-use scenario is for a 0-6 year old child (with the default lower inhalation rate and significantly lower body weight). This approach is considered to introduce an unnecessary level of conservatism as a child's exposure relative to body weight is approximately 2-3 times higher than that for an adult. A similar situation can arise where ingestion HBGVs are based on drinking water guidelines.

For the purposes of generating the C4SL it is therefore proposed that receptor-specific LLTCs are derived where they are based on airborne contaminant concentrations such as RfCs and Air Quality Standards/Objectives (mg m^{-3}) or drinking water guidelines (mg L^{-1}). However, it is not considered appropriate to derive receptor-specific LLTCs where there is uncertainty over the how the media concentration has been derived, i.e. a media concentration may be derived from a toxicologically-derived intake value but it may not be transparent as to whether this is based on child or adult physiological characteristics and consumption or respiration rates.

Physiological parameter values and respiration rates should be based on those recommended for the relevant age class(es) for derivation of the C4SL (see Section 3) and default water consumption rates of 1 $L.day^{-1}$ for children and 2 $L.day^{-1}$ for adults.

It is recommended that adult receptor characteristics are assumed for derivation of LLTC for commercial land-use or where lifetime averaging has been assumed.

2.4.9 OTHER TOXICOLOGICAL CONSIDERATIONS

In addition to the provision of an LLTC, the toxicological evaluation should also identify whether lifetime averaging should be performed during the exposure modelling. The

same considerations that apply to lifetime averaging discussed in Section 2.2.5 for derivation of the HCVs also apply to the derivation of LLTCs.

Further consideration must also be given with regard to whether modelled exposure via different routes need to be combined for the C4SL derivation. In simple terms, if the critical effect is systemic and can be induced following absorption into the body via any route – oral, inhalation or dermal - then exposure needs to be combined, on the assumption that a person can be exposed concomitantly. If the critical effect is local (e.g. site of contact carcinogenicity), then exposure from different routes does not need to be combined.

If local effects (e.g. skin allergy, skin cancer, lung irritation etc) are of potential concern (e.g. chromium VI allergy), this should be considered during the setting of the C4SLs. In all cases of HCVs derived to date by the Environment Agency, they have been protective of any local effects occurring and it is not expected that the modest increase represented by LLTCs would lead to any significantly increased risk of harm via the local route.

It should be noted that HCVs and LLTCs have been developed for chronic exposure scenarios and are not applicable to high dose acute exposure situations.

2.4.10 COMPARISON OF LLTCs WITH HCVs

The overall LLTC derivation methodology described above contains several elements which are similar to or, conversely, differ from, current approaches to deriving “minimal risk” HCVs. Key aspects of the similarities and differences between the approaches are summarised below:

Table 2.4: Key aspects of the derivation of LLTCs and HCVs.

Aspect	HCV	LLTC
Database	Expert body evaluation from authoritative sources as listed in SR2	Expert body evaluation from authoritative sources as listed in SR2
Pivotal study	Most appropriate study as chosen by a suitably qualified individual who understand the nature of the data as described in SR2	Most appropriate study as chosen by a suitably qualified individual who understand the nature of the data as described in SR2
Critical effect	Most sensitive effect	Most sensitive effect. Care must be taken to ensure that an LLTC derived using this data does not overlap the next most sensitive effect.
POD	NO(A)EL/LO(A)EL/BMDL*	BMD*/NO(A)EL/LO(A)EL
BMR	Not used in any HCVs to date 10% (animal carcinogenicity studies); <10% could be used if data sensitivity allows.	10% (animal carcinogenicity studies); <10% BMR could be used if data sensitivity allows. Maximally a BMR of 10%.
Uncertainty evaluation - threshold chemicals	Default generic UF/CSAF	CSAF/default generic UF
Uncertainty evaluation - non-threshold chemicals (animal data)	Default 10,000	CSM or generic 5,000
Uncertainty evaluation - non-threshold chemicals (human data)	Not used in any HCVs to date	CSM or generic margin to complement choice of BMR to achieve a notional ELCR between 1 in 10,000 – 1 in 50,000
ELCR	1 in 100,000	1 in 10,000 - 1 in 50,000
Policy-driven approach where necessary, if appropriate and scientifically justified	Applicable	Applicable

* SR2 states that a BMD approach could be taken to deriving an HCV but in practice it has never been adopted. In principle, a BMDL of the lowest response seen in the study would be the minimal risk POD. For an LLTC derivation, BMD modelling is suggested as the preferred approach, if data allow.

It is important to reiterate that, although the above table summarises the generalised LLTC derivation methodology (versus that used for deriving HCVs), deviations may be appropriate for certain substances, as long as the rationale for doing so is transparent and scientifically justifiable.

3. EXPOSURE MODELLING

Exposure modelling is an integral part of the assessment of risks to human health from soil contamination. It is an attempt to mathematically represent the conceptual model of exposure (IPCS, 2008) and involves the use of equations and associated input parameter values to estimate the intake (and/or uptake) dose of contaminant to a human receptor for a given exposure scenario. There are two general approaches to exposure modelling:

- A 'forward' modelling approach can be used to predict the exposure at a site from measured or estimated soil concentrations. The exposure can then be combined or compared with toxicological dose-response data to characterise risk;
- Alternatively, a 'reverse' modelling approach can be used to estimate the theoretical soil concentration at which the estimated exposure equals some predefined toxicological benchmark.

Both approaches can be used with the CLEA model, but it is the latter approach that is used to derive soil assessment criteria, which in simplified terms, estimates the theoretical soil concentration at which the Average Daily Exposure (ADE) from soil would equal the HBGV (e.g., the HCV). This soil concentration can be adopted as a GAC (e.g., a SGV) which, depending on the input parameters used, is land-use specific. As described in Section 1.2, SGVs and/or GACs are used as part of GQRAs for comparison with measured soil concentrations at a site to help characterise risk.

As discussed in Section 1.1, the CLEA model and associated land-use and contaminant specific parameter values have been chosen by the Environment Agency to derive SGVs that represent minimal or tolerable risk. This chapter assesses what modifications to the CLEA model and associated parameter values could be considered for the derivation of C4SLs.

3.1 BRIEF OVERVIEW OF CLEA

Common to all models for quantifying exposure from soil contamination, CLEA uses a series of equations to predict, or simulate, exposure to a 'critical' receptor from a given soil concentration via a number of exposure pathways. The critical receptor is dependent on land-use. SGVs have been previously derived by Defra/the Environment Agency for three generic land-uses: residential, allotments and commercial. The critical receptor is generally assumed to be a 0 to 6 year old child for residential and allotments land-uses[3] and a 16 to 65 year old adult for commercial land-use.

CLEA considers up to ten exposure pathways (soil and dust ingestion are combined), although not all may be active depending on the generic land-use modelled (Table 3.1). Other pathways not considered within the CLEA software may also be active at a specific site, such as consumption of eggs or diffusion of contaminants through water supply pipes. As described in Environment Agency guidance on using SGVs (EA, 2009a), the assessor should assess the applicability of assessment criteria derived using CLEA in the context of the conceptual model of risk developed for the site.

[3] Cadmium is an exception. The cadmium SGVs for residential and allotments land-uses are based on exposure over a lifetime (i.e. a 0 to 75 year old) – see Section 3.5.1.2.

Table 3.1: Exposure pathways modelled in CLEA

Exposure Pathway	Generic Land-use		
	Residential	Allotments	Commercial
Direct ingestion of soil (outdoors) and dust derived from soil (indoors)	✓	✓	✓
Ingestion of soil attached to fruit/vegetables	✓	✓	
Ingestion of fruit/vegetables	✓	✓	
Dermal contact with dust derived from soil (indoors)	✓		✓
Dermal contact with soil (outdoors)	✓	✓	✓
Inhalation of dust derived from soil (indoors)	✓		✓
Inhalation of dust derived from soil (outdoors)	✓	✓	✓
Inhalation of vapours (indoors)	✓		✓
Inhalation of vapours (outdoors)	✓	✓	✓

CLEA is used for deriving assessment criteria relating to human health from chronic exposure, and as such estimates daily exposure averaged over a number of years for comparison with the HCV. This is termed the ADE and it has units of mg kg^{-1} d^{-1} for direct comparison with the HCV. The generalised equation for estimating ADE for each exposure pathway is given below:

$$ADE_i = \frac{IR_i . EF_i . ED}{BW . AT}$$

Where,

ADE_i = Average daily exposure from pathway i (mg kg^{-1} d^{-1})
IR_i = chemical intake/uptake rate for pathway i (mg d^{-1})
EF_i = exposure frequency for pathway i (d yr^{-1})
ED = exposure duration (yr)
BW = body weight (kg)
AT = averaging time (d)

CLEA averages ADE over a series of age classes assumed to cover the most relevant or sensitive life stages of the critical receptor. Where the critical receptor is a 0 to 6 year old child, 6 age classes of 1 year duration each are used (age classes 1 to 6). Where the critical receptor is a 16 to 65 year old adult (age class 17), 1 age class of 49 years duration is used. Finally, for lifetime averaging (such as the case for cadmium for residential and allotments land-uses), 18 age classes are used: age classes 1 to 16 for the 0 to 16 year old, age class 17 for the 16 to 65 year old and age class 18 for the 65 to 75 year old.

Each exposure pathway has a unique equation (or series of equations) and associated input parameters for estimating the intake rate (IR). Exposure frequency may also vary between pathways. CLEA adds up ADE for groups of pathways and compares with the HCVs for oral and/or inhalation exposure. For compounds exhibiting a threshold health effect, an allowance for background exposure from non soil sources is also included in the ADE calculation. CLEA derives two assessment criteria (AC), as follows:

- AC_{oral}. This is the soil concentration at which the sum of the ADE (for relevant pathways) equals the oral HCV[4].
- AC_{inhal}. This is the soil concentration at which the sum of the ADE (for relevant pathways) equals the inhalation HCV.

Which of these assessment criteria is used to derive the GAC or SGV is dependent on whether the toxicological effects are systemic or localised. Where both oral and inhalation HCVs are based on systemic toxicological effects, the assessment criteria are "integrated" to derive the SGV/GAC[5]. Where one or more HCV are based on localised effects, the lowest of the two assessment criteria are generally[6] used as the SGV/GAC. Note that the pathways summed are dependent on the toxicological modes of action and the availability of HCV. Where HCV are available for oral and inhalation routes and are both based on systemic effects, ADE from the oral and dermal pathways are summed for comparison with the oral HCV and ADE from the inhalation pathways are summed for comparison with the inhalation HCV.

In total there are approximately 100 parameters used in the equations for predicting exposure in CLEA, however many of these apply to only one or two pathways. The parameters can be sub-divided into three broad types:

- **Contaminant specific**. Parameters related to the physico-chemical properties of the contaminant such as solubility, air-water partition coefficient and dermal absorption factor;
- **Receptor specific**. Parameters related to the critical receptor such as body weight, respiration rate and consumption rate of fruit and vegetables. CLEA allows different values to be attributed to each age class for the majority of these parameters; and
- **Site specific**. Parameters relating to the site itself such as soil properties (e.g. soil porosity, permeability and organic carbon content) and building properties (e.g. dimensions of buildings, pressure differential and rate of air exchange).

CLEA allows almost all the parameter values to be adjusted by the user but has an in-built set of "default" values for calculating SGVs and GACs for the generic land-uses.

3.2 UNCERTAINTY IN ESTIMATING EXPOSURE

CLEA is a deterministic model and as such provides one estimate of exposure from one set of parameter input values for one hypothetical critical receptor. The extent to which this estimate of exposure is accurate for an individual within the critical receptor group will be dependent on a number of factors:

- Uncertainty in the conceptual model. As shown in Table 3.1, CLEA assumes that exposure occurs via up to ten exposure pathways (although soil and dust ingestion are combined). As described in the EA SR3 report (EA, 2009c), these pathways are assumed to represent typical exposure scenarios for each of the generic land-uses. When applying the SGV or GAC it is important to consider the applicability of these pathways to the site in question. For example, as described in Section 3.1, there may be residential properties where chickens are kept and where the ingestion of eggs is a potentially significant route of

[4] Due to the general sparsity in dermal toxicity data for chronic exposure, health criteria for oral intake are typically used for assessing dermal as well as oral exposures.

[5] See for example method given in Chen (2010)

[6] Note that the SGV for arsenic is an exception and is based on the AC_{oral} only. This is because the ELCR associated with the oral HCV is significantly higher than the ELCR associated with the inhalation HCV (EA, 2009d).

exposure. Equally, there may be residential properties where there is no garden or exposed soils and thus virtually no plausibly significant exposure pathways (other than perhaps intrusion of vapours through the building foundations). Likewise, for allotments it may be reasonable to assume that a negligible proportion of allotment soils is tracked back to the residential property, but there may be some allotment holders who live adjacent to their allotment where tracking back of soils may be more significant. The CLEA framework regards such uncertainties as being most effectively assessed and managed when applying soil screening criteria on a particular site.

For the purposes of this project, the exposure pathways modelled for the SGV/GAC are also considered appropriate for derivation of the C4SLs. However, as with SGV/GACs, assessors should check the applicability of the C4SLs for GQRA in the context of the conceptual model for the site. Note that, as discussed in Section 5.1, separate C4SLs have been derived for residential with consumption of homegrown produce and residential without consumption of homegrown produce. C4SLs have also been derived for public open space land-uses (see Section 3.6).

- Uncertainty in the ability of the CLEA equations to accurately predict exposure. For some exposure pathways (such as incidental ingestion of soil and dust) the equations are relatively simple and robust, with the accuracy of prediction largely dependent on the input parameters rather than the equation itself. For other pathways, such as vapour inhalation, the equations are relatively complex and the accuracy of prediction is not only dependent on the input parameters but also on the validity of the assumptions underpinning those equations. Deviation from these underlying assumptions can lead to a significant under- or over- estimation of exposure

.

- Uncertainty in the input parameter values. This can be sub-divided into:

    - Aleatoric uncertainty (aka variability). This type of uncertainty can be measured but not reduced. Body weight, for example, is variable within each age class - not all 2 to 3 year old children weigh the same. With sufficient measurement it is possible to estimate average body weight within each age class to a reasonable degree of accuracy. It is also possible to estimate the probability of a random individual within an age class having a body weight in excess of a given value.
    - Epistemic uncertainty (aka systematic uncertainty). This is uncertainty that exists due to lack of data or difficulties in measurement/estimation of parameter values. It may be small for some parameters but more significant for others. For example, relatively few studies have been conducted to estimate the amount of soil that children ingest on a day to day basis (see Section 3.5.2.2). These studies were conducted outside the UK and in summer months only. It is possible to use these studies to estimate average daily soil ingestion rate but there will be relatively large epistemic uncertainty in this estimate when applied to UK children.

It should also be recognised that uncertainty associated with the use of SGV/GACs is typically greater than that associated with the use of site specific assessment criteria (SSACs) within a DQRA. The incorporation of site-specific information, such as details of the exposure scenario, receptor behaviour, soil type and foundation construction in the derivation of a SSAC allows a more realistic (and hence potentially more accurate) estimate of risk to be made than with the use of GACs, which are derived to be broadly applicable (and conservative) to a wide range of sites. The more encompassing a GAC, the less applicable it will be to any individual site and the greater the uncertainty becomes. Furthermore, it is highly unlikely that the overall generic scenario could ever be verified in the real world as most verification work applies to individual pathways in a specific set of circumstances.

There are a variety of approaches that can be used to assess and manage uncertainty in exposure modelling. Probabilistic modelling, such as Monte Carlo analysis, can help to quantify uncertainty in the exposure estimates caused by variability and (to a certain extent) epistemic uncertainty in the model parameter inputs, where the degree of variability or uncertainty is known (or assumed). In an earlier version of CLEA (CLEAUK), variability in a limited number of input parameters was modelled using Monte Carlo analysis to produce a frequency plot of ADE (Figure 3.1). In that model, the upper bound 95th percentile estimated ADE was used to calculate the SGV. Note that the resultant frequency distribution of ADE would likely have had a greater spread of values if uncertainty in all model input parameters had been taken into account.

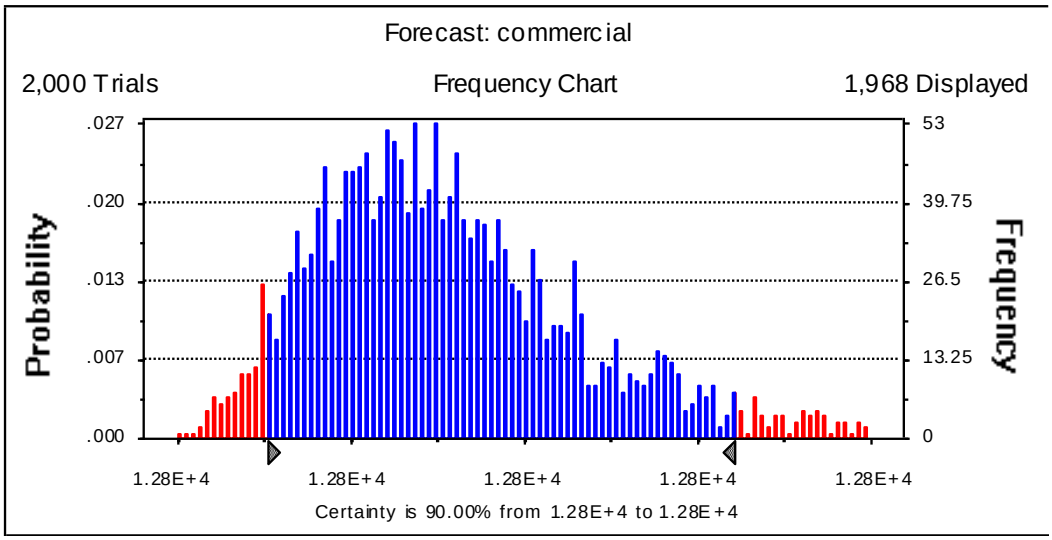


Figure 3.1: Frequency distribution of ADE from CLEAUK

Although uncertainty cannot be quantified using deterministic modelling, it can be considered explicitly and addressed indirectly. Adopting conservative values for all input parameter values decreases the probability of the model under-predicting exposure for an individual within the critical receptor group. The current configuration of CLEA uses a mixture of "central tendency" and "reasonable worst case" values and, as a result, is likely to over-predict exposure for the majority of individuals within each critical receptor group. However, the degree of conservatism in the estimates of ADE and the probability that it under-predicts exposure for a randomly selected individual from the critical receptor group is not known (see Figure 3.2). A better understanding of these aspects is required to help assess the suitability of the current CLEA model configuration for the derivation of C4SLs. This has been achieved by conducting the following work:

- Pathway analyses to identify the key pathways involved in deriving SGV/GACs for the generic land-uses (Section 3.3);
- Sensitivity analyses to identify the key pathways and parameters that lead to significant uncertainty in the estimates of exposure (Section 3.4);
- Critical review of the ability of the CLEA equations to accurately predict exposure for the key pathways (Section 3.5);
- Critical review of the key parameter values and in particular an appraisal of their level of conservatism for predicting exposure to the critical receptor groups (Section 3.5); and
- Probabilistic modelling to help quantify uncertainty in the CLEA exposure estimates and help ensure that the set of deterministic exposure parameter

values chosen results in C4SLs with a suitable level of precaution. This probabilistic modelling is discussed further in Sections 5.1.1 and 5.3.

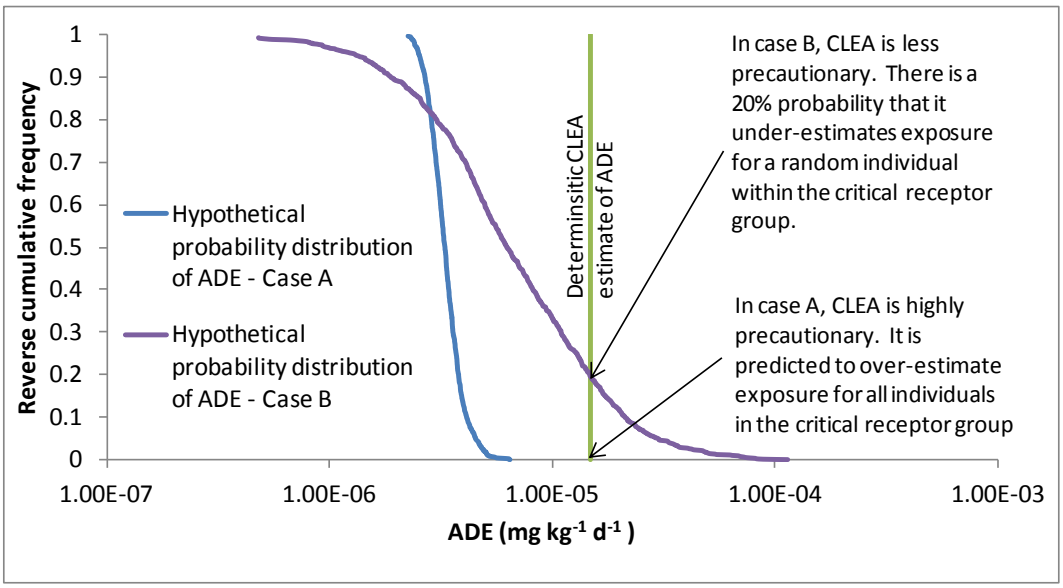


Figure 3.2: Schematic graph illustrating probability that CLEA under predicts exposure for a randomly selected individual from the critical receptor group

3.3 PATHWAY ASSESSMENT

As discussed in Section 3.1, the CLEA model estimates exposure via a number of pathways. The relative importance of each pathway to overall risk is dependent on the particular configuration of input parameters and will vary depending on contaminant and land-use. Figures 3.3 to 3.5 show the relative importance of each pathway to the derivation of SGVs/GACs for the six example contaminants (arsenic, benzene, benzo(a)pyrene, cadmium, chromium (VI) and lead) for residential, allotments and commercial land-uses (the standard land-uses in CLEA). As can be seen, the following pathways are important for one or more contaminants for one or more land-uses:

- direct soil and dust ingestion
- consumption of homegrown produce
- dermal contact outdoors
- inhalation of dust indoors
- inhalation of vapours indoors

These can be considered the key pathways and are considered further in this review.

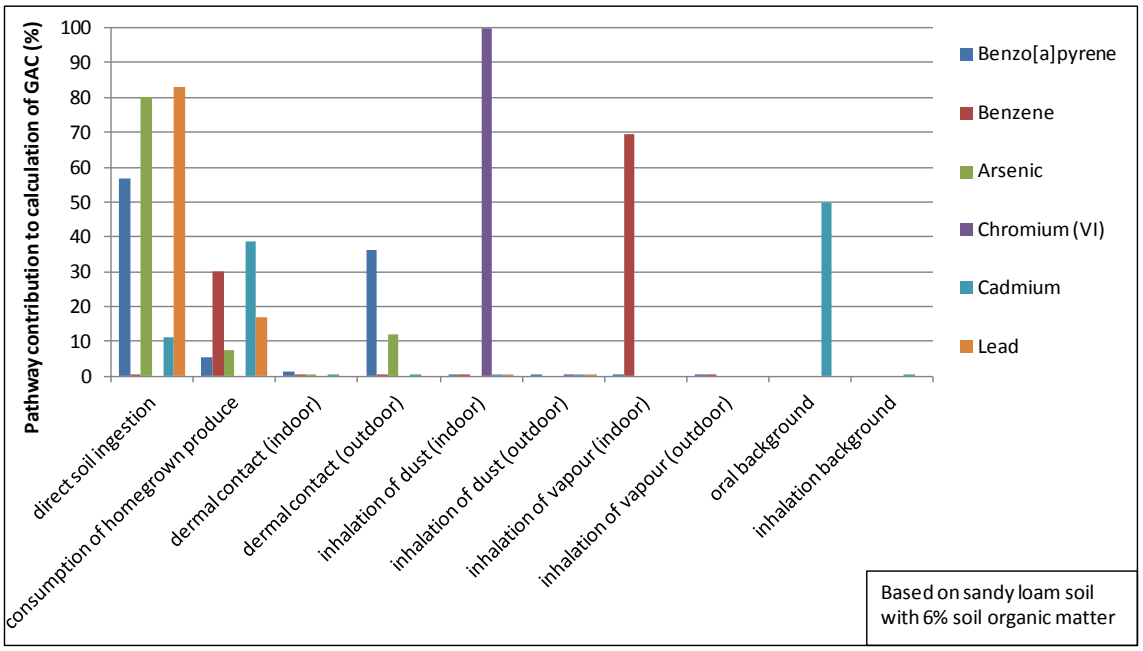


Figure 3.3: Relative importance of exposure pathways to SGVs/GACs for residential land-use with consumption of homegrown produce

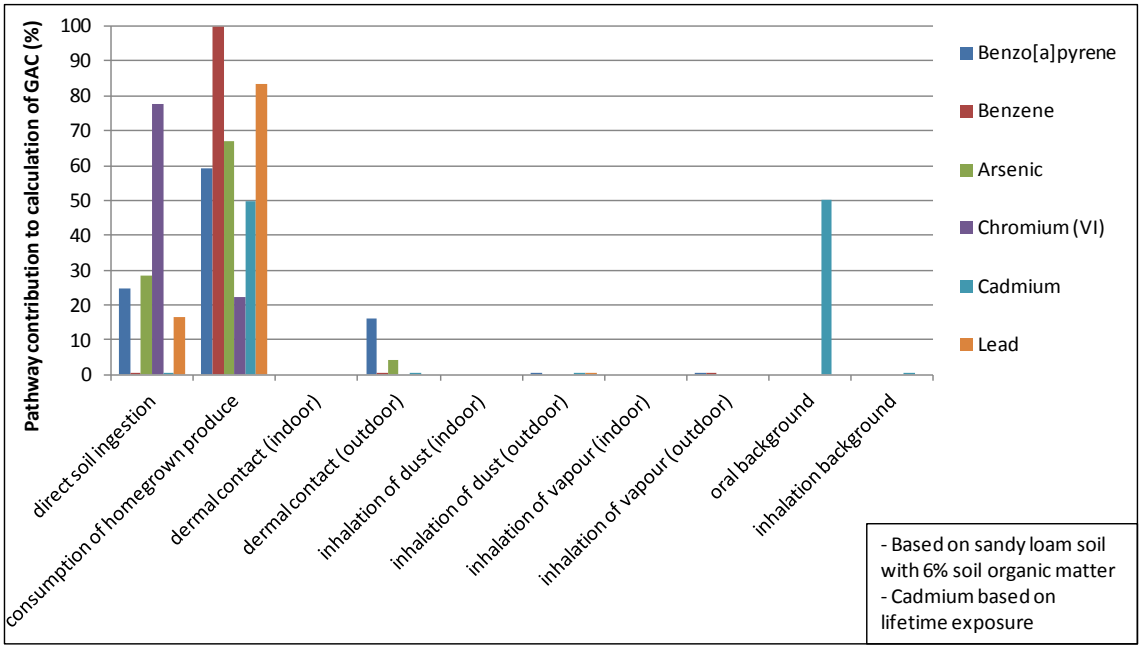


Figure 3.4: Relative importance of exposure pathways to SGVs/GACs for allotments land-use

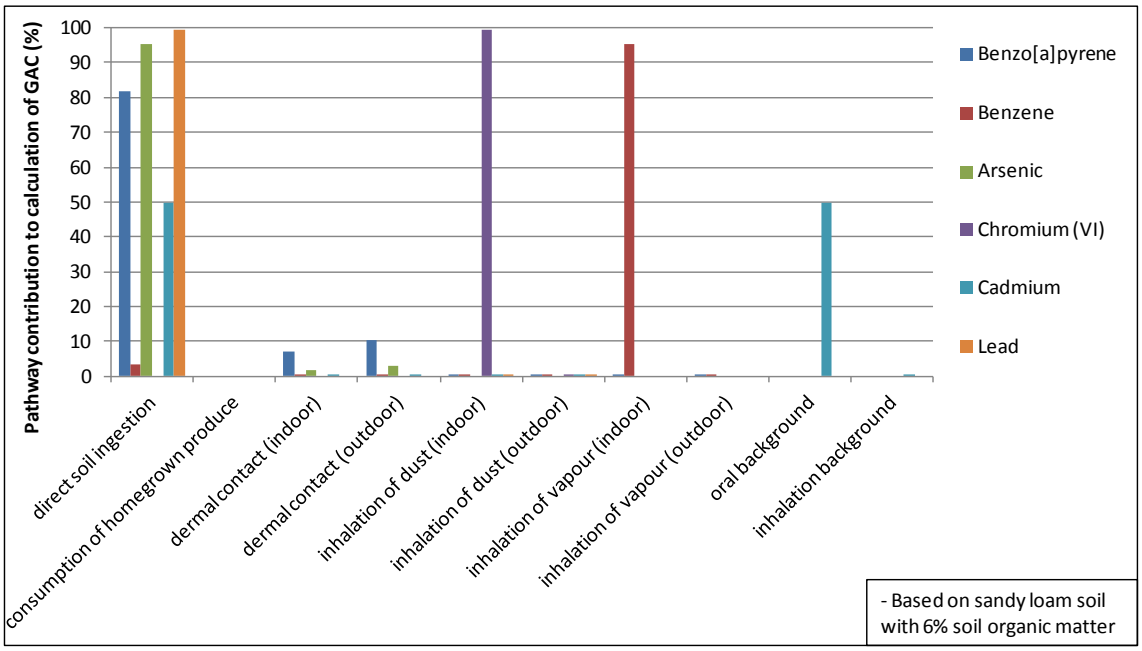


Figure 3.5: Relative importance of exposure pathways to SGVs/GACs for commercial land-use.

3.4 SENSITIVITY ANALYSIS

Sensitivity analysis provides a method for identifying the most significant sources of uncertainty in the estimates of ADE. Sensitivity analysis has been conducted using CLEA for the residential, allotments and commercial land-uses. The sensitivity analysis has been conducted by varying one input parameter at a time between a reasonable minimum and maximum value and assessing what effect this has on the GAC for each of the six focus contaminants. Only parameters that are used in the calculation of ADE from soil for the six focus contaminants have been tested. For example, empirical soil to plant concentrations factors have been used for the inorganic contaminants and this negates the need for parameters only used by the PRISM plant uptake model such as the soil-water partition coefficient (Kd) and root to shoot correction factors. A total of 58 parameters have been tested in the sensitivity analyses. The range of values tested and justification for each range are provided in Appendix A.

Figures A.1 to A.3 in Appendix A show the results of the sensitivity analyses. These show the ratio of modified GAC to original GAC for each parameter. Note that many parameter values used in CLEA already represent the reasonable maximum value (such as an exposure frequency of 365 days per year) and in these cases only one sensitivity run (using the minimum value) has been conducted.

The results of the sensitivity analyses show that there are a number of key parameters/assumptions that cause uncertainty in the derivation of GAC. These are listed below (with key associated pathways in brackets)

- Body weight (all pathways)
- Averaging time (all pathways)
- Soil and dust ingestion rate (soil & dust ingestion)
- Exposure frequency outdoors (dermal contact outdoors)
- Skin adherence outdoors (dermal contact outdoors)
- Maximum exposed skin fraction outdoors (dermal contact outdoors)
- Dermal absorption fraction (dermal contact outdoors)

- Inhalation rate (vapour and dust inhalation indoors)
- Dust loading factor (dust inhalation indoors)
- Soil to dust transport factor (dust inhalation indoors)
- Soil to indoor air correction factor (vapour inhalation indoors)
- Building footprint (vapour inhalation indoors)
- Living space height (vapour inhalation indoors)
- Soil to plant concentration factors (consumption of homegrown produce)
- Homegrown fraction (consumption of homegrown produce)
- Soil type (vapour inhalation indoors)[7]
- Produce consumption rate (consumption of homegrown produce)
- Soil organic matter (vapour inhalation indoors & consumption of homegrown produce).

As expected, these parameters are all related to the five key pathways identified in Section 3.3. The exposure models and associated parameter values used for these five key pathways are considered further in Section 3.5.

3.5 REVIEW OF EXPOSURE MODELS AND ASSUMPTIONS FOR KEY PATHWAYS

This section presents a critical review of the exposure algorithms, assumptions and parameter values used in CLEA for the five key pathways identified above. Where appropriate, modifications to parameter values are proposed for the purposes of deriving C4SLs for the residential, allotments and commercial land-uses.

As described below, the suggested modifications have been identified following feedback from the Steering Group and Stakeholder Workshops on an initial set of proposals made in a draft interim methodology document. Some of these initial proposals were amended or rejected, with the initial proposed modifications and subsequent amendments being explained in the relevant sections below.

As discussed in Section 3.2 above, probabilistic modelling has also been used to help determine whether the suggested modifications to the exposure parameters result in C4SLs with an appropriate level of precaution. In some cases the probabilistic modelling has resulted in further amendments being made to ensure that the C4SLs are suitably precautionary.

The final set of modifications suggested for deriving C4SLs are summarised in Section 3.5.7.

3.5.1 ESTIMATING AVERAGE DAILY EXPOSURE

As discussed in Section 3.1, ADE is estimated using the following generalised equation:

$$ADE_i = \frac{IR_i . EF_i . ED}{BW . AT}$$

This can be regarded as the internationally recognised standard equation for estimating ADE for chronic exposure durations and there is little doubt in its validity. Exposure frequency and the pathway specific equations used for estimating exposure

[7] The sensitivity analysis was conducted for soil type by assessing the change in GAC using the CLEA default parameter values for a clay and sandy soil respectively.

rate (IR) are discussed in Sections 3.5.2 to 3.5.6. The remaining parameter values used within the generalised ADE equation are discussed below.

3.5.1.1 Exposure Duration

CLEA uses the above equation to estimate ADE for up to 18 age classes which range in exposure duration from 1 year for the 0 to 16 year old age classes, 10 years for the 65 to 75 year old age class and 49 years for the 16 to 65 year old age class. The subdivision of ADE calculations into so many age classes is unique to CLEA. The exposure durations used in CLEA are effectively equal to the duration of age class and are thus irrefutable.

3.5.1.2 Averaging Time

The averaging time can have a large influence on the ADE estimates. USEPA guidance allows averaging time to be greater than exposure duration when estimating the excess lifetime cancer risk from land contamination. For example, exposure duration of 30 years (6 years for a child and 24 years for an adult) versus an averaging time of 70 years (assumed lifetime) is a common assumption when assessing carcinogens in the USA. This effectively assumes that there is no exposure from land contamination for 40 years of the receptor's lifetime, and is judged to be a reasonable worst case assumption regarding household mobility in the USA.

Even where averaging time is equal to exposure duration, the period over which exposure is averaged can have a large influence on the ADE. This arises because ADE is generally higher for children (due to higher exposure rate to body weight ratios) than adults as exemplified in Figure 3.6. Indeed CLEA predicts the average ADE over the first 6 years of a child's life to be 2.3 to 5.1 times higher (for the six focus contaminants under the residential scenario) than lifetime averaged ADE (assuming the receptor remains in the same residential property and that soil concentrations remain unchanged for their lifetime).

Lifetime averaging has been assumed by the Environment Agency for the derivation of the cadmium SGVs for residential and allotments land-uses. This is justified on the basis that the critical toxicological effect is based on body burden of cadmium built up over a lifetime. There may also be an argument for the use of lifetime averaged ADE for some non threshold compounds, depending on the substance specific toxicological review. This is discussed further in Section 2.4.9.

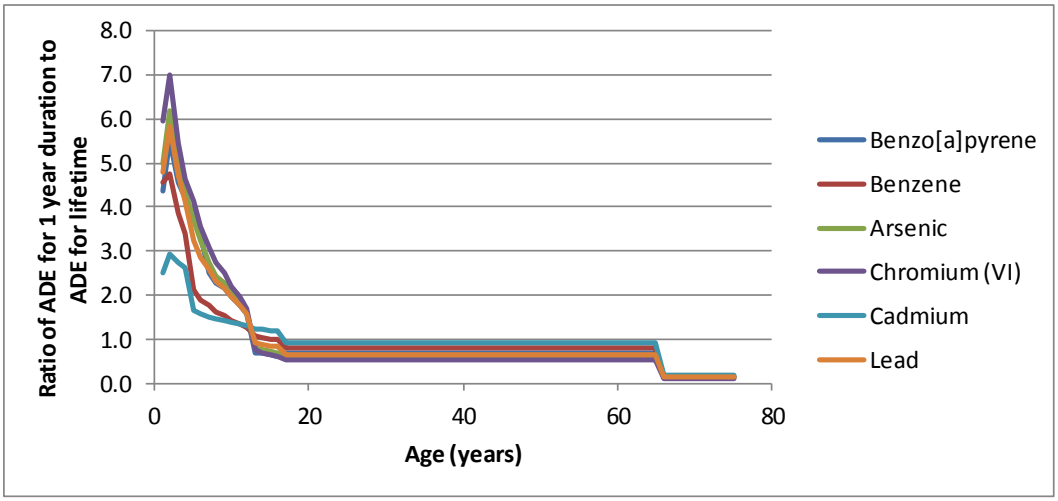


Figure 3.6: Total soil-derived ADE with age predicted by CLEA for residential land-use

3.5.1.3 Body Weight

Body weight varies between individuals and this will be one factor that leads to uncertainty in estimates of ADE. The current configuration of CLEA uses the arithmetic mean female body weight for each age class taken from the Health Survey for England 2003 (EA, 2009c). Whilst this represents central tendency for females it will tend towards an over-estimation of ADE for males whose arithmetic mean body weights are approximately 7 to 20% higher depending on age class. The use of central tendency values will tend to result in an over-estimation of ADE for some (lighter than average) individuals and an under-estimation for others (heavier than average). The sensitivity analyses showed that use of the 5th and 95th percentile body weights generally changed the ADE estimates by less than ± 30% and thus variability in body weight is unlikely to cause significant uncertainty in exposure estimates.

3.5.2 SOIL AND DUST INGESTION

Soil and soil-derived dust ingestion is a key exposure pathway for four of the six compounds considered. In CLEA, the exposure rate for this pathway is estimated using the following equation:

$$IR_{direct\_s\&d\_ing} = C_{soil} . RBA_{soil} . S_{ING}$$

Where

$IR_{direct\_s\&d\_ing}$ = exposure rate for soil and dust ingestion (mg d^{-1})
C_{soil} = concentration in soil (mg g^{-1})
RBA_{soil} = relative bioavailability of the contaminant in soil (fraction)
S_{ING} = direct soil and soil-derived dust ingestion rate (g d^{-1})

This equation is based on simple mass balance and there is no reason to doubt its ability to predict exposure accurately. Rather, it is uncertainty in the associated input parameters that affect uncertainty in the estimates of ADE as discussed below.

Note that CLEA uses a combined soil and soil-derived dust ingestion rate. This is justified on the basis that it is difficult to differentiate between these two types of exposure. However, as discussed below, there may be merit in considering both exposures separately to allow a more realistic assessment of exposure.

3.5.2.1 Soil Concentration

CLEA uses iteration to calculate the soil concentration at which the sum of ADE equals the relevant HCV. Thus, soil concentration is an output rather than an input when CLEA is used in reverse mode. In GQRA, uncertainty in the soil concentration at a particular site is considered when estimating the "representative exposure concentration" from measured concentrations for comparison with the GAC. This is discussed further in Section 6.2.

It is important to note that the soil concentration used in the soil and dust ingestion exposure equation is the concentration of contaminant in soil (and soil-derived dust) that is actually ingested, which may not necessarily be the same as the concentration in bulk soil samples. Incidental ingestion of soil and dust is likely to be limited to finer particles, which may have relatively higher or lower concentrations than the average concentration in bulk samples (SoBRA, 2011 & 2012). This uncertainty should be considered when developing the sample plan for the site and when conducting the GQRA.

3.5.2.2 Soil and Dust Ingestion Rate

The soil and dust ingestion rate is a key uncertainty highlighted by the sensitivity analysis. CLEA assumes an average daily soil and dust ingestion rate of 100 mg d^{-1} for 0 to 11 year old children and 50 mg d^{-1} for 12 to 75 year olds. These values are

consistent with central tendency values recommended by the USEPA and Netherlands (USEPA 2008, 2011; Lijzen *et al.*, 2001).

Relatively few studies on soil and dust ingestion rate have been conducted. Most of these are based on mass balance using tracer compounds naturally present in soil. Typically, the mass of tracer compounds (such as aluminium, silicon and titanium) are measured in the faeces, urine and non soil dietary intake of children over a 1 day to 2 week basis. Any excess excreted relative to intake is assumed to be due to ingestion of soil and dust. This excess mass is divided by the measured fraction in soil and dust to estimate the mass of soil and dust ingested per day.

Of the studies on children reviewed by the USEPA (2011), there appear to be five key studies on which their recommendations for a soil ingestion rate are based. These studies show considerable variability in ingestion rate on a day to day basis for each child and in the time averaged values between children. Considerable variability was also observed between tracers used.

Figure 3.7 presents the variability in the estimates of mean soil and dust ingestion rate derived from these key studies. The tracer compound used accounts for much of the variability. For example Calabrese *et al.* (1989) used 8 different tracers and this gave 8 different estimates of soil ingestion rate varying from -496 mg d^{-1} (using manganese as the tracer) to 483 mg d^{-1} (using silicon as the tracer). The large variability between tracers and the occurrence of negative estimates highlights the large measurement error and uncertainty in these studies.

Van Wijnen *et al.* (1990) is the only key study outside of the US. They conducted mass balance studies for three groups of children in the Netherlands: children in day care, children on campsites and children in hospital. They used titanium, aluminium and acid insoluble residue as the tracer compounds. Their methods differed slightly to those used in the US making direct comparison between studies difficult. Firstly, they do not report soil ingestion rate estimated from each tracer but instead report the lowest soil ingestion rate from all tracers. Secondly, they did not attempt to estimate mass of tracer ingested via food per individual but instead used the mean concentration of each tracer in the faeces of children in hospital to estimate dietary intake from non soil sources. Despite these differences the arithmetic mean soil ingestion rates derived by Van Wijnen *et al.* (1990) are similar to those from other studies.

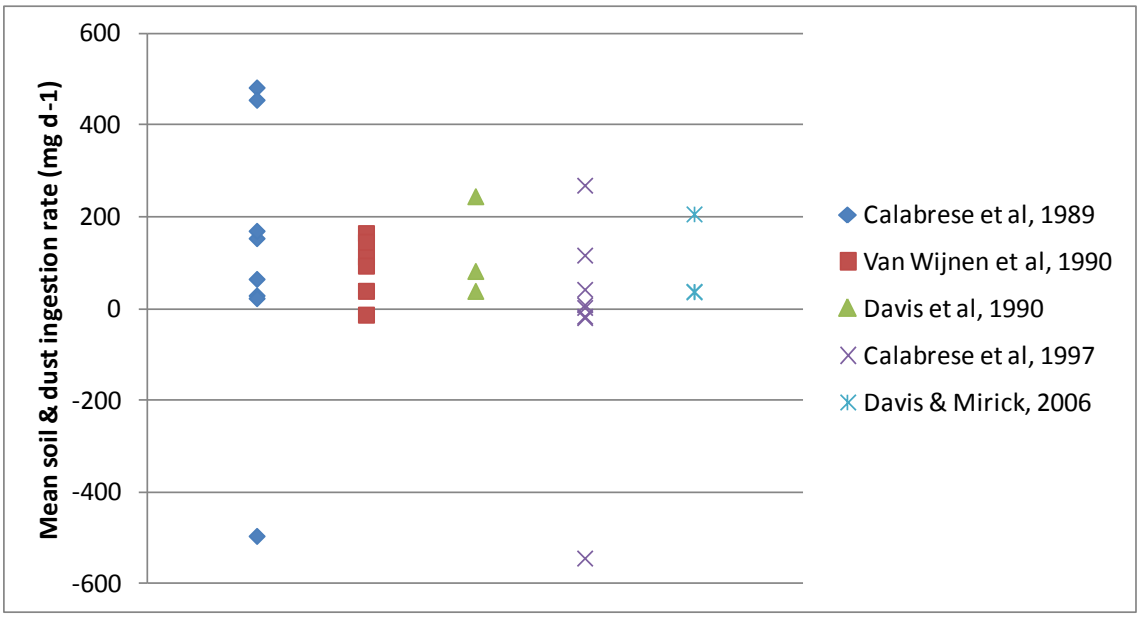


Figure 3.7: Estimates of soil ingestion rate in children from mass balance studies

An interesting finding from the Van Wijnen *et al.,* (1990) study was the difference between soil ingestion rates in children in day care and those in campsites. Samples of faeces were taken from children in day care on two occasions, one in early summer and one in late summer. The results were markedly different. The early summer estimates were similar to those of the campsite cohort, whilst the estimates from late summer were similar to those for the children in hospital. Van Wijnen *et al*. (1990) noted that the weather was poorer during the second sampling round, with a higher number of rainy days. They attributed the lower soil ingestion rate to less time spent outdoors. This is an important consideration as all of the key studies reviewed by the US were conducted during summer months when contact with soil is likely to be greater (either directly outdoors or with soil that has been tracked into the house). Thus, whilst a value of 100 mg d^{-1} may be a reasonable central tendency estimate of soil ingestion rate during summer months, it may be an over-estimate during winter months when children spend less time outdoors.

Another consideration when evaluating the soil ingestion studies is the source of the soil ingested. Van Wijnen *et al.,* (1990) found little difference in soil ingestion rate between children who resided in houses with and without gardens and assumed that the majority of soil ingestion occurred whilst outdoors at day care. Thus, it is reasonable to assume that a proportion of soil ingested by a 0 to 6 year old child will come from locations other than the home, such as the play park, streets, shops, day care and schools.

A recent meta-analysis of US based soil ingestion studies was conducted by Stanek *et al.* (2012). They re-assessed mass-balance data from four US studies and concluded that aluminium and silica were the most reliable tracers for estimating soil ingestion. Having screened the dataset to remove unreliable data points and outliers (such as subjects exhibiting soil-pica behaviour), they then used a "mixed model" approach with data for aluminium and silica from 216 children to assess soil ingestion rate. The results indicated a mean, median and 95th percentile soil ingestion rate of 26 mg.day^{-1}, 33 mg.day^{-1} and 79 mg.day^{-1}, respectively, i.e. significantly lower than previous estimates.

In summary, whilst there is much uncertainty over soil ingestion rate it is likely that the current assumptions of 100 mg d^{-1} for 365 days per year for residential land-use and 50 mg d^{-1} for 230 days per year for commercial land–use will tend towards an over-estimation of exposure for the majority of cases. It may be more realistic to use a weighted estimate of soil and dust ingestion rate based on assumed exposure frequencies indoors and outdoors. This could be calculated as follows:

$$S_{ING} = \frac{S_{ING\_indoors} \cdot EF_{indoors} + S_{ING\_outdoors} \cdot EF_{outdoors}}{EF_{soil\&dust.ing}}$$

Where,

S_{ING} = direct soil and soil-derived dust ingestion rate (g d^{-1})
$S_{ING\_indoors}$ = direct soil-derived dust ingestion rate indoors (g d^{-1})
$S_{ING\_outdoors}$ = direct soil ingestion rate outdoors (g d^{-1})
$EF_{indoors}$ = exposure frequency indoors (d yr^{-1})
$EF_{outdoors}$ = exposure frequency outdoors (d yr^{-1})
$EF_{soil\&dust.ing}$ = exposure frequency assumed for soil and dust ingestion pathway (d yr^{-1})

The USEPA (2011) recommend central tendency values of soil and indoor dust ingestion rates of 50 and 60 mg d^{-1} for children and 20 and 30 mg d^{-1} for adults, respectively. Whilst an exposure frequency of 365 d yr^{-1} may not be unreasonable for indoor exposure for residential land-use (see Section 3.5.2.4), this is likely to be highly precautionary for outdoor exposure. Data on which to base exposure frequency for a

child outdoors are lacking but it is not unreasonable to assume that this would be no greater than 170 days (approximately 50% of the year). For commercial land-use, based on the existing parameter values used within CLEA, it is not unreasonable to assign exposure frequencies of 230 and 170 d yr^{-1} for indoor and outdoor exposure, respectively. Use of these parameter values with the equation above results in weighted soil and dust ingestion rates for residential and commercial land-uses of approximately 80 and 40 mg d^{-1} for these land-uses, respectively. These soil and dust ingestion rates are still likely to be conservative estimates of central tendency as they do not account for the proportion of soil and dust ingested that comes from off-site sources.

The modification of soil ingestion rates for derivation of the C4SLs for residential and commercial land-uses was proposed in the draft interim methodology document and at the first Stakeholder Workshop. However there was mixed support from stakeholders for the proposed changes. Some felt that tracking back of soil could be higher in winter months and thus the logic that soil and dust ingestion in winter being less may not apply. Given the relatively high degree of uncertainty involved with this parameter it has been considered prudent to reject this proposed modification and retain the existing soil ingestion rates used within CLEA, which are accepted as being precautionary.

For allotments land-use, CLEA assumes that exposure via direct ingestion of soil and soil-derived dust only occurs whilst at the allotment, i.e. the tracking back of soils to the residential property is negligible. CLEA assumes that children ingest 100 mg d^{-1} soil from the allotment. Whilst this is higher than the central tendency value recommended by the USEPA (50 mg d^{-1}), it seems reasonable to assume that children might have greater regular contact with soils at an allotment than in a garden (due to the higher likelihood of direct contact activities), and thus the CLEA value of 100 mg d^{-1} is considered reasonable for this scenario.

3.5.2.3 Relative Bioavailability

Bioavailability is a consideration of how much chemical enters the systemic blood circulation and organs after absorption through the gut, lungs or skin. The Relative Bioavailability (RBA) is the ratio of the bioavailability of the contaminant in soil to the bioavailability of the contaminant in the critical study used to derive the HCV. In the case of the soil and dust ingestion pathway, it is the relative bioavailability of the contaminant to oral exposure that is relevant. The published SGVs are all based on the assumption of an RBA of 100%, i.e. that the bioavailability of the contaminant in soil is equal to that in the critical toxicological study. Toxicology studies for oral exposure are based on oral intakes of the contaminant dissolved in different media (e.g. water, oil, diet), where bioavailability can often be greater than contaminants in soil. Thus, the assumption of an RBA of 100% is most likely conservative in most cases.

As discussed in Oomen e*t al.* (2006), the oral bioavailability is defined as the fraction of ingested dose that reaches the systemic circulation. This can be conceptually sub-divided into three components:

- The bioaccessible fraction (F_B), i.e. the fraction of the contaminant that is mobilised from the ingested material (whether this be soil, food etc.) into the digestive juice (i.e. chyme);
- The fraction of F_B that is transported across the intestinal epithelium (F_A); and
- The fraction of FA that remains after passing through the liver, i.e. the fraction that is not metabolised by the liver (F_H).

The bioavailable fraction (F) of a contaminant in ingested material is therefore given by the equation:

$$F = F_B \times F_A \times F_H$$

A conservative measure of the oral bioavailability of a contaminant is therefore the bioaccessible fraction. For some substances (notably metals), *in-vitro* bioaccessibility data can be generated (Wragg *et al.,* 2009) to estimate the bioaccessible fraction and can therefore be used to provide an indication of the bioavailability of the contaminant in soil. If the bioavailability of the contaminant in the critical study used to derive the HCV is known then this information can be used to refine the value of RBA used in CLEA. Bioaccessibility can be highly variable, depending on soil properties and the speciation of the contaminant and thus it may be more appropriate for use as part of a site specific DQRA than for derivation of a generic screening value. This was discussed at the first Stakeholder Workshop and most agreed that the use of in-vitro bioaccessibility data was unlikely to form an appropriate basis for reducing the RBA for derivation of the C4SL.

However, consideration should be given to the use of conservative generic estimates of RBA to derive C4SLs, where there is strong evidence (e.g. from *in-vivo* studies) that the bioavailability of the contaminant in soil is significantly lower than that associated with the critical toxicological studies, such as is the case for lead (see Appendix H).

3.5.2.4 Exposure Frequency

The SGVs and GACs for residential land-use are based on the assumption that children aged 1 to 6 years are exposed to soil and soil-derived dust at their home 365 days per year. Whilst this is a worst case assumption, sensitivity analysis has shown that reducing this value to 350 days per year (which is likely to be closer to central tendency for the UK population) has a negligible effect on the GAC.

As discussed above, there is some evidence that the average soil and dust ingestion rate is correlated to amount of time spent outdoors, with the implication that the daily ingestion rate of soil derived dust indoors is significantly lower than that outdoors. Whilst an exposure frequency of 365 days per year may not be unreasonable for exposure to indoor dust, it is likely to be highly conservative for exposure outdoors. As discussed in Section 3.5.2.2, it is not unreasonable to assume that typical values for exposure frequency outdoors are less than 170 days per year. There could therefore be merit in calculating a weighted soil and dust ingestion rate based on different indoor and outdoor ingestion rates, but as described in Section 3.5.2.2, this proposal has been rejected for the purposes of deriving C4SL.

For commercial land-use, an exposure frequency of 230 d per year is assumed. This is based on an adult working 5 days per week for 46 weeks of the year and is likely to be a reasonable estimate of central tendency for indoor exposure to soil-derived dust. As discussed in Section 3.5.2.2, there may be merit in weighting the soil and dust ingestion rate to account for differences in indoor and outdoor exposure frequencies but, again, this proposal has been rejected for the purposes of deriving C4SL. Note that CLEA currently assumes an outdoor exposure frequency of 170 days per year for dermal contact outdoors for commercial land-use.

For allotments land-use, the exposure frequency varies according to age class. An exposure frequency of 258 days per year has been assumed as a reasonable worst case for adults, based on an activity survey from 1993 (EA, 2009c). Exposure frequencies for children are based on some proportion of this time, and range from 25 to 130 days per year. The highest frequency of 130 days per year is assumed for the 1 to <4 year old child, based on 50% of the adult exposure frequency. Whilst there may be some children who accompany their parents/guardians to the allotment 130 days per year, this is likely to be rare. Whilst the percentage of allotment holders with young families is rising, the activity data from 1993 is likely to be strongly biased towards retired adults. Central tendency exposure frequency for adults with young children visiting allotments is likely to be significantly lower than 258 days. Halving

the current set of exposure frequencies for allotments land-use may still provide a conservative estimate of central tendency exposure frequencies for the 0 to 6 year old child.

The proposal to halve exposure frequencies for allotments was presented in the draft interim methodology document and discussed at the first Stakeholder Workshop. There was mixed support for this modification from the steering group and stakeholders. Some raised concerns that the increasing trend in use of allotments by young families would mean that the proposed modification would not be sufficiently precautionary. There was also concern that there was large uncertainty in this parameter due to lack of relevant recent activity data. Given these concerns this proposed modification was rejected and the original CLEA value retained as a suitably precautionary value for the purposes of deriving C4SLs.

3.5.3 DERMAL CONTACT OUTDOORS

Dermal contact outdoors is a key exposure pathway for benzo(a)pyrene for residential land-use. In CLEA, the exposure rate for this pathway is estimated using the following equation:

$$IR_{dermal\_out} = C_s.n.AF.ABS_d.A_{skin}$$

Where

IR_{dermal_out} = chemical uptake rate from outdoor dermal contact with soil (mg d^{-1})
C_s = concentration in soil (mg g^{-1})
n = number of daily soil contact events (d^{-1})
AF = soil to skin adherence factor (mg cm^{-2})
ABS_d = dermal absorption fraction (dimensionless)
A_{skin} = exposed skin area (m^2)

This equation is based on the assumption that a proportion of mass of contaminant in soil on skin (ABS_d) will enter the bloodstream in a single event. It is a simplification of the skin diffusion process and does not explicitly describe the influence that partitioning and diffusion kinetics have on uptake. For example, the duration of adherence event is theoretically a key factor in the amount of contaminant that can enter the bloodstream but this is not a variable used in this equation. Rather, it is implicitly considered in the selection of the dermal absorption factor.

It is interesting to note that the original published CLEA methodology used an equation for dermal contact that did account for partitioning and diffusion kinetics (EA, 2002a). This was based on USEPA protocol but the USEPA (2004) later abandoned this method for soils in favour of the simplified version now used by CLEA, presumably because the increased model uncertainty associated with the simplified version was more than off-set by the decreased uncertainty in parameter value uncertainty. Nevertheless, the validity of the assumption that a fixed proportion of the mass of contaminant in soil adhered to the skin entering the bloodstream should be considered and is discussed further below in the context of the dermal absorption factor.

3.5.3.1 Soil Concentration

As discussed for soil and dust ingestion, soil concentration is an output and not an input in the CLEA model when used to derive GAC. Similar to soil and dust ingestion, it is likely to be the finer particles of soil that remain attached to skin and thus it is the concentration of contaminant in these finer particles that is important when predicting exposure via dermal contact.

3.5.3.2 Number of Daily Soil Contact Events

CLEA assumes that one exposure event occurs per day that exposure occurs, i.e. that soil adherence occurs and remains on the skin for a period of time before being washed off and that this happens once per day. This is consistent with the experimental methodology used to derive the dermal absorption factor (Section 3.5.3.6) and USEPA protocol (USEPA, 2004) and is therefore considered reasonable.

3.5.3.3 Soil to Skin Adherence Factor

The value of the soil to skin adherence factor (AF) is a key uncertainty highlighted by the sensitivity analysis. This factor refers to the amount of soil that adheres to the skin per unit of surface area. The soil to skin adherence factor varies with soil properties, different parts of the body and the activity undertaken (USEPA, 2004).

The CLEA model assumes an adherence factor of 1 mg cm^{-2} for children aged 0 to 12 years for residential and allotments land-uses. This is the approximate mid-point between the USEPA (1992) estimated upper 95^{th} percentile estimates for children playing on wet and dry soils. The most recent version of the USEPA Exposure Factors Handbook (USEPA, 2011) gives recommended central tendency values of soil adherence for common activities, including children in day care playing inside and outside and children playing soccer. The central tendency adherence estimates for children in daycare varied from 0.02 to 0.099 mg cm^{-2} depending on body part (Holmes *et al.* 1999). Central tendency estimates for children playing soccer varied from 0.011 to 0.031 mg cm^{-2} depending on body part (Kissel *et al*. 1996). The highest adherence occurred for hands. It should be noted that the estimates are based on very limited datasets. Holmes *et al*. (1999) tested 21 children in daycare. The children were washed beforehand and then re-washed (collecting the water from each body part) at the end of the day. The dry residue in the wash water was used to estimate the average soil adherence factor for each body part. The same method was used by Kissel *et al.* (1996) for 8 children playing soccer.

Based on this information a value of 0.1 mg cm^{-2} is considered a reasonable estimate of central tendency for soil adherence for children in residential gardens and has been adopted for deriving C4SLs for residential land-use. There was mixed support from stakeholders to this change when proposed in the first Stakeholder Workshop. The majority of concern related to whether the move towards central tendency would be sufficiently precautionary. Whilst a move towards central tendency is less precautionary it should be recognised that use of upper bound estimates for all parameters within an exposure pathway equation will lead to highly precautionary estimates of exposure. As discussed below, precautionary estimates of exposure frequency and skin area have been adopted and thus the overall estimates of exposure are still expected to be precautionary.

A higher value may be expected for children at allotments where more direct contact with soil is expected and thus it is considered appropriate to retain the assumption of 1 mg cm^{-2} soil adherence for the purposes of deriving C4SLs for allotments.

3.5.3.4 Exposure Frequency

The exposure frequency is a key uncertainty highlighted by the sensitivity analysis. The number of days per year that children have appreciable dermal contact with soils in their own garden will be highly variable. In general in the UK, exposure frequency is expected to be higher in summer than winter as a result of more favourable weather conditions, longer days and extended school holidays. Whilst a small proportion of children may spend most days of the year in their garden this is likely to be rare. On the basis of professional judgement, a child playing in the garden for one or two hours, two or three days per week during summer months and one day or less per week during winter months is likely to be closer to central tendency behaviour for UK children.

For the residential scenario, the CLEA model assumes that a child will be exposed to garden soil outdoors for 365 days a year. Based on the above rationale it is reasonable to conclude that this assumption will tend towards an over-estimation of exposure in the vast majority of cases. An average exposure frequency of approximately 3.5 days per week (170 days per year) may be a reasonable conservative estimate of central tendency for UK children living in properties with gardens. This was proposed as an appropriate exposure frequency for dermal contact outdoors for derivation of the C4SLs in the draft interim methodology document and first Stakeholder Workshop. There was mixed support from stakeholders. However, most agreed that the reduction to 170 d yr^{-1} was still likely to be a precautionary estimate and therefore this value has been adopted for derivation of C4SLs for residential land-use.

3.5.3.5 Exposed Skin Area

The fraction of exposed skin area is a key uncertainty highlighted by the sensitivity analysis. The CLEA model assumes that children in both the residential and allotments scenarios have face, hands, lower arms and lower legs exposed whilst outdoors for 365 days per year. This implies that the child wears shoes, long shorts and T-shirt for 365 days per year. The CLEA model also makes the assumption that one third of the exposed area has adhered soil. This amounts to approximately 9% of total body area, roughly equivalent to the hands and lower arms having contact with soil. Whilst children are likely to get the hands and lower arms dirty with garden soil on occasion, it is unlikely to be a daily occurrence, 365 days per year.

As discussed in Sections 3.5.3.3 and 3.5.3.4, estimates closer to central tendency have been adopted for the soil-adherence factor and exposure frequency for dermal contact outdoors for residential land-use. It is therefore considered reasonable to retain the fraction of skin exposed that had been used for the SGVs for the purposes of deriving the C4SLs to ensure that the estimates of dermal exposure are still precautionary.

3.5.3.6 Dermal Absorption Factor

The dermal absorption factor (ABS_d) is a key uncertainty highlighted by the sensitivity analysis. It is the proportion of contaminant mass in the adhered soil that enters the blood stream. It is a contaminant specific property and is a key parameter for contaminants where dermal contact is a principal pathway, such as benzo(a)pyrene. The Environment Agency SR3 guidance (EA, 2009c) provides recommended dermal absorption factors for some contaminants/groups of contaminants, which are based on USEPA recommended values. These have generally been derived from experimental studies on animals or humans involving one exposure event over a 24 hour period (USEPA, 2004). Uncertainty in the values used has been considered on a substance by substance basis and the reader is referred to the substance-specific appendices for further details.

3.5.4 DUST INHALATION INDOORS

Dust inhalation indoors is a key exposure pathway for chromium (VI) for residential and commercial land-uses. The ADE from dust inhalation is actually relatively small compared to other pathways, but of the six focus contaminants, chromium (VI) has the greatest ratio of the HCV_{oral} to $HCV_{inhation}$, with the latter being three orders of magnitude lower than the former. This large contrast in HCVs for the oral and inhalation pathways results in dust inhalation being a key route of exposure, despite the relatively low ADE.

The CLEA model uses the following equation to assess the exposure from the inhalation of indoor dust.

$$IR_{dust\_inhal\_in} = C_s \cdot \left[\frac{1}{PEF} + TF.DL \right] V_{inh} \frac{T_{site}}{24}$$

Where

$IR_{dust\_inhal\_in}$ = chemical intake rate from inhalation of dust from indoor air (mg d^{-1})

C_s = concentration in soil (mg g^{-1})

TF = soil to dust transport factor according to soil type (g g^{-1})

PEF = particulate emission factor (m^3 kg^{-1})

DL = indoor dust loading factor (g m^{-3})

V_{inh} = daily inhalation rate (m^3 d^{-1})

T_{site} = indoor site occupancy period (hr d^{-1})

In simplified terms, the exposure rate via inhalation of dust indoors is equal to the volume of indoor air inhaled in a day multiplied by the concentration of suspended soil particles less than 10 µm in diameter (PM10) multiplied by the concentration of the contaminant in the suspended soil PM10. The terms in the square bracket in the equation estimate the concentration of soil particles as PM10 in indoor air. The first term (1/PEF) is the estimated PM10 concentration outdoors arising from exposed soil at the property. This outdoor PM10 is assumed to enter the house and be available for indoor inhalation. The second term (TF.DL) is the estimated PM10 concentration indoors arising from re-suspension of soil-derived floor dust. It is equal to the assumed indoor PM10 concentration (the dust loading factor, DL) and the fraction of indoor dust that is composed of soil from the property (TF).

There are a number of uncertainties associated with this equation:

- Firstly, there is an element of double counting, as the dust loading factor should already account for the outdoor PM10 contribution to indoor PM10. However, as discussed below, the effect of this double counting is negligible, as the predicted outdoor PM10 arising from soils (1/PEF) is minimal relative to the second term (TF.DL);
- Secondly, not all PM10 will be inhaled. The majority of PM10 are deposited in the nose or throat and later ingested rather than inhaled. Indeed it is believed that PM2.5 (i.e. particles less than 2.5 um diameter) are responsible for much of the health effects attributable to PM10 (HPA, 2010). Thus, use of PM10 concentration could over-estimate exposure via inhalation of dust. However, the appropriateness of the PM10 size fraction should also be considered in the context of the critical study upon which the HCV for inhalation exposure is based.

3.5.4.1 Soil Concentration

As previously discussed, soil concentration is an output and not an input in the CLEA model when used to derive GAC. When applying GAC it should be recognised that airborne dust is likely to be derived from the finer particles of soil, rather than the coarser fractions. Thus, as with the soil/dust and dermal contact pathways it is the concentration of contaminant in the finer particles that is important when predicting exposure via dust inhalation.

3.5.4.2 Daily Inhalation Rate

Inhalation rate (V_{inh}) is a key uncertainty highlighted by the sensitivity analysis. The inhalation rates used in CLEA are based on mean inhalation rates from Lordo *et al.* (2006) that had previously been recommended by the USEPA (2006). USEPA has since updated its recommendations for inhalation rates (USEPA, 2011) and their most recent recommended mean and 95th percentile values for long-term inhalation are compared to previous recommended mean values in Table 3.2 below. Given that the CLEA values are based on a now outdated USEPA draft report, in the draft interim

methodology document and first Stakeholder Workshop it was proposed to update the values in CLEA to those given in USEPA (2011) for derivation of C4SLs for residential and commercial land-uses. There was widespread support for this modification from the steering group and stakeholders and therefore this proposed modification has been adopted for derivation of the C4SL.

Table 3.2: Comparison of inhalation rates from USEPA, 2006 and USEPA, 2011

CLEA Age Class	Inhalation rate (m^3 day^{-1})		
	USEPA, 2006	Recommended mean value from USEPA, 2011	Recommended 95th percentile value from USEPA, 2011
1	8.5	5.4	9.2
2	13.3	8.0	12.8
3	12.7	8.9	13.7
4-6	12.2	10.1	13.8
7-11	12.4	12.0	16.6
12-16	13.4	15.2	21.9
17	14.8 [1]	15.7 [1]	21.3 [1]
18	12.0 [2]	13.6 [2]	17.4 [2]

Notes
1. Average value for 16 to <65 year old
2. Average value for 65 to <75 year old

3.5.4.3 Time Indoors

For residential land-use CLEA assumes that 0 to <4 year old children spend 23 hours per day in the property and that 5 to < 12 year olds spend 19 hours per day in the property. This is based on the assumptions that 0 to <4 year old children spend all their time at home (with 1 hour per day outdoors) and that primary school age children spend all their time at the property (with 1 hour per day outdoors) whilst not at school. Whilst this may be the case for some children it is likely to be an over-estimate of central tendency, as many children will spend time away from the home, e.g. at the playpark, shopping with parents, at friends and in child care. Nevertheless, whilst the assumed times indoors are likely over-estimates of central tendency, the sensitivity analysis has shown that uncertainty in this parameter does not have a significant bearing on the GACs for residential land-use (i.e. the use of values more likely to represent central tendency do not result in appreciably higher GACs).

For commercial land-use CLEA assumes that working adults spend an average of 8.3 hours per day indoors on working days. Whilst time indoors will be related to the type of work conducted and length of shift, this value is likely to be a reasonable estimate of central tendency.

3.5.4.4 Dust Loading Factor

The Dust Loading (DL) factor is a key uncertainty highlighted by the sensitivity analyses. It is effectively the assumed concentration of PM10 concentration indoors. The CLEA assumed values of 50 $\mu g\ m^{-3}$ for residential land-use & 100 $\mu g\ m^{-3}$ for commercial land-use are based on indoor PM10 estimates presented by Oatway & Mobbs (2003), Oomen & Lijzen (2004) and Simmonds *et al.* (1995).

PM10 indoors is related to physical activity in the house with increased activity generally leading to increased PM10. Figure 3.8 shows monitored dust concentrations in a terraced residential property in Bristol. The concentrations of PM10 are lowest during the night when the occupants are in bed and portions of the day when the house is vacated. Note that for this monitoring event, the concentration of PM2.5 indoors was, on average, 40% of the PM10 concentration.

As discussed in Section 3.5.4, depending on the basis of the inhalation HCV, consideration could be given to the use of the concentration of PM2.5 to predict

inhalation exposure. Values of 25 μg m^{-3} and 50 μg m^{-3} may be reasonable estimates of indoor PM2.5 concentrations for residential and commercial land-uses, respectively based on available data. However, there was mixed support for this modification from the steering group and stakeholders. Whilst there is increasing recognition that the majority of health effects are associated with PM2.5 there was concern that the toxicological data were unlikely to relate to PM2.5, and thus this proposal was rejected. The more precautionary approach of using the estimated indoor air concentrations of PM10 (i.e. 50 μg m^{-3} for residential land-use & 100 μg m^{-3} for commercial land-use) for estimating exposure has therefore been retained.

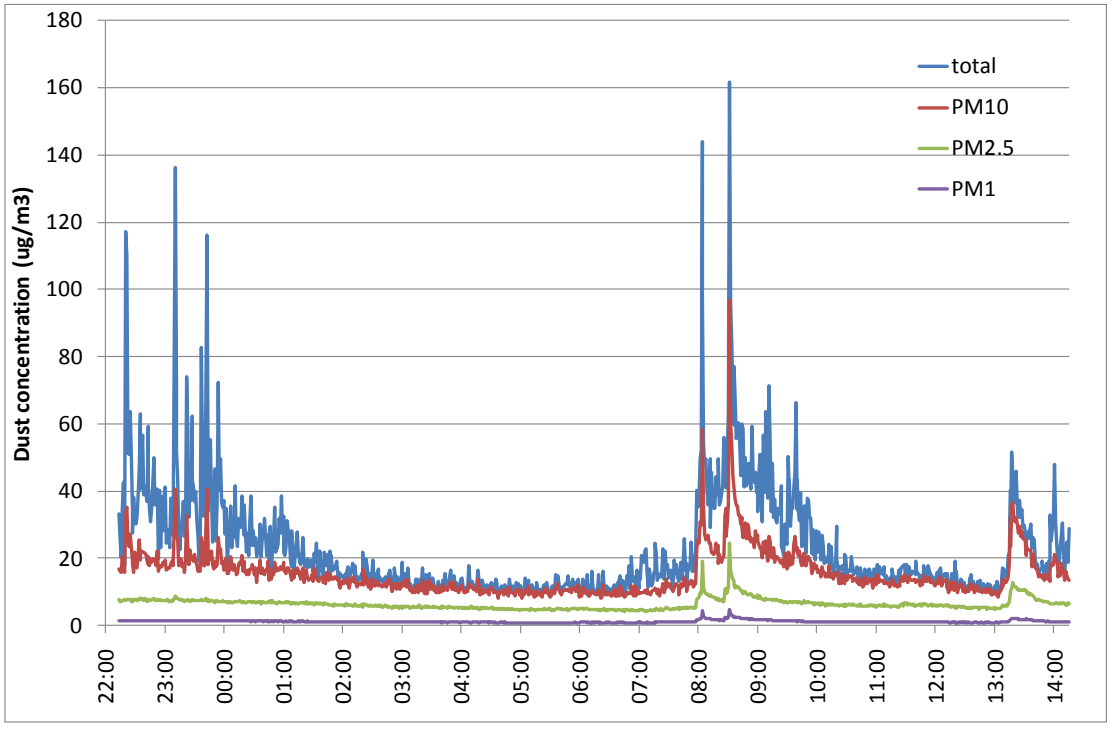


Figure 3.8: Monitored dust concentrations in terraced residential property in Bristol (Firth Consultants, 2010).

3.5.4.5 Transport Factor

The transport factor (TF) is a key uncertainty highlighted by the sensitivity analyses. It is the fraction of indoor PM10 derived from soil. In practice, estimates of the mass fraction of soil in indoor dust (i.e. not just PM10) are generally used as a surrogate for this parameter. Various studies have attempted to correlate indoor dust concentration with soil concentration (see for example, USEPA 1998; Trowbridge & Burmaster, 1997; Oomen & Lijzen, 2004). The mass fraction of soil in indoor dust can be highly variable between houses, dependent on factors such as the number of children and pets that may track in soil, environmental factors such as climate, the extent of vegetative cover in gardens and the deposition of soils transported from neighbouring properties (USEPA, 1998). Estimates of average mass fraction have typically ranged from 0.3 and 0.7 and the midpoint of 0.5 has been assumed as a default in the CLEA model. Based on the available data this is considered a reasonable estimate of central tendency.

3.5.4.6 Exposure Frequency

For residential land-use CLEA assumes that children are at home 365 day a year, which is a highly precautionary assumption. Central tendency for the UK population is more likely to be between 350 and 365 days per year, but as shown by the sensitivity analysis, use of these values results has negligible effect on the GAC.

CLEA assumes an exposure frequency of 230 days per year for commercial land-use. As discussed in Section 3.5.2.4, this is likely to be a reasonable estimate of central tendency for the UK workforce.

3.5.5 CONSUMPTION OF HOMEGROWN PRODUCE

The consumption of homegrown produce is a key exposure pathway for all six focus contaminants for allotments land-use. Its predicted contribution to overall exposure can also be significant for residential land-use, particularly for benzene, cadmium and lead.

CLEA models exposure from consumption of homegrown produce via two pathways: 1) ingestion of soil attached to produce; and 2) uptake of contaminants into produce which are then consumed. The sensitivity analysis has shown that by far the greatest uncertainty arises from the latter and therefore this section focuses on that pathway.

The exposure from uptake of contaminants into homegrown produce that is consumed is calculated using the following equation:

$$IR_{plant\_uptake} = \sum_{all\_produce\_groups} C_s.CF_x CR_x.BW.HF_x$$

Where

IR_{plant_uptake} = chemical intake rate from uptake of contaminants into homegrown produce that is then consumed (mg d^{-1})
C_s = concentration in soil (mg g^{-1})
CF_x = soil to plant concentration factor for each produce group (mg g^{-1} fresh weight [fw] per mg g^{-1} dry weight [dw])
CR_x = food consumption rate per unit body weight for each produce group (g fw kg^{-1} bw d^{-1})
BW = body weight (kg)
HF_x = homegrown fraction for each produce group (dimensionless)

This equation uses simple mass balance to calculate the average mass of contaminant ingested each day for a range of produce types. The exposure rate for each produce type is equal to the estimated concentration of contaminant in the produce, multiplied by the average amount of homegrown produce consumed in a day. One source of uncertainty with this equation relates to the assumption that there is a linear relationship between the concentrations of contaminant in soil and within the plant. This may not be the case, especially where solubility limits are exceeded in soil, which will tend to limit the transfer of contaminants to the plant via passive uptake, which is a more likely pathway for organic contaminants[8].

However, the majority of uncertainty associated with estimation of exposure for this pathway likely relates to the parameter values and is discussed further below.

3.5.5.1 Soil Concentration

As previously discussed, when deriving GAC, soil concentration is solved iteratively and is therefore an output and not an input in the CLEA model. In CLEA, the soil concentration is multiplied by the soil to plant concentration factor to estimate the

[8] With exception of hormone-like chemicals, there is no evidence of active uptake and transport for anthropogenic chemicals (Trapp & McFarlane, 1995).

concentration of contaminant in the portion of the plant that is consumed. As discussed further below, the concentration factor is either estimated from empirical data relating plant concentration to soil concentration or via uptake algorithms which attempt to model the partitioning between contaminants sorbed to soil, in soil pore water and within various parts of the plant. Either way, unlike the other pathways described above, the total concentration of contaminant in soil (as opposed to the concentration in the finer particles) is likely to be more appropriate for estimating exposure from this pathway.

3.5.5.2 Soil to Plant Concentration Factor

The value of the soil to plant concentration factor is a key uncertainty highlighted by the sensitivity analyses. It is the ratio of the concentration of contaminant in the portion of plant consumed to the concentration of contaminant in soil in contact with the plant. CLEA allows contaminant specific soil to plant concentration factors to be set for each plant-type. These can be either empirical based estimates entered directly by the user (e.g. from studies where soil and plant concentrations have been correlated) or modelled using a series of plant uptake algorithms within CLEA. Irrespective of which method is used, there will generally be a high degree of uncertainty associated with the estimates, for the following reasons:

- There is generally a high degree of variability in the contaminant specific soil to plant concentration factors reported in the literature. This is likely due to a variety of factors such as variability in soil characteristics (such as clay content, pH and organic matter content), differences in plant uptake between species and differences in experimental design;
- In addition, for organic contaminants, experimentally derived soil to plant concentration factors are often based on the uptake of radio-labelled carbon (rather than speciated analysis of organics within the plant material). This method ignores metabolic degradation of the contaminant within the plant and can therefore over-estimate uptake;
- Equations used to predict soil to plant concentration factors generally have a poor predictive capacity, i.e. there is often a large discrepancy between modelled and empirically based estimates;
- In particular, the equations used by CLEA for predicting uptake for inorganic contaminants are heavily reliant on the value of the soil to water partition coefficient for the contaminant. This parameter can be highly variable depending on soil type and mineralisation. Literature values typically range over several orders of magnitude.

Despite the high variability in estimates derived from empirical studies, where available, these are generally preferred to modelled estimates.

The Environment Agency SGV addendum reports for arsenic and cadmium summarise available literature values of contaminant specific soil to plant concentration factors for each plant type (EA, 2009 d & e). These typically range across two or three orders of magnitude. A lognormal distribution in values is considered a reasonable assumption and on this basis the Environment Agency has used geomean values as an estimate of central tendency for derivation of the SGVs for these contaminants.

The Environment Agency considered there to be insufficient empirical data reported in the literature to derive empirical soil to plant concentration factors for benzene (EA, 2009f). The SGVs for benzene are therefore based on modelled estimates of the soil to plant concentration factors. As discussed above, there is a large degree of uncertainty associated with these modelled estimates. In particular, the equations used have largely been derived from empirical correlations based on studies of plant uptake of pesticides and to a lesser extent, polycyclic aromatic hydrocarbons and their use for different classes of compound has not been validated. Soil organic matter is a

key input in these equations and as illustrated by the sensitivity analyses this parameter can have a large influence on exposure estimates.

There are a number of further uncertainties that should also be considered when applying the estimated soil to plant concentration factors for predicting exposure concentrations in produce consumed:

- A key assumption in the use of these factors is that there is a linear relationship between soil concentration and plant uptake. However, for some contaminants aqueous solubility will limit plant uptake at relatively low concentrations. For example, the CLEA model predicts that the soil pore water concentration will become fully saturated with benzo(a)pyrene at a soil concentration of 2.7 mg kg^{-1} in a sandy loam soil containing 3% soil organic matter. In theory, plant uptake is unlikely to increase appreciably above this soil concentration;
- Another key assumption is that the predicted concentrations in raw produce are representative of the concentrations in ingested produce. Direct partitioning from soil pore water to skin can be the key uptake mechanism for root and tuber vegetables such as carrots and potatoes. For these vegetables, whether or not the skin is peeled or ingested can have a significant bearing on exposure. Cooking may also reduce contaminant concentrations, with contaminants being volatilised or leached into cooking water that is later discarded.

Overall, it is concluded that the soil to plant concentration factors used to derive SGVs are based on best estimates of central tendency where experimental data are available[9], but that there is a high degree of uncertainty in these estimates and there is a potentially greater uncertainty associated with the algorithms used to predict uptake of organic chemicals.

3.5.5.3 Consumption Rates

Produce type Consumption Rate (CR) is another key uncertainty identified in the sensitivity analyses. Consumption rate is the average amount of each produce type consumed daily. The consumption rates used in CLEA are the 90th percentile estimates for those who consume each produce type derived from UK surveys conducted in 1986, 1992, 1997 and 2000 (EA, 2009c).

One of the modifications proposed in the draft interim methodology document was the use of central tendency values for fruit and vegetable consumption rates rather than the 90th percentile values that had been used for deriving the soil guideline values (SGVs). There was mixed support for this from the first Stakeholder Workshop. Furthermore, probabilistic modelling (see Sections 5.1.1 and 5.3) indicated that this change may lead to an insufficient level of precaution in the C4SLs, where consumption of homegrown produce is a dominant pathway.

To ensure that the C4SLs are sufficiently precautionary a middle ground approach has been adopted, whereby 90th percentile consumption rates have been used for the two homegrown produce groups expected to give the highest exposure, and mean consumption rates have been used for the remaining groups. This approach (albeit using 95th percentile consumption rates), known as the “top two” method, has been recommended for assessing exposure from radionuclides to avoid an overly conservative risk assessment that considers an individual as an upper centile consumer of all food groups (Byrom *et al*, 1995; Smith and Jones, 2003).

[9] Where direct measurements of plant uptake are available the geometric mean is calculated from a review of the experimental data

The top two most important homegrown produce types have been calculated for each relevant age class using the CLEA model and can vary between substances and land-use. CLEA has been used to estimate exposure from the consumption of homegrown produce for each produce type using mean consumption rates for all produce types, the homegrown fractions used to derive the SGVs (EA, 2009c) and geomean or modelled soil to plant concentration factors. The two produce groups giving the greatest exposure to the critical receptor are considered the "top two". This exercise is then repeated using 90th percentile consumption rates to check that the same "top two" produce types are derived. The top two produce types varied for each of the six test substances are shown in Table 3.3.

Table 3.3: Top two produce types for the six test substances for residential and allotments land-uses

Substance	"Top two" produce types					
	Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit
Arsenic	✓					✓
Benzene		✓				✓
Benzo(a)pyrene		✓	✓			
Cadmium	✓	✓				
Chromium VI			✓			✓
Lead	✓		✓			

Note: Although plant uptake is not considered a viable exposure route for chromium VI, exposure via consumption of produce may still occur via attached soil.

The consumption rates used to derive the C4SLs have been updated using the most recent data from the National Diet and Nutrition Survey (NSDS) (2008/2009 to 2010/11). This presents consumption statistics for 1.5 to 3 year olds, 4 to 10 year olds, 11 to 18 year olds, 19 to 64 year olds and 65+ year olds. These data have been interrogated and used to derive mean and 90th percentile consumption rates for age classes 2 to 18 for derivation of the C4SL. No more recent surveys are available for age class 1 and therefore the 90th percentile consumption rates for this age class are those reported in SR3 (EA, 2009c). The mean consumption rates for this age class were not available and have therefore been estimated from the 90th percentile consumption rates presented in SR3 multiplied by the ratio of the mean rates from the recent NSDS survey to 90th percentile rates in SR3 for age class 2. The age of the survey (1986) combined with the uncertainty in mean consumption rates means that there is a relatively high level of uncertainty associated with the consumption rates for age class 1. However, given that this age class is only associated with 6 months exposure for the consumption of homegrown produce, the significance of this uncertainty on the estimation of ADE over the whole exposure duration considered for the critical receptor is diluted.

The mean and 90th percentile consumption rates used for derivation of the C4SLs are presented in Table 3.4 below. As discussed above, the 90th percentile consumption rates are used for the "top two" produce types for each substance and mean consumption rates are used for the remainder.

Table 3.4: Mean and 90th percentile consumption rates used for derivation of the C4SL

Age Class	Mean Consumption Rate (g.FW.kg^{-1} BW.day^{-1})						90th Percentile Consumption Rate (g.FW.kg^{-1} BW.day^{-1})					
	Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit	Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit
AC1	3.47	5.22	9.22	0.89	1.07	1.87	7.12	10.7	16.0	1.83	2.23	3.82
AC2	3.34	1.61	3.14	1.93	0.26	5.84	5.87	2.83	6.6	3.39	0.46	10.3
AC3	3.34	1.61	3.14	1.93	0.26	5.84	5.87	2.83	6.6	3.39	0.46	10.3
AC4	3.34	1.61	3.14	1.93	0.26	5.84	5.87	2.83	6.6	3.39	0.46	10.3
AC5	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC6	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC7	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC8	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC9	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC10	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC11	2.54	1.20	2.65	1.25	0.11	2.89	4.53	2.14	4.95	2.24	0.19	5.16
AC12	1.03	0.49	1.60	0.51	0.04	1.18	1.87	0.89	3.05	0.93	0.08	2.13
AC13	1.03	0.49	1.60	0.51	0.04	1.18	1.87	0.89	3.05	0.93	0.08	2.13
AC14	1.03	0.49	1.60	0.51	0.04	1.18	1.87	0.89	3.05	0.93	0.08	2.13
AC15	1.03	0.49	1.60	0.51	0.04	1.18	1.87	0.89	3.05	0.93	0.08	2.13
AC16	1.03	0.49	1.60	0.51	0.04	1.18	1.87	0.89	3.05	0.93	0.08	2.13
AC17	1.26	0.60	1.18	0.69	0.09	1.27	2.36	1.12	2.35	1.29	0.18	2.38
AC18	1.35	0.64	1.25	0.74	0.10	1.36	2.34	1.12	2.36	1.28	0.18	2.37

3.5.5.4 Homegrown Fraction

The Homegrown Fraction (HF) is the fraction of consumed produce that is grown in the residential garden or allotment and is another key uncertainty identified by the sensitivity analyses. The homegrown fractions used in CLEA are based on results from a 2004/5 Expenditure and Food Survey where 6798 households provided data on the amount of fruit and vegetables purchased and obtained for free, with the latter presumed to include homegrown produce (EA, 2009c). The survey was conducted over a one year period with each household keeping a diary of food purchased/obtained over a two week period (Defra, 2010b), such that the entire survey was equally distributed throughout the year. This survey indicated that 85% of people did not obtain food for free during their two week food diary and thus were assumed not to consume homegrown produce in that time. The remaining 15% did obtain varying proportions of food for free and thus potentially did consume homegrown produce (albeit not necessarily grown in their own garden or allotment). It is possible that the percentage of people consuming homegrown produce has been under-estimated as some people who occasionally eat homegrown produce may not have done so on the particular fortnight in which they kept their food diary. However, this is likely to be balanced by some respondents eating atypically (for them) high quantities of certain produce types during the two week study period.

The average proportion of free produce obtained across all respondents was 2 to 9%, depending on produce type and these percentages have been used in CLEA for residential land-use. However, it is doubtful whether these “average” values are truly representative of residents. For the 85% of residents who don’t grow produce, these average values are over-estimates of the amount of homegrown produce they consume. Of the 15% of residents who do grown produce, some of these will

presumably be allotment holders who grow a relatively large proportion of the produce they consume and some will grow a relatively modest amount of produce in their own gardens. It is interesting to note that the most recent Defra survey from 2009 (Defra, 2011a) indicates that, on average, about 3% of fruit and vegetables entering the household in 2009 came from free sources, considered to be mainly gardens and allotments. This survey concluded that the fraction of home-grown produce had remained the same over the last four yearly surveys (i.e. since 2006).

The homegrown fractions used in CLEA for deriving SGV for residential land-use equate to an estimated yearly yield of 43 kg of produce grown in the garden for a family of two adults and two children (EA, 2009c). Theoretically, this yield could be produced from a 4 x 5 m vegetable plot (EA, 2009c). Whilst some gardeners in the UK no doubt fulfil this yield, it is probable that the homegrown fractions assumed in CLEA for residential land-use are over-estimates for the vast majority of residential properties where soil contamination is a potential concern. Consideration could be given to reducing the homegrown fractions used for deriving C4SLs, but this may be un-protective of a relatively small subgroup of the population. The steering committee and stakeholders were generally not in favour of reducing the assumed homegrown fractions for residential land-use for the purposes of deriving C4SLs. The homegrown fractions used for derivation of the SGVd have therefore been retained for derivation of the C4SLs.

The average homegrown fractions assumed for allotments land-use are judged not to be unreasonable estimates of central tendency for allotment holders.

3.5.5.5 Body Weight

Body Weight (BW) is a parameter used in the consumption of homegrown produce algorithm. However, when combined with the general equation for predicting ADE, body weight appears on both the top and bottom of the equation for this pathway and thus is effectively cancelled out. Thus body weight is not a key parameter in the prediction of ADE from consumption of homegrown produce.

3.5.5.6 Exposure Frequency

Exposure frequency (EF) is assumed to be 365 days per year for the consumption of homegrown produce with the exception of the 0 to 1 year old, where a value of 180 days is assumed. Whilst it is unlikely that homegrown produce will actually be consumed every day of the year in most cases, it is important to recognise that the consumption rates assumed for this pathway are based on estimated average annual consumption and thus an exposure frequency of 365 days per year is appropriate in this instance.

3.5.6 VAPOUR INHALATION INDOORS

The inhalation of vapours that have intruded through the foundation into buildings is a key exposure pathway for benzene for residential and commercial land-uses. The CLEA model uses the following equation to assess exposure from the inhalation of contaminant vapour indoors:

$$IR_{vap\_indoor} = C_{indoor\_air} . V_{inh} . \left(\frac{T_{site}}{24} \right)$$

Where

$IR_{vap\ indoor}$ = chemical intake rate from inhalation of vapour from indoor air (mg d^{-1})
$C_{indoor\ air}$ = contaminant concentration in indoor (mg m^{-3})
V_{inh} = daily inhalation rate (m^3 d^{-1})
T_{site} = occupancy period (hr d^{-1})

This equation is considered robust, although more recent inhalation rate (V_{inh}) parameter values than those used in CLEA v1.06 are available from USEPA (2011; see Section 3.5.4.2 and Table 3.2).

3.5.6.1 Modelling of indoor air concentration

Calculation of the contaminant concentration in indoor air is complex and involves multiple steps, starting with the estimation of a soil gas concentration based on simplified equilibrium partitioning, as follows:

$$C_{vap} = \frac{K_{aw}.C_s}{K_{sw}}$$

Where:

C_{vap} = soil gas concentration (mg m^{-3})
C_s = total concentration of contaminant in soil (mg kg^{-1})
K_{aw} = air-water partition coefficient at ambient temperature ($cm^3\ cm^{-3}$)
K_{sw} = total soil-water partition coefficient ($cm^3\ g^{-1}$)

Calculation of the indoor air concentration is then achieved by the application of an attenuation factor (α) to the soil gas concentration, as follows:

$$C_{indoor\_air} = \alpha.C_{vap}$$

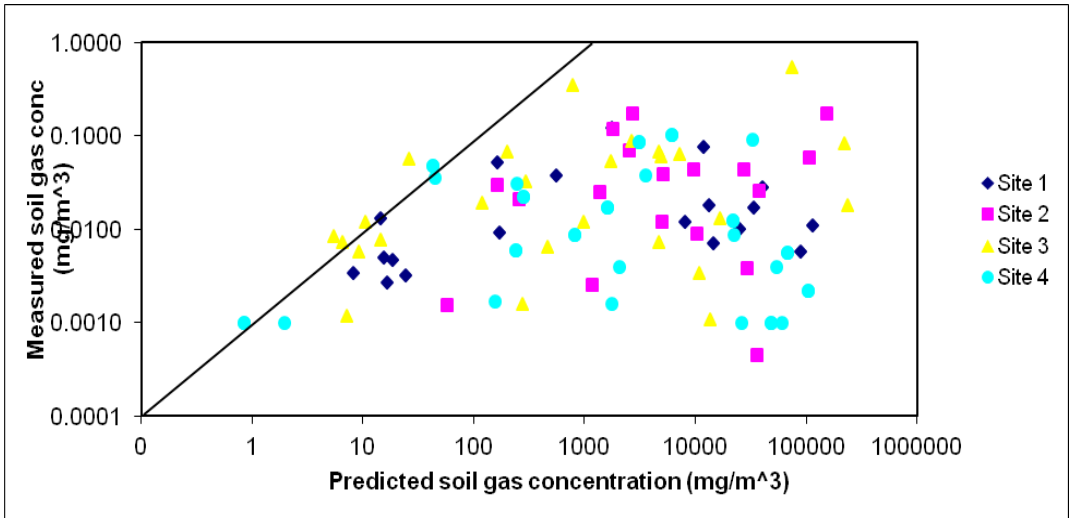
3.5.6.2 Equilibrium partitioning to estimate soil gas concentrations

Hartman (2002) states that the equilibrium partitioning assumption is the major source of over-estimation when using the Johnson-Ettinger model and the CLEA Report (EA, 2009c) acknowledges that the solid, aqueous and vapour phases are unlikely to achieve equilibrium in an open soil system. The CIRIA VOC Handbook (CIRIA, 2009) attributes over-prediction of soil gas concentrations to the use of Henry's Law constant[10] and a failure to take account of the influence of biodegradation on relatively biodegradable compounds such as the BTEX[11] and other low-medium molecular weight hydrocarbons.

Figure 3.9 (taken from CIRIA, 2009) plots measured soil gas concentration of a range of volatile and semi-volatile petroleum hydrocarbons against the predicted soil gas concentration estimated using equilibrium partitioning. This demonstrates that calculation of soil vapour based on equilibrium partitioning from measured contaminant concentrations in soil and groundwater results tends to produce overestimates of several orders of magnitude (the solid line plotted on the graph indicates a thousand-fold over-estimation of soil gas concentrations).

[10] Henry's Law constants for medium-low volatility compounds are commonly estimated based on vapour pressure and aqueous solubility; the very low solubility of these compounds leads to a high estimated value for H^c which is not observed in reality.

[11] Benzene, toluene, ethylbenzene and xylenes.



Ref. CIRIA, 2009

Figure 3.9: Comparison of measured and predicted gas concentrations

3.5.6.3 Estimation of the soil to indoor air attenuation factor

In CLEA, the attenuation factor (α) is calculated using the Johnson and Ettinger model (Johnson and Ettinger, 1991), as shown below:

$$\alpha = \frac{\left[\left(\frac{D_{eff}.A_B}{Q_b.L_T}\right)\exp\left(\frac{Q_s.L_{crack}}{D_{crack}.A_{crack}}\right)\right]}{\left[\exp\left(\frac{Q_s L_{crack}}{D_{crack.}A_{crack}}\right)+\left(\frac{D_{eff}.A_B}{Q_b.L_T}\right)+\left(\frac{D_{eff}.A_B}{Q_s.L_T}\right)\left[\exp\left(\frac{Q_s L_{crack}}{D_{crack.}A_{crack}}\right)-1\right]\right]}$$

Where,

α = steady-state attenuation coefficient between soil and indoor air (dimensionless)
D_{eff} = effective diffusion coefficient for unsaturated soils ($cm^2\ s^{-1}$)
A_B = area of enclosed floor and walls below ground (cm^2)
Q_b = building ventilation rate ($cm^3\ s^{-1}$)
L_T = source-building separation (cm)
Q_s = volumetric flow rate of soil gas into the enclosed space ($cm^3\ s^{-1}$)
L_{crack} = foundation slab thickness (cm)
A_{crack} = floor crack area (cm^2)
D_{crack} = effective diffusion coefficient through the cracks (assumed equal to D_{eff} in CLEA) ($cm^2\ s^{-1}$)

This equation is based on the integration of a number of equations that attempt to model three processes:

1. The upwards flux of contaminants from the soil source zone into the advective zone beneath the building foundation;
2. The advective flow of atmospheric air into the soil surrounding the building, beneath the foundations and into the building via cracks in the foundations/floor. This flow occurs due to reduced air pressure in the building relative to outdoors as a result of stack and wind effects; and
3. Dilution within the building caused by air flow through windows, doors, ventilation vents etc.

Although the Johnson and Ettinger model is widely used, it is acknowledged to over-predict indoor vapour concentrations in some circumstances and for certain contaminants such as petroleum hydrocarbons (Wilson 2008; EA, 2009c). It has also been demonstrated to sometimes under-predict indoor vapour levels, including those of chlorinated solvents (EA, 2009c).

The Johnson and Ettinger model is based on the assumption that the building has a solid slab foundation or basement-type structure. While this type of housing is common in the USA, many UK houses have a suspended floor over a void meaning that the bottom of the floor slab may be at or above the external ground level. In this circumstance the Johnson and Ettinger model is likely to significantly overestimate vapour ingress to the building (EA, 2009c; Wilson, 2008).

CLEA assumes a contaminant source that is less than one metre beneath the surface (i.e. 0.5m below the bottom of the floor). This is relatively shallow and it therefore assumes only a limited potential for biodegradation to occur as vapour migrates towards a building. An indoor air correction factor is currently applied in CLEA to petroleum hydrocarbons, to take account of some of the acknowledged over-prediction for this class of compounds when using equilibrium partitioning and the Johnson and Ettinger model (see SGV reports for BTEX compounds; e.g. EA, 2009f). This could be increased on a substance or site-specific basis where this is evidence that a compound is highly biodegradable or that the use of equilibrium partitioning significantly over-estimates vapour phases concentrations in soil.

Although the Johnson and Ettinger model has a number of acknowledged deficiencies and leads to overestimates for certain types of housing construction and for certain classes of contaminants (specifically petroleum hydrocarbons), it is considered appropriate as a screening tool that will give protective estimates of the potential indoor air concentrations of volatile contaminants across all types of housing. However, the Johnson and Ettinger model is unlikely to be suitable for the assessment of vapour risk for UK new build housing (on the basis that it is likely to be highly conservative for the reasons described earlier) and alternative approaches such as that proposed by Wilson (2008) may be more suitable in this instance.

It is considered that alternative approaches to the assessment of the vapour inhalation pathway should be incorporated at the level of site-specific assessment, rather than for the development of C4SLs. On actual sites, the verification of any risk posed by volatile contaminants can be achieved by direct gas or vapour measurement either in the ground or in buildings and recent guidance has been published detailing how this can undertaken when assessing the vapour risk from contaminated land (CIRIA, 2009).

3.5.7 SUMMARY OF SUGGESTED CHANGES TO CLEA

Pathway and sensitivity analyses have been used to identify key pathways and parameters that lead to uncertainty in the exposure modelling performed by CLEA. The equations and associated assumptions and parameter values for these key pathways and parameters have been critically reviewed to qualitatively assess the level of precaution they represent and, where appropriate, to make suggestions regarding modifications which could be made to CLEA to enable the development of C4SLs. Feedback from the steering committee and stakeholders, along with the outcome of probabilistic modelling, has refined these proposals to derive a set of modifications to the CLEA input parameters that are considered appropriate for derivation of C4SLs for residential, allotments and commercial land-uses.

The key findings for each pathway are summarised below:

Soil and Dust Ingestion

- Soil and dust ingestion is a key exposure pathway for one or more contaminants for all three generic land-uses. Key parameters are soil and dust ingestion rate, exposure frequency and relative bioavailability.
- There is a relatively high level of uncertainty associated with the input parameters for this pathway due to limited data. Nevertheless, from the available data it is reasonable to conclude that the combination of the soil and dust ingestion rates and exposure frequencies used for residential and commercial land-uses are more likely to over-estimate than under-estimate exposure for a random, typical individual living/working on the property[12]. Consideration was given to use of reduced soil ingestion rates based on weighted indoor and outdoor exposure to more accurately reflect central tendency for residential and commercial land-uses. However, due to uncertainty in winter soil ingestion rates it was decided to maintain the values used to derive the SGVs for the derivation of C4SLs.
- The assumption of a RBA of 100% is likely to be conservative for some contaminants (e.g. arsenic, lead and benzo(a)pyrene) for the majority of sites investigated in the UK. However, bioavailability is often highly dependent on the characteristics of the soil and speciation of the contaminant and thus can be highly variable between sites. Thus, in most cases consideration of bioavailability will be more appropriate on a site by site basis rather than within the derivation of generic screening levels. Nevertheless, consideration will be given to reducing the RBA below 100% for derivation of C4SLs for contaminants where there is strong evidence that the bioavailability of the soil bound contamination is significantly lower than that associated with the critical toxicological studies (such as lead).

Dermal Contact Outdoors

- Dermal contact outdoors is a key exposure pathway for benzo(a)pyrene for the residential land-use. Key parameters are the soil to skin adherence factor, the area of skin with adhered soil, the dermal absorption factor and exposure frequency.
- Upper percentile values are currently used in CLEA for each of these parameters and the combined effect likely results in an over-estimation of exposure in the vast majority of cases. The uncertainty in the input parameters is high due to limited data, but not appreciably greater than the soil and dust ingestion pathway. Values closer to central tendency for the soil to skin adherence factor and exposure frequency outdoors are proposed for derivation of C4SLs. These values are still likely to be conservative estimates of central tendency and in combination with highly precautionary estimates of exposed skin area result in estimates of dermal exposure that are still precautionary.

Dust Inhalation Indoors

- Dust inhalation indoors results in a relatively low contribution to overall ADE but can be a key exposure pathway for the residential and commercial land-uses for contaminants with a HCV for inhalation orders of magnitude lower than the HCV for oral exposure such as hexavalent chromium. Key parameters are the concentration of airborne respirable dust particles indoors (the dust loading factor), the proportion of airborne indoor dust derived from soil at the property (the transport factor), time spent indoors and the respiration rate indoors.

[12] High levels of soil ingestion resulting from pica behaviour or geophagia (considered psychopathological conditions) are not considered in the proposed approach or the CLEA framework on which it is based, and should be assessed on an individual basis, where relevant.

- Best estimates of central tendency values have been used for these parameters for derivation of the SGVs and it is proposed that these are retained for derivation of the C4SLs. However, it is proposed that the respiration rates used in the model are updated to more recent values recommended by the USEPA for derivation of the C4SLs.

Consumption of Homegrown Produce

- The uptake of contaminants into the edible portions of fruit and vegetables followed by their consumption is a key pathway for five of the six focus contaminants for allotments land-use and for benzene and cadmium for residential land-use. Key parameters are the soil to plant concentration factor, consumption rates of fruit and vegetables and the fractions of these that are for homegrown produce.
- In general, the values for the soil to plant concentration factors used for derivation of published SGVs can be regarded as best estimates of central tendency, but it should be recognised that there is a high degree of uncertainty associated with these estimates.
- The consumption rates used for the derivation of the SGVs are based on the 90^{th} percentile estimates for consumers of each fruit and vegetable type from various UK surveys. It was initially proposed to use central tendency estimates for derivation of the C4SL, but following steering committee and stakeholder feedback and the results of the probabilistic modelling it was decided to use a "top two" approach, whereby 90^{th} percentile rates are used for the two produce types expected to lead to greatest exposure and mean consumption rates are used for the remainder.
- The homegrown fractions likely represent upper percentiles for the UK population. However, whilst the values likely over-estimate homegrown fraction for the vast majority of the UK population, they are not unreasonable estimates of central tendency for the sub-group of the population who are keen fruit and vegetable growers and so have been retained for derivation of the C4SL.

Vapour Inhalation Indoors

- Calculation of the contaminant concentration in indoor air is complex and involves multiple steps, including the estimation of a soil gas concentration, based on simplified equilibrium partitioning, and an attenuation factor, based on the Johnson and Ettinger model.
- Although the Johnson and Ettinger model has a number of acknowledged deficiencies, which can lead to considerable overestimates of indoor air concentrations, it is considered appropriate as a screening tool that will give protective estimates of the potential indoor air concentrations of volatile contaminants in all types of housing.

A summary of the initial modifications to exposure modelling parameters proposed and those finally adopted for derivation of the C4SLs are summarised in Table 3.5.

Table 3.5: Initially proposed and final modifications to CLEA exposure parameter values for the derivation of C4SLs

Proposed change	Change invoked?		
	Residential	Allotments	Commercial
Reduce soil ingestion rates for residential and commercial land-uses	✗		✗
Halve exposure frequencies for children on allotments		✗	
Reduce soil adherence factors in children (AC1 to AC12) for residential land-use from 1 to 0.1 mg cm^{-2}	✓		
Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year (AC1 to AC18)	✓		
Update vapour inhalation rates to the mean values recommended in USEPA, 2011 (AC1 to AC18 – see Table 3.2)	✓		✓
Reduce indoor dust loading factors for residential and commercial land-uses to better reflect likely concentration of PM2.5	✗		✗
Use of 90th percentile estimates of consumption rates for "top two" produce types and mean consumption rates for remainder (see Tables 3.3 & 3.4) *	✓	✓	
Reduce the fraction of homegrown produce for residential land-use	✗		
Exclude the quantitative consideration of background exposure from the derivation of C4SLs	✗	✗	✗

Notes
* - Initial proposal was to use mean consumption rates for all produce types by this was modified in light of steering committee/stakeholder comments and results of the probabilistic modelling.

3.6 C4SLs FOR PUBLIC OPEN SPACE

This section presents the proposed approach for the development of C4SLs for public open space (POS). This land-use has not been considered during the development of SGVs although it is commonly encountered during the assessment of sites under Part 2A. It is therefore considered that the development of generic C4SLs for public open space will be particularly useful to local authorities and the wider contaminated land community. The help of WS Atkins and Lynette MacDonald is acknowledged in relation to this aspect of the project (Atkins, 2013 and MacDonald, 2005). It should be noted that the nature of public open space is highly variable and it is therefore important that the assessor understands in detail the conceptual model on which the C4SL is based and is able to judge how this relates to the site in question.

3.6.1 TYPES OF PUBLIC OPEN SPACE

There are a large variety of land-uses that could be considered "public open space", with receptor and exposure characteristics likely to vary significantly between them. For example, the following land-uses could all be considered as examples of public open space, with each possessing distinct exposure characteristics:

- Grassed area that is rarely used, adjacent to residential housing;
- Grassed area where children play on a regular basis adjacent to residential housing (potentially comparable to garden without home-grown produce);
- Play park in close proximity to housing where some children play regularly and others less so;
- Public park with football pitch where children play or practice sport several times per week and teenagers/adults play once per week;

- Dedicated sports grounds where exposure only occurs to players and ground-workers; and
- Nature reserves or open ground with a low-level of activity (e.g. dog walking).

It could therefore be considered necessary to model more than one exposure scenario to generate C4SLs that are suitable as screening levels for the public open spaces that are most likely to be assessed. However, it would be impractical to generate a large number of C4SLs and efforts have instead focussed on land-use scenarios that are commonly encountered and are based on the most sensitive receptors (i.e. young children who have higher exposure relative to body weight).

The critical evaluation of the exposure parameters used for the residential, commercial and allotments land-uses undertaken for the C4SL project (Section 3.5 of this report) has also been used in setting exposure characteristics for the public open space land-use scenarios. Key factors in defining the POS land-use scenarios are the age of the critical receptor and exposure frequency. As far as possible, values for these parameters have been based on available surveys (e.g. those used by Atkins in developing their screening levels for open spaces (Atkins, 2013) and surveys on outdoor activities undertaken by Natural England[13]) and this information has been supplemented by reasonable assumptions about behaviour and exposure.

3.6.2 APPROACH TO DEVELOPING C4SLs FOR POS

In the interim methodology report and second Stakeholder Workshop it was proposed to develop C4SLs for two types of POS:

- The scenario of green space close to housing that includes tracking back of soil (POS_{resi}); and
- A park-type scenario where the park is considered to be at a sufficient distance that there is negligible tracking back of soil (POS_{park}).

These two scenarios are considered to be most relevant to young children who are generally the critical receptors in the majority of conceptual models for potentially contaminated land. Other potential POS land-use scenarios were discounted on the basis that they would are not relevant to young children and/or they are used less frequently resulting in lower levels of exposure. Playing fields used exclusively for sports are only used a few times a week by older children and adults and data from Atkins (2013) and Natural England (2012) indicate that on average, nature reserves and country parks are only visited by children a few times per month. There was widespread support from the steering committee and stakeholders for the scenarios selected leading to C4SLs being derived for the two scenarios listed above.

The most sensitive receptors for both types of POS scenario are considered to be young children. Different age classes will be considered for the two types of POS based on the age of children considered to use them most frequently and for longer periods of occupancy.

3.6.3 LAND-USE SCENARIO FOR POS_{resi} (PUBLIC OPEN SPACE NEAR RESIDENTIAL HOUSING)

3.6.3.1 Site Characteristics

The use of land as 'public open space in close proximity to residential housing' (POS_{resi}) includes the predominantly grassed areas adjacent to high density housing

[13] http://www.naturalengland.org.uk/ourwork/research/mene.aspx

and the central green area around which houses are located, as on many housing estates from the 1930s to 1970s. It is also anticipated that this land-use would include the smaller areas commonly incorporated in newer developments as informal grassed areas or more formal landscaped areas with a mixture of open space and covered soil with planting.

POS_{resi} is considered to generally be a predominantly grassed area of up to 500 m^2 (0.05 ha) and a considerable proportion of this (up to 50%) may be bare soil. The site is in close proximity to residential housing and is regularly used by children for playing and may be used for informal sports activities such as a football "kickabout".

This type of land-use is an important resource for children and the area near their homes is acknowledged as one of the main play places for many children, in both urban and rural areas (NCB, 2002). The success of housing estates in relation to children's play activities was assessed in a study by Wheway & Millward (1997) and was measured by criteria including the percentage of children observed at play and the widest range of activities engaged in by the children. The most successful estates had grassy areas set back from the roads, a footpath network (for pedestrians and cycles) around and through the estate linking into the public open spaces; and/or cul-de-sac layout and informal play areas.

The study by Wheway and Millward (1997) found that approximately 20% of children were observed outdoors at any one time and that 18% of children were using public open spaces or grassed areas. It was also observed that children tended to move around and not stay in one particular place.

3.6.3.2 Critical Receptor Characteristics

The critical receptor is judged to be a female child (lower body weight than male and therefore more sensitive) and covers CLEA age classes 4 - 9[14] (i.e. age >3 - <9 years old). A six year exposure duration is selected in accordance with international practice for a child receptor (i.e. to adequately address chronic exposure and cover the range of exposure characteristics across different ages) and an exposure duration covering age classes 4 - 9 is considered to be appropriate for the youngest children who would use this type of space on a regular basis. The exception is where lifetime averaging applies, such as is the case for cadmium[15]. It is acknowledged that younger children supervised by parent or carers may also use this land but it is considered likely that this would occur on a less frequent basis. This assumption was supported by the majority of stakeholder responses, who indicated preference for the selection of a critical receptor of CLEA age classes 4-9 rather than 1-6.

An unsupervised child is assumed to use this type of POS more frequently and a survey undertaken on behalf of Natural England (2009) found that nearly half of children aged 7-11 said that they were not allowed to play outside unsupervised (Natural England, 2009). Based on age groups this breaks down to 31% of 7-9 year olds and 45% of 10-11 year olds being allowed to play unsupervised in the streets near their home (data were not available for younger children).

3.6.3.3 Exposure Pathways and Activity Patterns

Little information was identified that could be used to underpin the detailed derivation of an exposure scenario for this type of land-use so exposure assumptions are instead

[14] CLEA age class 4 corresponds to 'age 3 to < 4' and age class 9 corresponds to 'age 8 to <9'

[15] 71 years (i.e age classes 4-18) is assumed when lifetime averaging is used (e.g. for cadmium)

based on an adaptation of the CLEA residential land-use scenario without consumption of homegrown produce and vapour ingress to the building.

POS_{resi} is based on the revised residential land-use scenario described earlier in this report and the key exposure parameters are defined in Section 3.5. This open space is considered to be in sufficiently close proximity to the place of residence for tracking back of soil to occur. Exposure modelling therefore includes assessment of indoor exposure pathways as in the existing residential land-use scenario within CLEA. Therefore, the relevant exposure pathways for POS_{resi} are assumed to be:

- Ingestion of soil and dust (outdoors and indoors, respectively)
- Dermal contact with soil (outdoors; and soil-derived dust indoors)
- Inhalation of dust (outdoors and indoors)
- Inhalation of vapours outdoors

Specific aspects of this conceptual model are described below and listed in Table 3.3.

The receptor for this scenario is defined as a child using the site on a regular basis (1 hour at a time, in common with the outdoor occupancy period in the standard CLEA residential scenario, and for 170 days per year as defined by the revised exposure frequency selected for the derivation of C4SLs for residential land-use scenarios).

The consumption of homegrown produce is discounted as public open space, such as this, is not anticipated to be used for the growing of fruit and vegetables. Where urban spaces are being used to cultivate such produce this land-use scenario would not be applicable. It is also assumed that the place of residence is not directly above the area of land that makes up the public open space. Therefore, C4SLs derived for this land-use scenario expressly do not include consideration of the potential risk to nearby buildings from volatile contaminants that may be present in soil.

Tracking back of soil and therefore indoor exposure pathways such as ingestion and inhalation of soil-derived dust and dermal contact with dust are considered to be active. This is considered to be a relatively conservative assumption in most instances as this type of public open space will generally be further from entrances to the home than a standard garden.

A slight reduced soil ingestion rate (compared to the residential land-use) of 75 $mg.day^{-1}$ is used for POS_{resi} on the basis of the observation that there is commonly an approximately 50:50 ratio between ingestion of soil and soil-derived dust (USEPA, 2011 & Environment Agency, 2009a). The standard ingestion rate of 100 $mg.day^{-1}$ is used for the 170 days per year that the child plays outside and 50 $mg.day^{-1}$ is used for the other 195 days per year when ingestion is assumed to be due to soil-derived dust indoors only (USEPA, 2011). A soil ingestion rate of 75 $mg.day^{-1}$ is judged to be a reasonable estimate of average ingestion over the year as there will be less tracking back of soil into the home than from a garden and it is unlikely that this type of site will be used or walked across as frequently during wet weather.

The conceptual model and exposure characteristics for POS_{resi} are detailed in Table 3.6 below with details provided for all exposure characteristics that deviate from those for the revised CLEA residential receptor.

Table 3.6: POS_{resi}; Public Open Space scenario for grassed area adjacent to residential housing

Parameter	Value	Notes
Default Receptor	CLEA female residential	POS_{resi} land-use based on residential scenario
Age Group	>3 - <9 yr old child (or full lifetime from 3 years onwards where lifetime averaging assumed)	Six-year exposure period covering ages at which young children will use this type of land most frequently
CLEA Start Age Class	4	
CLEA End Age Class	9 (18 where lifetime averaging assumed)	
Exposure Duration	6 years (or 71 years where lifetime averaging assumed)	Common international practice for child receptor
Averaging Time	6 years (or 71 years where lifetime averaging assumed)	
Soil ingestion rate	AC 1-12: 75 $mg.day^{-1}$ AC 13-18: 37.5 $mg.day^{-1}$	170 $days.year^{-1}$ at 50 $mg.day^{-1}$ and 195 days at 100 mg.day (rounded to 75 $mg.day^{-1}$). Teenagers and adults assumed to ingest soil at half the rate of children
Exposure frequency (outdoor pathways)	170 $days.year^{-1}$	On the basis that the open area is used regularly, up to several times per week
Exposure frequency (indoor pathways – dermal and dust inhalation)	365 $days.year^{-1}$	CLEA residential default on the basis that the indoor exposure pathways may occur every day due to the presence of tracked back soil
Soil to skin adherence factor outdoors	0.1 $mg.cm^{2}$	Updated value based on USEPA (2011) (see Section 3.5.3.3 of this report)
Occupancy period (outdoors)	1 $hour.day^{-1}$	CLEA residential default (EA, 2009c)
Occupancy period (indoors)	AC 4: 23 $hour.day^{-1}$ AC 5-12: 19 $hour.day^{-1}$ AC 13-16: 15 $hour.day^{-1}$ AC 17-18: 16 $hour.day^{-1}$	CLEA residential defaults (EA, 2009c)
Exposure pathways	Oral • Direct soil and dust ingestion Dermal • Outdoors • Indoors Inhalation • Outdoor dust • Outdoor vapour • Indoor dust	
Fraction of site with hard or vegetative cover	0.5	Half of site may be bare soil from excessive use
Soil type	Sandy loam	CLEA default
Soil organic matter	6%	CLEA default
Air dispersion factor at 0.8m	500 $g.m^{-2}.s^{-1}$ per $kg.m^{-3}$	Value for area of 0.05 Ha, (CLEA report Table 9.1, EA, 2009c)
Air dispersion factor at 1.6m	2000 $g.m^{-2}.s^{-1}$ per $kg.m^{-3}$	Value for area of 0.05 Ha, (CLEA report Table 9.1, EA, 2009c)

3.6.3.4 Summary of POS_{resi}

This generic scenario is based on consideration of a largely grassed area next to housing that is used by children on a regular basis. The key assumptions for the 'public open space near residential housing' model are as follows:

- Critical receptor is a child covering CLEA age classes 4-9 and exposure duration is 6 years (with the exception of contaminants where lifetime averaging applies (such as cadmium) where average daily exposure is estimated for age classes 4-18 over a 71 year duration);
- Land is grassed or landscaped area and in close proximity to housing (leading to potential tracking back of soil to the home);
- Exposure pathways include direct soil and indoor dust ingestion, skin contact with soil and dust, inhalation of vapours outdoors and inhalation of soil-derived dust indoors and outdoors

3.6.4 LAND-USE SCENARIO FOR POS_{park} (PUBLIC PARK)

3.6.4.1 Site Characteristics

A public park is an area of open space provided for recreational use and usually owned and maintained by the Local Authority. It is anticipated that POS_{park} could be used for a wide range of activities, including the following:

- Family visits and picnics;
- Children's play area;
- Sporting activities such as football on an informal basis (although this POS is not considered as a dedicated sports pitch); and
- Dog walking.

Wheway and Millward (1997) state that children's favourite places to play include parks, other open spaces and play areas and parks are considered to offer younger children, especially in urban areas, freedom and a play space away from traffic (NCB, 2002). The green spaces, trees, plants and small animals found in parks may be the only regular access city children have to the natural environment. Parks frequently have other features attractive to children for play; these include trees and bushes, wide-open flat green spaces, informal sports facilities, ponds and paddling pools, fountains, hills and slopes and smooth paths and surfaces.

In modelling for POS_{park}, a public park is considered to be a relatively large area (>0.5 ha) of predominantly grassed open space with no more than 25% of exposed soil.

3.6.4.2 Critical Receptor Characteristics

The observational studies and questionnaire data compiled by Lynette MacDonald for deriving Atkins screening levels for public parks (MacDonald, 2005; Atkins, 2013)) indicate that very young children appear to be the critical receptors. These children will visit the park several times a week or daily during good weather and play on the grass and sit/fall down regularly. A six year exposure duration is selected in accordance with international practice for a child receptor and age classes 1 - 6 are modelled except in the consideration of lifetime exposure where exposure is averaged over age classes 1 to 18 (74 years, e.g. for cadmium).

Following the usual assumption within CLEA land-use scenarios that consider children, the critical receptor is a female child as they have lower body weight and therefore a higher relative exposure. The child is considered to be physically active during a visit to the park and receptor characteristics are based on the allotment scenario receptor as it is anticipated that young children will be active to a similar extent during a visit to the park, e.g. for breathing rate it is assumed that for age classes 1 – 3 the child engages in light activity two thirds of the time and moderate

activity one third of the time; for age classes 4 – 6 there is a 50:50 split between light and moderate physical activity.

3.6.4.3 Exposure Pathways and Activity Patterns

For the development of C4SLs for POS_{park} the approach used in CLEA for allotments has been followed in considering it reasonable to assume that tracking back of soils into the place of residence will be negligible based on the distance between the two places. As such, the key exposure pathways for POS_{park} are considered to be:

- Ingestion of soil outdoors
- Dermal contact with soil outdoors
- Inhalation of dust outdoors
- Inhalation of vapours outdoors

Atkins (2013) report that the majority of the population visit an open space such as a park at least once per week and data compiled on the frequency of visits to parks shows a normal distribution with the peak at 156 days per year. Analysis by MacDonald (2005) of data compiled by Local Authorities and the Environment Agency indicates that only 20% of people visit parks more frequently than this. On this basis it was concluded that an exposure frequency of greater than once per week, probably several times per week should be used to account for the majority of people without being too conservative.

A lower frequency of visits to parks is indicated by an ongoing Natural England survey of people's engagement with the natural environment, which includes visits to parks in towns and cities (Natural England, 2012). The average number of visits to the natural environment taken per adult during 2011/12 was 65 times per year with 38% of these to green spaces within towns and cities (Natural England, 2012). Less than 25% of respondents to the survey had visited the natural environment (including parks) more than once in the previous week. 11% visited the natural environment every day over the previous 12 months and the remaining 89% visited 'several times per week' or less.

The data reported by Atkins to establish the frequency of visits do not distinguish frequency of visit according to CLEA age class and it may not be that the critical receptor is also making the most number of visits. Indeed, it is acknowledged that adults of working age are the most frequent visitors to parks followed by children under 5 (Atkins, 2013). This conclusion is confirmed by Natural England (2012) who report that 54% of visits to the natural environment during 2011-12 were undertaken by an adult on their own, while 22% of visits were taken with children present.

It is proposed to use an outdoor exposure frequency of 170 days.year^{-1} for age classes 2-18 for POS_{park} (the same number used for outdoor activity in the revised residential scenario and POS_{resi}) as this is slightly higher than the modal value from the Atkins data and is considered to be conservative for the majority of park users and specifically, young children. Exposure frequency is reduced to 85 days.year^{-1} for age class 1 (age 0-1 years) as babies are considered to have minimal contact with soil during the first six months (Environment Agency, 2009c).

In selecting a value for occupancy period outdoors Atkins (2013) chose a value of 1.5 hours.day^{-1} for time spent in the park based on the 90th percentile of data collected; this was considered to be a reasonable maximal exposure approach. Natural England (2012) report similar figures and state that the average visit to the natural environment lasts just under 2 hours (1 hour 58 minutes). An outdoor occupancy period of 2 hours.day^{-1} is selected for modelling of POS_{park}.

A value of 50 mg.day^{-1} is selected as the soil ingestion rate for POS_{park} for age classes 1-12 on the basis of the proportion of the daily ingestion rate (100 mg.day^{-1}) assigned by the USEPA (2011) to direct soil ingestion from outdoor sources (50%). A soil ingestion rate of 20 mg.day^{-1} is assigned to adults by the USEPA (2011) and this value

is recommended here when considering age classes 13 to 18 (e.g. for lifetime exposure). It is considered that the park is a sufficient distance from the home that there will be negligible track back of soil and the ingestion of soil-derived dust indoors is not considered to be significant. The exclusion of tracked back soil is a **critical** assumption for this generic land-use scenario and is one that the risk assessor may need to consider when assessing the suitability of a POS_{park} C4SL value for a specific site.

The conceptual model and exposure characteristics for POS_{park} are detailed in Table 3.7 below with details provided for all exposure characteristics that deviate from those for the default CLEA allotment receptor.

Table 3.7: POS_{park}; Park Type Public Open Space Scenario

Parameter	Value	Notes
Default Receptor	CLEA female allotment	Receptor assumed to be active when using POS_{park}
Age Group	0-6 yr old child (or full lifetime as appropriate)	Critical receptor selected from observational studies (MacDonald, 2005)
CLEA Start Age Class	1	
CLEA End Age Class	6 (18 where lifetime averaging assumed)	
Exposure Duration	6 years (or 74 years where lifetime averaging assumed)	
Averaging Time	6 years (or 74 years where lifetime averaging assumed)	
Soil ingestion rate	AC 1-12: 50 $mg.day^{-1}$ AC 13-18: 20 $mg.day^{-1}$	Ingestion rates of soil outdoors based on USEPA Exposure Handbook (USEPA, 2011). Teenagers assumed to ingest same amount of soil as adults.
Exposure frequency	AC 1: 85 $days.year^{-1}$ (AC 2-18) 170 $days.year^{-1}$	On the basis that a baby will have minimal contact with soil until 6 months of age. On the basis that the park is visited regularly, up to several times a week over a year (reasonable worst case assumption based on observations underpinning Atkins screening values and a conservative conclusion on the basis of survey data collected by Natural England).
Soil to skin adherence factor outdoors	0.1 $mg.cm^{2}$	Updated value based on USEPA (2011) (See Section 3.5.3.3 of this report)
Occupancy period (outdoors)	2 $hour.day^{-1}$	Average time spent on visits to the natural environment including parks in towns and cities (Natural England, 2012)
Exposure pathways	Oral • Direct soil ingestion outdoors Dermal • Outdoors Inhalation • Outdoor dust • Outdoor vapour	
Fraction of site with hard or vegetative cover	0.75	Park is predominantly grassed but there may be borders and other areas of exposed soil
Soil type	Sandy loam	CLEA default

Parameter	Value	Notes
Soil organic matter	6%	CLEA default
Air dispersion factor at 0.8m	120 $g.m^{-2}.s^{-1}$ per $kg.m^{-3}$	Value for area of 0.5 Ha, (CLEA report Table 9.1, EA, 2009c)
Air dispersion factor at 1.6m	280 $g.m^{-2}.s^{-1}$ per $kg.m^{-3}$	Value for area of 0.5 Ha, (CLEA report Table 9.1, EA, 2009c)

3.6.4.4 Summary of POS_{park}

This generic scenario is based on consideration of a public park that is used by children on a regular basis. The key assumptions for the 'public open space park' model are as follows:

- Critical receptor is a child covering CLEA age classes 1-6 and exposure duration is 6 years (with the exception of contaminants where lifetime averaging applies (such as cadmium) where average daily exposure is estimated for age classes 1-18 over a 74 year duration);
- Public park is grassed and may also contain landscaped areas and children's play equipment:
- Exposure pathways include direct soil ingestion, skin contact with soil, inhalation of vapours and of dust outdoors;
- There are no buildings; and
- Land is predominantly grassed and not in close proximity to housing and thus tracking back of soil to the home is not considered a significant pathway.

4. BACKGROUND EXPOSURE

Background exposure to a contaminant from non-soil sources can be an important consideration in the evaluation of risks from soil contamination and in the derivation of generic screening criteria. Consideration of background is discussed in the context of the existing CLEA methodology and the suggested approach to the derivation of C4SLs, below.

4.1 APPROACH USED FOR THE DERIVATION OF SGVs AND GACs

According to the existing CLEA framework, background exposure should be accounted for in the derivation of SGVs and GACs for threshold substances using the following approach (note that the framework does not require background exposure to be included in the exposure calculations when deriving GACs for non-threshold substances):

1. The mean daily intake (MDI) from non-soil sources (water, food and air) is estimated for the critical receptor.
2. CLEA uses the above information to calculate the ADE from non-soil sources and adds this to the ADE from soil to calculate a total ADE for the critical receptor.
3. The total ADE is then compared to the HCV to calculate the assessment criteria.

This method is based on the principle that total exposure to a contaminant (whether from soil or non-soil sources or both) should ideally not exceed the TDI. However, for contaminants where the MDI accounts for a large proportion of, or exceeds the TDI, the allowable exposure from soil can be disproportionately low. As a consequence of this, government policy (Defra, 2008) allows CLEA to limit the ADE from non-soil sources to 50% of the TDI. This policy allows for the modelled total combined exposure from soil and non-soil sources to exceed the TDI, in some cases.

4.2 BACKGROUND EXPOSURE IN THE REVISED STATUTORY GUIDANCE

Paragraph 4.21 of the revised Statutory Guidance describes the type of land that should be placed into Category 4 for Human Health, which includes:

> *"(d) Land where estimated levels of exposure to contaminants in soil are likely to form only a small proportion of what a receptor might be exposed to anyway through other sources of environmental exposure (e.g. in relation to average estimated national levels of exposure to substances commonly found in the environment, to which receptors are likely to be exposed in the normal course of their lives)."*

This suggests that a different approach could be used for the consideration of background when deriving C4SLs compared to that used for the derivation of the SGVs and GACs. Firstly, unlike the derivation of SGVs and GACs, in the SG no distinction is made between threshold and non-threshold compounds. Secondly, rather than limiting the ADE from soils to some proportion of the HCV, the statement above implies that exposure from soils is of low concern where it is a small proportion of typical exposure from non-soil sources, irrespective of the health effects (presumably the rationale for this policy is that there is unlikely to be an appreciable benefit to human health from managing risks from soil contamination if the major source of exposure of a particular contaminant is from non-soil sources such as food, water or air).

The potential significance of soil contamination in the context of background exposure is illustrated in Table 4.1, below. This table shows the estimated contribution of soil to

the total ADE for the residential scenario for a selection of the focus contaminants, assuming the CLEA-derived SGV or GAC as the representative soil concentration. The ADE estimates for background exposure are based on the Environment Agency's estimated MDIs for UK children, whilst the ADE estimates from soil have been calculated using the current configuration of CLEA for the generic residential scenario (and the SGV).

Table 4.1: Estimated ratio of soil ADE to total ADE (soil + non-soil sources) for a residential land-use with soil concentrations equal to the SGV/GAC

	Ratio of soil ADE to total ADE	
	Oral/dermal exposure	**Inhalation exposure**
Arsenic	61 %	60 %
Benzene	64 %	6 %
Benzo(a)pyrene	71 %	13 %
Cadmium	40 %	25 %
Chromium (VI)	15 %	9 %

As discussed in Section 3, the current configuration of CLEA is likely to over-estimate central tendency exposure from soil and thus, the true ratios are likely to be lower than those shown in the table. As it stands, however, the table illustrates that remediation of soil contaminated with benzene, chromium (VI) or benzo(a)pyrene at their respective GACs/SGVs is unlikely to result in a significant (>20%) reduction in exposure via critical pathways.

4.3 SUGGESTED APPROACH TO CONSIDERING BACKGROUND IN THE C4SLs

4.3.1 CONSIDERATION OF BACKGROUND EXPOSURE WHEN SETTING LLTCS

Based on the above, and given the requirements of the revised SG, it could be appropriate to consider background exposure within the derivation of the C4SLs. This could be done when setting the LLTC, by undertaking a check to ensure that the LLTC is not less than some "small proportion" (to be defined) of the MDI. The exact proportion used depends on how the word "small" is interpreted, but a value of 10 to 25% may not be unreasonable for the purposes of setting a C4SL. At present an ADE of up to 50% of the TDI from non-soil sources is allowed (Defra, 2008).

There was mixed support for this proposal from the steering committee and stakeholders. Review of their comments suggested that whilst background exposure from non soil sources was a consideration in deciding whether a site was in Category 4 for human health it should not be used to over-ride the toxicology when setting the LLTC. It is considered more appropriate to compare the estimated exposure from soil at the C4SL with other exposures for that contaminant, such as exposure from soil at the Normal Background Concentration (NBC) and non-soil sources (such as background air quality and dietary exposure). This comparison could be used as a consideration when setting the C4SL (see Section 5.1.5) and would assist assessors in deciding whether or not the land they were assessing was in Category 4.

4.3.2 CONSIDERATION OF BACKGROUND EXPOSURE IN THE ESTIMATES OF ADE

Consideration could also be given as to whether exposure from non-soil sources should be included in the exposure estimates that are ultimately compared with the LLTC to derive a C4SL. In particular, the following points could be considered:

- As discussed in Section 4.1, current Defra policy allows for combined contaminant exposure from soil and non-soil sources to exceed the TDI in some cases; and

- Other countries (e.g. USA and Netherlands) do not generally account for exposure from non-soil sources in calculations used to derive generic soil screening criteria.

Given that the C4SLs are intended to describe a higher level of risk (albeit low) than the SGVs and GACs, and in the light of the points described above, consideration was given to excluding estimates of background exposure from the calculations of ADE for the purposes of deriving C4SLs for threshold compounds, as is currently done for non threshold compounds. However, there was mixed support for this modification from steering committee members and stakeholders. In particular, there was concern that exclusion of MDI from the estimates of ADE would not be sufficiently precautionary for threshold compounds. This proposed modification was therefore rejected and the methodology maintains the current CLEA approach of including background exposure considerations for threshold substances and excluding them for non-threshold.

5. METHODOLOGY TO DERIVE C4SLs

This section describes how the findings of the previous sections can be combined to develop C4SLs. The proposed methodology has evolved as the project has progressed, with an initial framework being developed prior to the published interim methodology document, which was later refined as feedback was obtained and the method was tested on the six substances (see Appendices C to H).

The evolution of the methodology has inevitably resulted in some of the initial proposals being rejected or modified, either as a result of Steering Committee or stakeholder feedback, or as a result of unexpected difficulties in their implementation on one or more of the six test substances. Section 5.3 attempts to capture the main "lessons learned" from this process that are not discussed elsewhere in this report.

There are a number of aspects of the methodology where it could potentially be simplified to facilitate development of C4SLs for other substances. A possible simplified methodology is therefore presented in Section 5.4.

5.1 DETAILED METHODOLOGY

As indicated previously, the overall methodology suggested for the development of C4SLs consists of the retention and use of the CLEA framework of exposure modelling and toxicological assessment, with modifications that are designed to help achieve Defra's policy objectives as set out in the revised Statutory Guidance. These modifications take the form of the derivation and use of LLTCs, in place of HCVs (on which SGVs/GACs are based), along with a series of modifications to the calculation of exposure using the CLEA model. Proposals are also provided on how to account for background exposure from non-soil sources.

The suggested overall methodology is illustrated in Figure 5.1. Steps 1-3 of the methodology comprise the proposals for modified toxicological assessment and exposure modelling, as set out in Sections 2 and 3, above. The modified exposure model is then used in step 4 to calculate the soil concentration that would result in an exposure equal to the LLTC: this soil concentration is the provisional C4SL (pC4SL). In step 5, a probabilistic version of CLEA is used to estimate the probability 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 pC4SLs 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 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 (by the authority responsible for setting them), 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, they could be adjusted by reviewing and revising the modifications to the toxicological assessment or exposure modelling (steps 1-3), in which case steps 4-7 would then be repeated, to derive revised pC4SLs and re-assess the level of precaution provided.

This cycle of steps could be repeated until final C4SLs with the appropriate degree of precaution are derived.

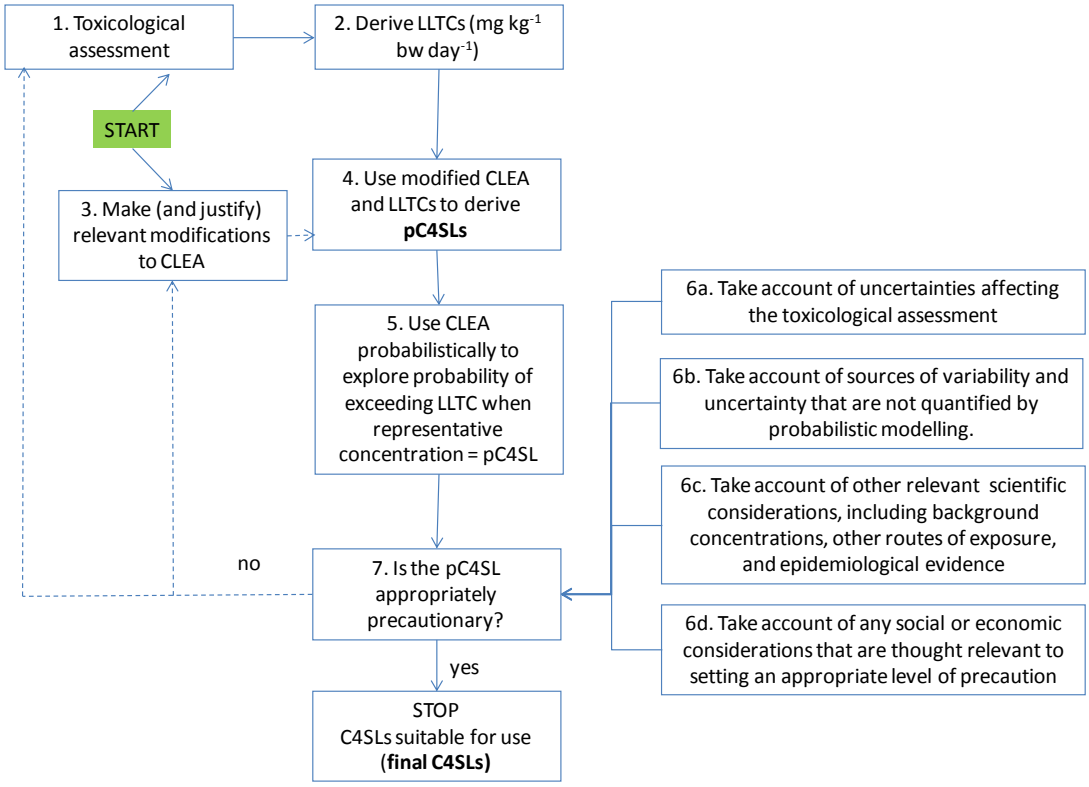


Figure 5.1: Suggested overall methodology for developing C4SLs.

The following sections provide more detail on the various steps. Note that the suggested use of probabilistic modelling in setting C4SLs (at step 5) does not imply a requirement for probabilistic modelling when using them, although probabilistic modelling might be one option for conducting a DQRA.

5.1.1 STEPS 1 AND 2: TOXICOLOGICAL ASSESSMENT AND DERIVATION OF LLTCs

The first steps of the framework are to derive LLTCs for the substance. Where appropriate, separate LLTCs are derived for the oral, inhalation and dermal routes of exposure, although typically, route-to-route extrapolation from the oral LLTC is assumed for dermal exposure. Steps 1 and 2 are discussed in detail in Section 2 and illustrated in Figure 2.2.

5.1.2 STEPS 3 AND 4: EXPOSURE MODELLING AND DERIVATION OF C4SLs

Step 3 involves the critical review of the CLEA exposure parameter values used to derive the SGVs and modification of these, where appropriate, for the purposes of deriving the C4SLs. This review is presented in Section 3 and the proposed modifications to parameter values presented in Section 3.5.7 for the residential, allotments and commercial land-uses. Exposure parameter values appropriate for developing C4SLs for the POS land-uses are presented in Section 3.6. The CLEA model (v1.06) is then used with the C4SL exposure parameters and the LLTCs to derive the pC4SLs for each land-use. The applicable pathways modelled for each land-use are summarised in Table 5.1.

Table 5.1: Exposure pathways modelled in CLEA for derivation of the pC4SL

Exposure Pathway	Generic Land-use					
	Residential		Allot-ments	Comm-ercial	Public Open Space (Resi.)	Public Open Space (Park)
	With home grown prod.	Without home grown prod.				
Direct ingestion of soil (outdoors) and dust derived from soil (indoors)	✓	✓	✓(1)	✓	✓	✓(1)
Ingestion of soil attached to fruit/vegetables	✓		✓			
Ingestion of fruit/vegetables	✓		✓			
Dermal contact with dust derived from soil (indoors)	✓	✓		✓	✓	
Dermal contact with soil (outdoors)	✓	✓	✓	✓	✓	✓
Inhalation of dust derived from soil (indoors)	✓	✓		✓	✓	
Inhalation of dust derived from soil (outdoors)	✓	✓	✓	✓	✓	✓
Inhalation of vapours (indoors)	✓	✓		✓		
Inhalation of vapours (outdoors)	✓	✓	✓	✓	✓	✓

1. Ingestion of soil outdoors only

The critical receptor types and age ranges/classes modelled for each land-use are summarised in Table 5.2.

Table 5.2:..Critical receptor types and age ranges modelled in CLEA for derivation of the pC4SL

Land-use	Critical Receptor	Age range modelled	CLEA Age Classes (AC)
Residential with consumption of homegrown produce	Female child	0 to < 6 years	1-6 [1]
Residential without consumption of homegrown produce	Female child	0 to < 6 years	1-6 [1]
Allotments	Female child	0 to < 6 years	1-6 [1]
Commercial	Female worker	16 to < 65 years	17
POS_{resi}	Female child	3 to <9 years	4-9 [2]
POS_{park}	Female child	0 to <6 years	1-6 [1]

Notes

1. For residential, allotments and POS_{park} land-uses, where lifetime averaging is considered appropriate (e.g. cadmium), the critical receptor is a female child/adult and age classes 1-18 are modelled
2. For POS_{resi} land-use, where lifetime averaging is considered appropriate (e.g. cadmium), the critical receptor is a female child/adult and age classes 4-18 are modelled

5.1.3 STEP 5: PROBABILISTIC MODELLING

As discussed in Section 3.2, the CLEA model estimates one ADE for each pathway from one set of parameter input values. However, in reality, exposure will vary between individuals, even where the land-use and average soil concentration is the same, due to natural variability. For example, not all 2 year old children weigh the same and they do not all ingest the same quantity of soil or consume the same amount of homegrown produce. Similarly, the uptake of contaminants by homegrown produce will vary from one soil type to another, and one plant to another, and this can cause variation in exposure between individuals living at different properties.

The probabilistic modelling conducted for step 5 attempts to model the effect that such variability has on the estimates of exposure, to help in assessing the overall level of conservatism in the deterministic exposure modelling used to derive the pC4SLs. The probabilistic modelling has been conducted for the residential, allotments and commercial land-uses. The main components of the approach used for the probabilistic modelling are illustrated in Figure 5.2 and summarised below:

- Probabilistic modelling using CLEA to derive a distribution of ADE estimates for the pC4SL. This distribution can be presented as a "reverse cumulative frequency" (RCF) curve for each alternative pC4SL that shows the relationship between reverse cumulative frequency (on the y axis) versus ADE (on the x axis). This curve can be used to estimate the probability that an ADE might exceed the LLTC for a random individual receptor (within the critical receptor group) exposed to an estimated soil concentration equal to the pC4SL. Note that for comparative purposes RCFs have been produced for alternative pC4SLs, based on alternative exposure assumptions, as follows:
    - pC4SLs derived using the LLTCs and exposure parameter values as presented in the CLEA SR3 report (most conservative);
    - pC4SLs derived using the LLTCs and the finalised set of exposure parameter values for derivation of pC4SLs, as presented in Section 3.5.7 (less conservative); and
    - pC4SLs derived using the LLTCs and the initial set of modifications to exposure parameters proposed in the draft interim methodology document (least conservative) (see Table 3.5).
- The probabilistic results can then be used to derive a curve that shows the relationship between probability of exposure exceeding the LLTC and soil concentration. This curve can be used to estimate the probability that an ADE will exceed the LLTC for a large range of soil concentrations, including the pC4SLs, using alternative sets of exposure parameters, as described above.

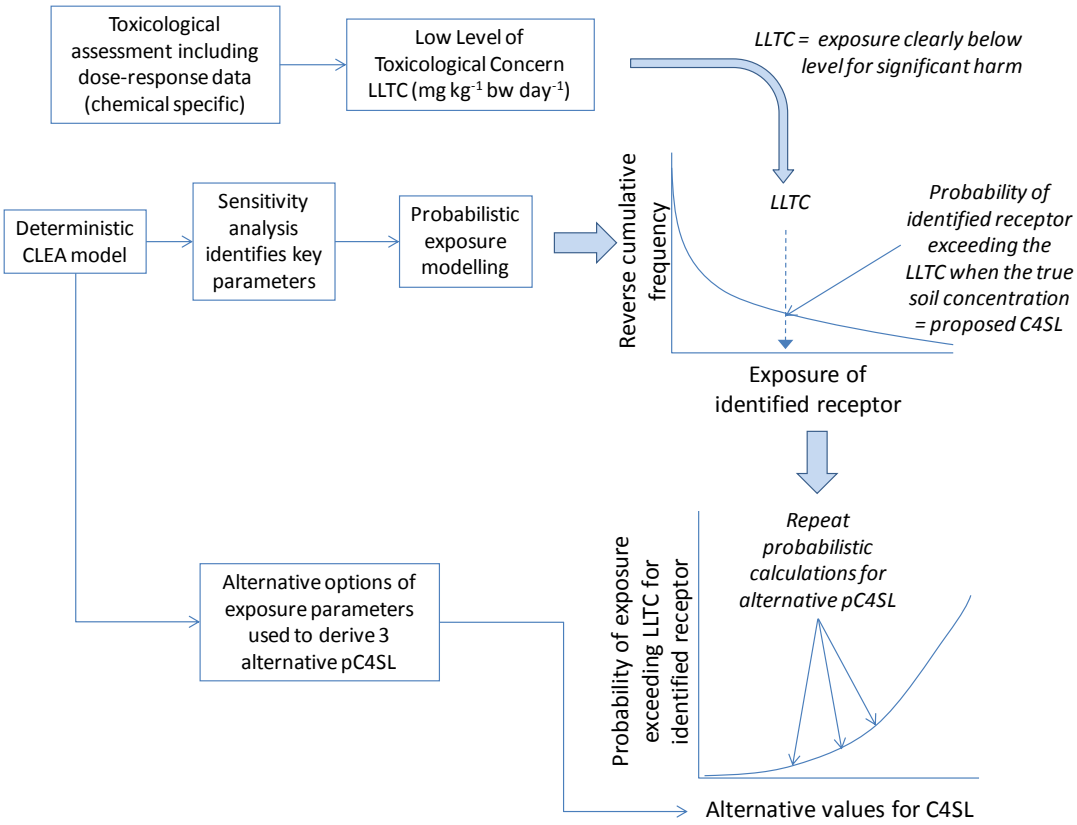


Figure 5.2: Outline of probabilistic methodology for estimating the probability of exceeding the LLTC.

Whilst the probabilistic modelling helps quantify variability in the exposure estimates it is important to recognise that its results are in themselves uncertain. This is largely due to uncertainty in the probability density functions (PDFs) and correlations between them used as model inputs. This "residual uncertainty" should be assessed in the qualitative appraisal of uncertainty in the exposure modelling (see Section 5.1.4).

As discussed in Section 5.3, sensitivity analysis has also been undertaken to explore how uncertainty in the PDFs affects the estimates of probability of exceeding the LLTC. In some cases (and in particular the consumption of homegrown produce pathway) there is significant uncertainty in the PDFs and this leads to significant uncertainty in the estimates of probability of exceedence. The qualitative assessment of residual uncertainties described in Section 5.1.4, in combination with the probabilistic modelling sensitivity analysis, helps to determine whether the probability of exceedence is more likely to have been over or under-estimated and the extent to which this may have occurred. This issue is discussed further in Section 5.3.

One uncertainty that is not addressed in steps 5 or 6b of the methodology is uncertainty in the representative exposure concentration. The probabilistic modelling assumes that the *true* average soil concentration is equal to the C4SL. In practice, the probability of exceeding the LLTC at a particular site will also be influenced by the sampling and measurement uncertainty associated with the concentration data for that site. As with the SGV, it is proposed that this uncertainty be addressed when comparing site measured concentrations with the C4SL. Further discussion of this aspect is provided in Section 6.2.

The outputs of the probabilistic modelling can be used to investigate how the combined effects of deterministic exposure parameter values affect the overall level of conservatism in the pC4SLs. In combination with the qualitative assessment of uncertainty (step 6b – see Section 5.1.4), this step can help determine an appropriate set of deterministic parameter values for derivation of the final C4SL.

Further details of the probabilistic modelling are provided in Appendix B.

5.1.4 STEPS 6A AND 6B: QUALITATIVE EVALUATION OF UNCERTAINTY

The proposed approach for setting C4SLs includes a number of sources of uncertainty that cannot be quantified in a form that allows probabilistic evaluation. These may relate to the use of CSAFs in the toxicological assessment and some of the uncertainties affecting exposure assessment. Since it is never possible to quantify all uncertainties, additional assessment is needed to identify those uncertainties that remain unquantified and evaluate (mainly by expert judgement) their potential impact on the C4SLs.

A qualitative (or semi-quantitative) appraisal of such residual uncertainties can be conducted using an "uncertainty table" approach, based on the framework developed by Fera for the FSA (Fera, 2010). A similar approach was applied by Fera in their 2009 study for Defra entitled "Potential health effects of contaminants in soil" (Fera, 2009), although, in that study, a less quantitative approach than that developed for the FSA (and suggested here) was applied. The more quantitative version has been recently applied by EFSA (eg, EFSA, 2012).

Uncertainty tables can be used in this way to describe the key residual uncertainties and their impact on the choice of LLTC (Step 6a) and exposure estimates (Step 6b). As illustrated in the example given in Table 5.3, below, the residual uncertainties can be listed in the left hand column of the table, whilst the right hand column contains a subjective evaluation of the impact of each uncertainty, using plus (+) and minus (-) symbols.

The number of symbols provides an estimate of the approximate magnitude of the over- or under-estimation, based on a scale, such as that shown in Figure 5.3. A dot (●) represents an assumed negligible impact (< ±10 %), while symbols separated by a forward slash represent an uncertain impact (e.g. -/++ indicates between 0.5x underestimate and x5 overestimate). Note that the implications of the symbols differ between toxicity and exposure: a "+" for exposure implies an assumed overestimation of exposure, and hence a potential overestimation of risk, while a "+" for the LLTC implies an assumed overestimation of the LLTC which results in a potential underestimation of risk.

Finally, at the foot of each table, a qualitative assessment is given of the overall impact of the identified uncertainties. The assessment of the overall impact is necessarily a subjective judgement, taking into account the evaluation of the individual uncertainties (as shown in the individual rows) and how they might combine (including potential dependencies between them where relevant). Importantly, further sources of un-assessed (and potentially unknown) uncertainty may still remain in any risk-based modelling of this nature.

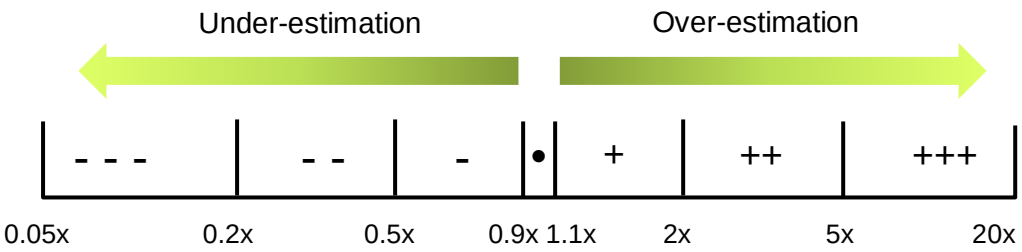


Figure 5.3: Key for symbols used to express judgements about the magnitude of potential over- or under-estimation of the LLTC and exposure

Table 5.3: Example qualitative appraisal of key residual uncertainties (not captured by probabilistic modelling) for exposure modelling of benzo(a)pyrene for residential land-use

Source of Uncertainty	Evaluation of uncertainty
Soil and dust ingestion rate. The PDF used is based on the mean and 95th percentile soil ingestion rates estimates by Stanek, *et al.* (2012) from a meta-analysis of the key soil ingestion studies conducted in the USA. There is uncertainty over how the soil and dust ingestion rates derived from these studies relate to UK receptors and average annual conditions (i.e. winter and summer). It should also be recognised that the estimates for children do not just relate to soil and dust they ingest from their own property, but will also include soil and dust ingested outside the home, in the nursery/school, play park, car etc. There is also some uncertainty in the shape of the PDF, but this uncertainty is unlikely to result in more than a factor of two over or under-estimation in exposure. Overall, it is considered possible that the PDF will over-estimate average annual ingestion of soils from UK residential properties by up to a factor of 2.	● / +
Relative bioavailability (RBA). The CLEA modelling (deterministic and probabilistic) is based on the assumption of 100% RBA. As discussed in Section 4.1.2, based on in-vitro bioaccesibility testing on soils, there is some evidence that the oral biovailability of BaP in soils is typically less than 100%. The bioavailability of BaP in the Culp study used as the basis of the LLTC is unknown but given that BaP was administered in acetone or coal tar mixed with food, it is likely to be higher than aged BaP contamination in soils. Thus the assumption of an RBA of 100% may over-estimate oral exposure from ingestion of soils by a factor of 2x or more.	● / ++
Surrogate marker approach. The pC4SLs are based on BaP used as a surrogate marker for the risk from the typically analysed genotoxic PAHs. As such the assumption is made that the ratio of soil concentration to exposure from BaP is a reasonable surrogate for this ratio for the other genotoxic PAHs. In essence this implies that the dermal absorption factor and soil to plant concentration factors for BaP are equally applicable to these other PAHs. Like BaP, the other genotoxic PAHs have a relatively high molecular weight and consequently have similar physico-chemical properties to BaP. As such, their dermal absorption factors and soil to plant concentration factors are likely to be similar, although it should be recognised that there will be some variability between PAHs. The effect of this variability on overall risk from a PAHs mix is considered small, and unlikely to lead to an over- or under-estimate of overall risk of more than a factor of 2.	- / +
OVERALL EVALUATION OF UNCERTAINTY FOR RESIDENTIAL LAND-USE: Based on the above it is considered likely that the total exposures predicted by the probabilistic modelling have been over-estimated	

5.1.5 STEPS 6C AND 6D: FURTHER CONSIDERATIONS

Steps 6c and 6d of the suggested overall methodology for developing C4SLs requires the pC4SLs to be evaluated further in the light of other scientific considerations (Step 6c) and/or any relevant social or economic considerations (Step 6d). Other scientific considerations that may be relevant in Step 6c include background concentrations in soil, background exposure via routes other than soil and epidemiological evidence for or against health effects from the substance under assessment, with the following being particularly relevant:

- Background soil concentrations in the British Geological Survey reports on normal background concentrations (NBCs) (Johnson *et al*., 2012; Ander *et al*., 2013) to which people are exposed during normal daily life;

- Comparing intakes from soil alone with current exposure levels from non-soil sources (this provides information on whether soil is a major contributor to the total exposure of a contaminant, and ensures that focusing solely on the soil for exposure reduction would have a beneficial impact on a person's health); and
- Defra and the Welsh Government have stated that, to their knowledge, no site in England or Wales has been determined as contaminated due to it causing actual significant health effects (Defra, 2012b). Moreover, recent research has found limited evidence to support a link between adverse health effects and the level and type of land contamination found in England and Wales (Fera, 2009; Bull, 2012). However, lack of evidence does not mean a lack of effect, as this could be the result of limitations in risk assessment or epidemiological techniques (Kibble and Saunders, 2001; Fera, 2009).

It is also recommended that there is a sense check on whether the pC4SLs could exceed odour, phytotoxicity or visual acceptability thresholds, or available GACs for potential acute effects (see Section 6.3).

Social and economic considerations that might be relevant in Step 6d include the cost and proportionality of setting C4SLs so low as to be always exceeded (resulting in further assessment being necessary) and societal perceptions relating to the acceptability of risk, if C4SLs are set too high. The probability of exceeding the LLTCs at the C4SLs might also be relevant, as might the likelihood, nature and severity of harm if they are exceeded.

5.1.6 STEP 7: DECIDING WHETHER THE C4SL IS SUFFICIENTLY PRECAUTIONARY

The final decision on whether a pC4SL is sufficiently precautionary to be adopted as a "final C4SL" is likely to fall to the relevant authority, in the form of a central government body (e.g., Defra) or a local council. Such a decision should take into account all appropriate considerations (qualitative and quantitative) and should result in a level of precaution which is consistent with the intentions of Defra's policy objectives outlined above. However, we have recommended pC4SLs based on our interpretation of the policy objectives.

5.2 WORKED EXAMPLES

As indicated previously, the above methodology has been tested on six substances, to both demonstrate its application and help refine certain aspects. Individual substance-specific reports are presented as Appendices C to H, with pC4SLs being provided for each substance. It should be noted that a range of pC4SLs is provided, in each case, to reflect the different options and assumptions available for their derivation.

5.3 FEEDBACK AND LESSONS LEARNED

As described previously, an initial draft of the suggested methodology for deriving C4SLs was developed early on in the project and adjusted on the basis of feedback from the Steering Group and stakeholders, as well as the consortium's experiences with the six test substances, to produce the version described herein. Some of the feedback is described in the relevant sections above (in relation to exposure assessment), whereas other aspects relating to the toxicological framework are described below. Several identifiable "lessons learned" in relation to the probabilistic modelling have also become evident, and these are also presented below.

5.3.1 FEEDBACK IN RELATION TO THE TOXICOLOGICAL FRAMEWORK

There has been strong support from the Steering Group and stakeholders on the use of BMD modelling approaches, rather than NOAELs and LOAELs, wherever possible,

in order to provide a robust, descriptive quantitative dataset. The six test substances had either data that was conducive to BMD modelling in support of LLTCs or human data where ELCRs had been calculated. Further feedback is summarised in Table 5.4.

Table 5.4: Feedback on elements of the toxicological framework

Question	Stakeholder feedback
Should a BMD or BMDL be used as the POD from which to derive the LLTC?	It was considered appropriate that a BMD (rather than a BMDL) could be used as a POD to define 'low concern', as it is the best central estimate of the benchmark dose.
Should a BMR of 10% be used for carcinogenic endpoints or can this be increased to 15% or 20% when defining the LLTC?	A BMR of 10% is currently accepted as good practice in "minimal risk" evaluations of carcinogenicity data given the sensitivity often seen in such datasets. A higher BMR was deemed inappropriate as this level of incidence was regarded as potentially too high to represent 'low concern'. Lower BMRs should be used if the sensitivity of the data allows, with appropriate margins to reflect an agreed level of protection/caution.
Could a generic margin of 5,000 be used to derive the LLTC for non-threshold chemicals, as representative of low concern?	Most feedback was in agreement that a margin of 5,000 could be used for non-threshold chemicals.
Use a higher ELCR than 1 in 100,000 (e.g. a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).	A mixed response was received in regard to a level higher than 1 in 10,000 ELCR as being equivalent to "low risk".

5.3.2 LESSONS LEARNED FROM THE PROBABILISTIC MODELLING

Probabilistic modelling is incorporated into the methodology to help estimate the overall level of conservatism in the deterministic exposure modelling element of the C4SL derivation process. Its use in this way, in relation to the six test substances, has also informed the refinement of the suggested modifications to the CLEA model, as explained below.

Probabilistic modelling of the allotments and residential with consumption of homegrown produce scenarios showed an uncomfortably high probability of exceedence using mean consumption rates in comparison to the use of 90th percentile consumption rates. As a consequence, it was concluded that the level of precaution associated with the former was insufficient and this, along with steering committee and stakeholder feedback, resulted in the decision to use the "top two" approach for consumption rates, as described in Section 3.5.5.3.

The RCF graphs have also proved useful to the investigation of the probability of exceeding exposures which are significantly higher than the LLTCs (i.e., 2x, 5x or 10x the LLTC) and for comparing the range in estimated exposures with typical background exposure from non-soil sources. For example, for cadmium under the

residential land-use with consumption of homegrown produce, the estimated probability of exceeding 10x the LLTC at the pC4SL of 26 mg.kg^{-1} was approximately 10% (see Figure 5.4), whereas for chromium (VI) for the same land-use, despite the relatively high probability of exceeding the LLTC at 21 mg.kg^{-1}, there is a negligible probability of exceeding 10x the LLTC (see Figure 5.5). This information has helped in the "other considerations" component of the framework.

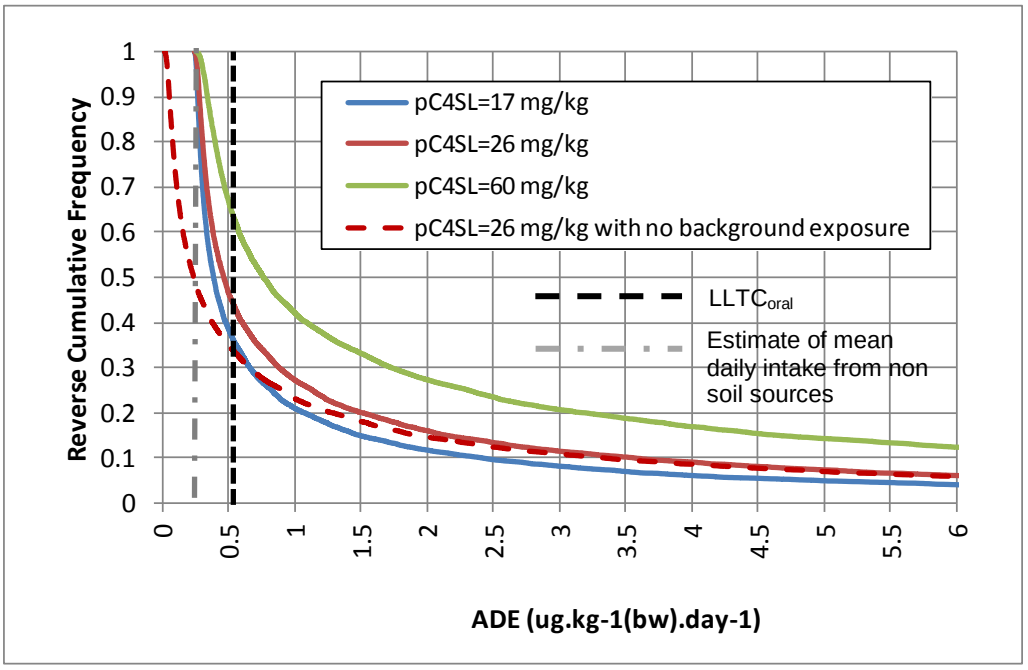


Figure 5.4: Reverse cumulative frequency graph of oral and dermal ADE combined for alternative values of pC4SL for cadmium for residential (with consumption of homegrown produce) land-use

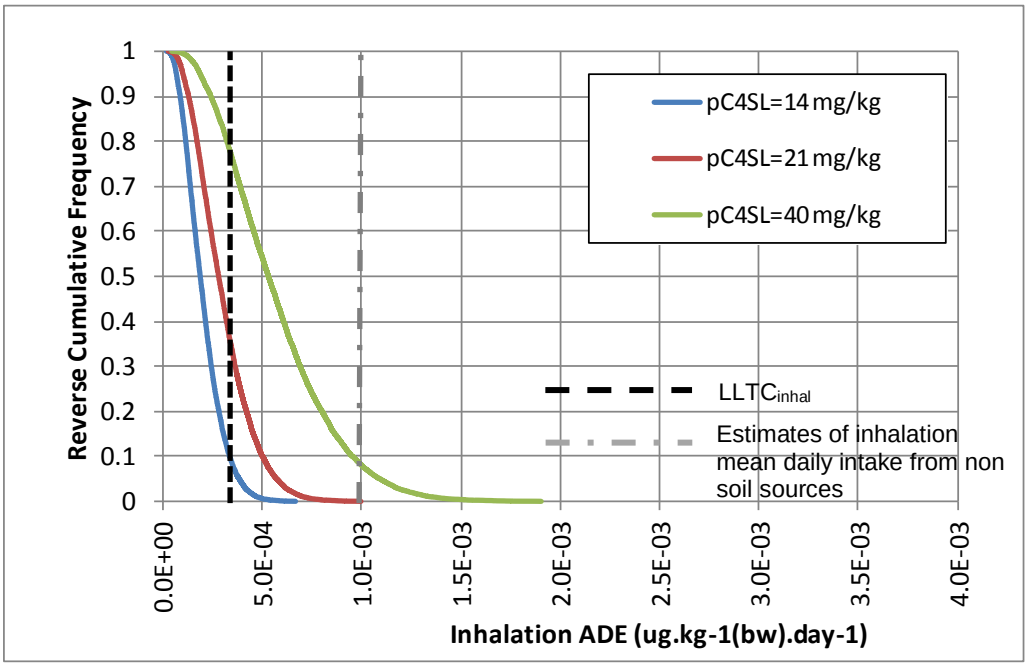


Figure 5.5: Reverse cumulative frequency graph of inhalation ADE for alternative values of pC4SL for chromium (VI) for residential (with consumption of homegrown produce) land-use

One issue that became apparent with the probabilistic modelling is the effect that uncertainty in the PDFs used for the modelling had on the precision of the model results. This was particularly the case for the consumption of homegrown produce pathway, whether this was for residential or allotments land-uses. Exposure from this pathway is related to three key parameters: 1) the soil to plant concentration factor; 2) the consumption rate; and 3) the homegrown fraction. There is a high degree of variability/uncertainty associated with each of these parameters and this creates significant uncertainty in the estimates of probability of exceedence. The effects of this uncertainty have been explored further using sensitivity analysis. For example, Figure 5.6 shows the probability of exceedence versus soil concentration for cadmium, for allotments land-use, using alternative distributions for some key PDFs. The "base case" line shows how the probability of exceedence varies with soil concentration using the base set of PDF assumptions. The alternative lines show how the probabilities of exceedence vary with varying PDFs. For example, the probability of exceedence is predicted to increase significantly if the highly conservative assumption is made that the 100% of the produce that the random individual within the critical receptor group consumes is grown on their allotment. On the other hand, if the PDF for soil to plant concentration factors is based on empirical data from an extensive crop survey conducted in Devon and Cornwall (rather than an amalgamation of a wide range of literature based estimates), the probabilities of exceedence are significantly less. Equally, if there is assumed to be no correlation between homegrown fraction and consumption rate (i.e. homegrowers don't necessarily eat above average amounts of fruit and vegetables) the probabilities of exceedence decrease.

This type of uncertainty in the probabilistic modelling must be accounted for when interpreting the model results. As discussed in the substance specific appendices (Appendices C to H) a generally conservative approach has been taken for the derivation of the PDFs and therefore the probabilities of exceedence are likely to be over-estimates. In the case of the homegrown produce pathway, the extent of the over-estimation could be significant. Further work could be conducted to reduce the level of uncertainty in the PDFs and increase the precision in the final estimates of probability of exceedence.

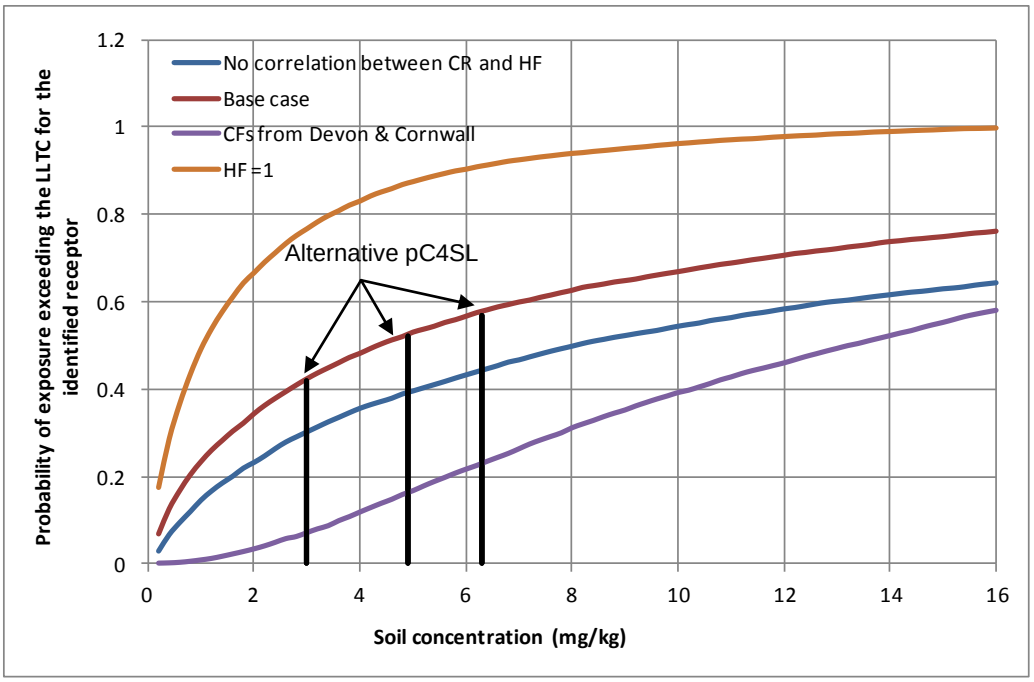


Figure 5.6: Probability of exposure exceeding LLTC for cadmium for allotments land-use with alternative PDFs

As indicated above, the probabilistic modelling conducted for the six test substances has helped to finalise a set of deterministic exposure parameters considered to give

an appropriate level of precaution in the exposure estimates for derivation of C4SL. The six test substances chosen have helped to test the assumptions and parameter values selected for the following five key exposure pathways:

- Soil and dust ingestion
- Consumption of homegrown produce
- Dermal contact outdoors
- Dust inhalation indoors
- Vapour inhalation indoors

The relative importance of each of these pathways varies between contaminants and land-uses and this has helped to demonstrate that an appropriate level of precaution is associated with the input parameters selected for each one. Going forwards, this means that further probabilistic modelling is arguably not necessary when deriving C4SLs for other contaminants, provided that the key pathways are amongst those listed above. This is likely to be the case for the vast majority of other contaminants.

5.4 POSSIBLE SIMPLIFIED METHODOLOGY

The methodology described in Section 5.1, and demonstrated in Appendices C to H, is the culmination of a process of development that began with a draft interim methodology document. The process involved feedback, at various stages, from the Steering Group and stakeholders, as well as the consortium's experiences with the six test substances.

Based on the project's findings, the following simplified methodology can be suggested for the development of C4SLs. While the methodology is likely to be applicable to the majority of substances, some substances may require a more bespoke approach:

- Steps 1 and 2 (Toxicological Assessment):
    - Use the BMD (that correlates to the 'minimal risk' BMDL for the most sensitive effect) as the POD for LLTC derivation, wherever possible, unless there are justifiable reasons to choose otherwise.
    - If data do not support the derivation of a BMD, NOAELs / LOAELs (or possibly a median value between the two) may be used as the POD (note that none of the six test substance evaluations in Appendices C-H have required this approach). Alternatively, existing HCVs can be used in place of LLTCs.
    - For data from animal carcinogenicity studies, use a BMR of 10%.
    - When using a $BMDL_{10}$ from an animal carcinogenicity study, a generic margin of 5000 should be used.
    - For data from human epidemiology studies with large populations, BMD modelling should be used in preference to an ELCR, where data allow. Lower BMRs should be used as the sensitivity of the data allows (e.g. as have been used for arsenic, cadmium and lead).
    - A maximum BMR of 10% should be used in relation to all types of data, unless toxicology supports the use of a higher BMR such as when it is associated with no adverse effects.
    - If referring to an authoritative evaluation that uses an ELCR from human data, use an ELCR of 1 in 10,000 to 1 in 50,000 to signify a 'low risk' banding.
    - With human data, use a generic margin with the BMD (as defined by the sensitivity of the dataset) to correspond to the 'notional ELCR' of 1 in 10,000 to 1 in 50,000 (see Table 5.5). It should be noted that there may be cases where a

CSM should be used instead of a generic margin, where additional considerations need to be factored in, from chemical-specific information.

- If an LLTC devised by the scientific route leads to a pC4SL that is not practicably achievable, or is significantly different from an existing guideline in another regime, then a scientifically-informed policy choice can be made for the LLTC. Such a position could lead to a value that is not of low toxicological concern – and it should be devised in a transparent way, and benchmarked using the scientific data if possible, as to where the pC4SL lies on the scale of human health risk.

Table 5.5: Possible margins for use with BMD(L)s of different corresponding BMRs, and the notional ELCR to which these relate.

BMR	Margin	Corresponding ELCR estimate
0.50%	50-250	1 in 10,000 – 50,000
1%	100-500	1 in 10,000 – 50,000
5%	500-2000	1 in 10,000 – 50,000
10%	1000-5000	1 in 10,000 – 50,000

- Steps 3 and 5 (Exposure Modelling). The probabilistic modelling conducted for the six test substances has assessed the key pathways in CLEA, namely soil and dust ingestion, dermal contact outdoors, dust inhalation indoors, consumption of homegrown produce and vapour inhalation indoors. This modelling has informed the choice of deterministic exposure parameter values for these pathways and confirmed that this choice represents an appropriate level of conservatism for the derivation of pC4SLs. Assuming that the key exposure pathways for other substances (i.e. those not considered by this project) are among those listed here, it can be assumed that the choice of deterministic parameter values presented in Section 3.5.7 would also represent an appropriate basis for the derivation of their pC4SLs. Thus, provided the assessor is confident that the key exposure pathways for another substance are amongst those tested in this project, there would be no requirement for step 5.

- Steps 6a to 6d (Other Considerations):

  - Step 6a: qualitative appraisal of uncertainty to take account of the degree of precaution in the toxicological assessment. The generic guidelines proposed above help to standardise the degree of precaution in the LLTCs. However, it is still important for the assessors to consider whether these generic guidelines are appropriate for derivation of pC4SLs for other substances.
  - Step 6b: qualitative appraisal of uncertainty in exposure modelling. As with the probabilistic exposure modelling, the qualitative appraisal of residual uncertainty in the exposure modelling conducted for the six test substances has helped to derive a set of deterministic parameter values suitable for the derivation of pC4SLs which would apply equally to other substances. However, the assessor should consider (and document) any additional residual uncertainty associated with the exposure modelling for the substance under assessment, such as soil to plant concentration factors or soil to dust transport factors, or model uncertainty (such as the ability of the plant uptake algorithms to adequately represent plant uptake from soil).
  - Step 6c: take account of other relevant considerations (e.g., background concentrations, background exposure and epidemiological evidence). Whilst background concentrations and exposure are material considerations in how

effective a C4SL will be for reducing exposure (and therefore risk) to a substance, they have no direct link with the setting of the C4SL. However, assessors should compare the pC4SL with normal background concentrations and LLTCs with non-soil sources of exposure, where these are available. This provides useful context when conducting the risk evaluation part of GQRA or DQRA. As found by Fera (2009), there is limited epidemiological information on the link between exposure to contaminants in soil and adverse health effects and so unless evidence of a link can be found, such epidemiological information is unlikely to be an important consideration when setting pC4SLs for other contaminants.

  - Step 6d: any social or economic considerations relevant to setting an appropriate level of precaution. This step may be a material consideration where, for example, the pC4SL is below normal background concentrations, analytical limits of detection or is based on an LLTC which is well below background exposure from non soil sources. Under such circumstances, the assessor should consider the possible socio-economic impacts of such a C4SL, for example, whether the costs (both monetary and otherwise) of using the C4SL would outweigh the benefits.

- Step 7 (Setting the C4SL): the selection of the final C4SL should be based on a review of the pC4SLs within the light of the findings of Steps 6a to 6d. It is expected to be carried out by a "relevant authority" and seek an outcome which strikes the right balance between the benefits and impacts of regulatory action (i.e., further assessment under Part 2A), within the context of Defra's stated policy objectives for C4SLs. Further information on the suggested use of (final) C4SLs is provided in the next section.

6. CONSIDERATIONS IN RELATION TO THE USE OF C4SLS

This section outlines certain considerations regarding the potential use of C4SLs. As with the suggested C4SL development approach, the aim has been to retain and refer to as much of the existing technical framework for SGVs as possible, in the form of the Environment Agency's "Using Soil Guideline Values" document, which provides the main technical context for this section (EA, 2009a).

6.1 OVERALL APPROACH

The "Using Soil Guideline Values" document describes the tiered process of risk assessment outlined above, and identifies how SGVs should be used during a GQRA. It also reiterates some of the guidance and signposting to additional guidance provided in CLR 11 (Defra & EA, 2004). Although the document relates explicitly to the use of SGVs, much of its guidance is likely to be applicable to the use of C4SLs, and could be adapted here.

Several steps are shown in a "GQRA flowchart for human health risk assessment" which is presented in the document, and forms the basis of section and sub-section headings within that document, as follows:

- Step 1 - Confirm outline conceptual model and context of risk assessment
- Step 2 - Define objectives of risk assessment
    - Are published SGVs available?
    - Are SGVs appropriate?
- Step 3 - Select approach to develop Assessment Criteria
- Step 4 - Calculate GAC
- Step 5 - Determine most appropriate method for data comparison
    - Is data sufficient?
- Step 6 - Screen data against SGV
    - Are concentrations below SGV?
- Step 7 - Review context, information and criteria to decide next step
    - Is further risk assessment appropriate?
- Step 8 - Consider what further assessment is needed as part of a DQRA

Since it is anticipated that C4SLs will be adopted as generic screening levels that can be used within a GQRA (albeit that they describe a higher level of risk than the SGVs), the above steps and their associated guidance are generally relevant to the use of C4SLs. Key aspects of the use of C4SLs in line with this guidance are summarised in Table 6.1, while considerations regarding specific aspects are provided below.

Table 6.1: Summary Guide to Using C4SLs (adapted from EA, 2009a)

C4SLs are likely to be:	C4SLs are unlikely to be:
• Scientific risk-based generic assessment criteria. • A numerical definition of exposure related to a chemical in soil which is associated with a low level of toxicological concern (LLTC). • Based on generic reasonable worst-case exposure scenarios for long-term aggregated exposure that are health protective for the vast majority of the UK population. • Concentrations in soil which can be used to screen out significant human health pollutant linkages under Part 2A when the generic land-use scenario used to derive the C4SL is sufficiently representative of the site under evaluation.	• Remediation standards. • Applicable to every site. • Minimal risk values. • A definition of SPOSH under Part 2A. • Screening values applicable to construction workers and occupational exposures. • Screening values applicable to other receptor groups such as ecology and property. • Protective of potential acute risks to human health from soil contamination.
GQRA data screening using a C4SL is likely to be:	**GQRA data screening using a C4SL is unlikely to be:**
• A means of identifying an area of land and/or a specific contaminant that does not warrant further, more detailed, evaluation under Part 2A. • A mechanism for focusing subsequent effort on likely risk-driving areas/chemicals/exposure pathways. • Designed to simplify the risk assessment process.	• Valid unless the assumptions inherent in the C4SL are broadly applicable to the site in question. • Mandatory. • A substitute for a thorough qualitative understanding of a site's condition and the risks it might pose to human health.

6.2 STATISTICAL CONSIDERATIONS

It is anticipated that C4SLs will be used in a similar manner to SGVs and GACs, in that they will be compared with measured chemical concentrations in soil at a subject site as part of an overall risk-based decision-making framework. This requires assessors to understand the contaminant profile of the soil under investigation (e.g., via intrusive sampling and chemical testing) and it may involve the application of statistics to test results (as outlined in Step 5 of the "Using Soil Guideline Values" document).

Although the Environment Agency has not produced detailed guidance on the application of statistical methods to land contamination decision-making, Step 5 of the

"Using Soil Guideline Values" document outlines the concepts involved and signposts several other sources of guidance for doing so, including:

- Guidance on Comparing Soil Contamination Data with a Critical Concentration" (CIEH/CL:AIRE, 2008); and
- Guidance from authoritative international bodies, such as the US Environmental Protection Agency (USEPA).

Historically, guidance on the statistical evaluation of data was also available from Defra and the Environment Agency, in the form of the CLR 7 document entitled "Assessment of Risks to Human health from Land Contamination: An Overview of the Soil Guideline Values and Related Research", although this document has now been withdrawn (Defra & EA, 2002).

As explained in the "Using Soil Guideline Values" document, statistical methods should only be employed for the interpretation of site investigation data where such data are considered appropriate and sufficient for the assessor to do so. Data objectives, quality and quantity are important in this regard, with data quality being judged on the basis of factors such as the following (EA, 2009a):

- Choice of sampling points. Is it judgemental or unbiased? How certain is it that contamination present has been identified?
- Sampling method. Does it follow good practice guidance? Does it maximise the integrity of the sample?
- Sample handling and storage. Does it minimise contaminant losses or transformation?
- Sample preparation. Is it in accordance with good practice and appropriate for the contaminant of interest?
- Analytical detection limit relative to the SGV. The analytical limit of detection (LOD) should be sufficiently below the SGV so quantification uncertainty at the LOD does not affect the assessment.
- Analytical method quality assurance. MCERTS accredited analytical methods must be used when available.

6.2.1 SUGGESTED STATISTICAL APPROACH TO THE USE OF C4SLS

In the event that it is judged appropriate to use statistical approaches when using C4SLs to interpret data at a given site, given the overall objectives of the C4SLs (i.e., to assist with the making of decisions on when a site could not pose the level of risk to human health required for determination under Part 2A), it is considered that the 95% upper confidence limit (95% UCL) of the arithmetic mean of a substance's relevant, unbiased data, across the site or "averaging area", should be compared with its C4SL. An "averaging area" is defined as the area over which exposure occurs and the use of averaging areas must be justified on the basis of relevance to the particular exposure scenario (EA, 2009a).

The use of an estimate of the arithmetic mean concentration within a site or averaging area is considered to be appropriate since the C4SLs are based on a hypothetical individual's modelled long-term average exposure and the LLTCs are relevant to long-term exposure periods also. The arithmetic mean is considered appropriate regardless of the pattern of daily exposures over time, or the type of statistical distribution that might best describe the sampling data, since if one assumes that an exposed individual moves randomly across a site or averaging area, then the spatially-averaged soil concentration can be used to estimate the true average concentration contacted over time (and the average concentration contacted over time would equal the spatially averaged concentration over the site). While an individual may not actually exhibit a truly random pattern of movement across a site, the assumption of

equal time spent in different parts of the site is a simple but reasonable approach (USEPA, 1992).

The use of a 95% UCL of the arithmetic mean, rather than the arithmetic mean itself, is considered appropriate, to account for uncertainty due to limited data. The 95% UCL of the arithmetic mean is defined as a value that, when calculated repeatedly for randomly drawn subsets of site data, equals or exceeds the true mean 95% of the time. As the number of samples increases, uncertainty decreases and the 95% UCL moves closer to the true mean (USEPA, 1992).

Notwithstanding the above, USEPA (1992) guidance suggests that a value other than the 95% UCL can be used, provided it can be demonstrated that high coverage of the true population mean occurs (i.e., the value equals or exceeds the true population mean with high probability).

The EA's "Using Soil Guideline Values" document should be followed in connection with the above, with detailed guidance on statistical methods for estimating the 95% UCL of the arithmetic mean being available from the CIEH/CL:AIRE document, as well as USEPA sources (e.g., USEPA, 2002a, 2006). The CIEH/CL:AIRE guidance forms the basis of an Excel™-based spreadsheet application, which is available commercially (ESI, 2013), while USEPA has published freely downloadable software for performing statistical analyses of environmental data (USEPA, 2013). A review of the CIEH/CL:AIRE guidance, conducted by Fera as a part of this project, is provided in Appendix I.

6.2.2 SAMPLE SIZE

Of critical importance when planning and executing an intrusive site investigation, and using its results to make decisions (particularly in any statistical analysis), is the number of samples that have been analysed and, therefore, the size of the resulting data set. There are two potential features of contaminated land that influence the number of samples needed to adequately characterise the concentration of contaminant: 1) the underlying random variation of contaminant concentration; and 2) the presence of hotspots.

The possibility of occurrence of hotspots might be evaluated on the basis of site-specific information (usage history, historic plans, etc) and field observations (borehole logs, underlying geology/hydrogeology, etc), as well as a review of the sampling strategies employed and the laboratory test results obtained. However, where there is little information about site history and risk assessors are relying on the results of sampling and testing as the only or primary means of deciding whether hotspots might be present, then the ability of the sampling plan to generate results that can be used to reliably detect previously unknown hotspots is important. Statistical methods can be used to estimate the maximum size of a hotspot that might be missed by a sampling plan: the general rule is that increasing numbers of samples are needed to detect smaller hotspots. Statistical methods such as those described in the Department of the Environment's CLR 4 can be used to produce plans with high probabilities of detecting hotspots of a particular size (DoE, 1994).

The extent of variation across an averaging area can also have an effect on the number of samples needed to adequately estimate the average concentration of a contaminant in an averaging area. This is because the UCL moves further from the estimated mean as the extent of variation increases and, more importantly, both the estimated average concentration and value of the UCL tend to be biased downwards if variation is large and the number of samples is too low.

Guidance and research on sample size and density at potentially contaminated sites are available from the British Standards Institution (BSI, 2012), the Environment Agency (EA, 2000) and the USEPA (2000; 2002b), as well as the CIEH/CL:AIRE document referred to above and Appendix I.

USEPA (1992) has also stated the following in this regard:

> *"Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95 percent UCL), while data sets with 10 to 20 samples per exposure are provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95 percent UCL is close to the sample mean). Remember that, in general, the UCL approaches the true mean as more samples are included in the calculation."*

In addition, the following table (Table 6.2), taken from Appendix I, provides an estimate of the *approximate* number of samples needed to reliably provide a representative estimate of the average concentration, based on the variation in concentration across the averaging area.

Table 6.2: Approximate number of samples needed to reliably provide a representative estimate of the average concentration, based on the variation in concentration across the averaging area

Likely ratio of the concentrations at high-concentration and low-concentration parts of the area (excluding hotspots) [1]	Number of samples
10 fold	6
15 fold	10
20 fold	15
25 fold	20
30 fold	30
45 fold	50
60 fold	75
70 fold	100

1. For example, 10 fold means that the highest concentration is 10 times the lowest concentration

6.3 CONSIDERATION OF POTENTIAL ACUTE EXPOSURE

The guidance associated with Step 6 of the "Using Soil Guideline Values" document (see above), states that it is important to consider:

- *"(the) potential for acute risks to human health being present if "hotspots" of highly elevated individual concentrations (above the SGV) are present, and the significance of chronic risk is low based on exposure averaging; and*
- *(the) potential for acute risks to human health if there is a significant increase in the value of a GAC as a result of simple site-specific adjustment."*

Given that the focus of the C4SLs is on chronic exposure scenarios, and they are designed to be higher than SGVs, these considerations are particularly relevant to the use of C4SLs.

This potential for risks arising from acute exposure may be of particular concern for C4SLs derived for the commercial and park-type public open space (POS_{park}) land-uses, as these C4SLs can be relatively high for some contaminants and they could pose an acute risk to young children who are assumed to be the critical receptors. This may also be a specific issue for contaminants whose screening criteria for residential land-use are driven by the inhalation exposure pathway, since this pathway

has little relevance to POS_{park} and C4SLs are consequently much higher for this land-use than residential or indeed, POS_{resi}, as illustrated by the pC4SLs derived for POS_{park} for chromium (VI) and benzene, which are 10 and >200 times higher, respectively, than the pC4SLs for residential land-use (see Appendices D and F). As indicated in the previous section, it is recommended that acute risk is also assessed before final C4SLs are identified.

Although there is no government guidance on the assessment of acute risks from soil contamination in the UK, a site was recently determined under Part 2A on the basis of acute risks (Macklin *et al.,* 2012) and work is being undertaken on this topic by a sub-group of the Society of Brownfield Risk Assessment (SoBRA, 2013).

6.4 CONSIDERATION OF POTENTIAL CONTAMINANT MIXTURE EFFECTS

The guidance associated with Step 6 of the "Using Soil Guideline Values" document (see above) also states that it is important to consider:

- *"possible toxic additivity if chemical mixtures are present – refer to Environment Agency (2009b) for further information."*

Toxic additivity, or combined effects, result from interactions between chemicals to which a receptor is simultaneously exposed and/or their effects within the body, such that there is greater toxicity, less toxicity, or the same toxicity as might occur if each chemical dose was received individually. The document referred to in the above (SR2) identifies four main types of additive effects, comprising: 1) dose additivity; 2) response additivity; 3) supra-additivity; and 4) sub-additivity.

Due to the almost infinite permutations of potential chemical exposure, and the necessarily limited amount of toxicity testing that can be carried out, the reliable prediction of potential additive effects at specific sites is normally not possible due to limited toxicity data available. As a consequence, SR2 states that:

> *"Where there is evidence for chemical interaction, this should be taken into account; when such evidence is not available, each chemical should be assumed to be acting independently."*

A simple method for addressing potential additivity of toxic action, where this is assumed to be possible, and where there is a common toxicological mode of action (otherwise this will be conservative/precautionary in the absence of evidence for additivity or synergism), is described in both SR2 and SR3, in the form of the hazard quotient / hazard index approach (the reader is referred to these documents for further details). Additional UK guidance on the risk assessment of chemical mixtures can be found in the Interdepartmental Group on Health Risks from Chemicals report "Chemical Mixtures: A framework for assessing risks to human health" (IGHRC, 2009), while the US Agency for Toxic Substances and Disease Registry has published a number of "Interaction Profiles" which evaluate data on the toxicology of 'whole' priority mixtures (if available) and on the joint toxic action of chemicals in the mixture in order to recommend approaches for the exposure-based assessment of the potential hazard to public health (ATSDR, 2013).

Finally, it should be noted that SR2 states that:

> *"...interactions, whether synergistic or antagonistic, often occur only once a metabolic or cellular threshold is breached. Such effects are therefore unlikely at exposures below the HCV."*

Where effects of synergism are suspected or hypothesised (e.g. concomitant exposures to different metals), an aspect of precaution can be applied by using higher uncertainty factors or captured in a qualitative uncertainty analysis. In some instances,

human study evaluations have attempted to account for aspects of confounding from co-exposure to substances, therefore care should be taken not to account for such effects more than once in the evaluation or attempt to apply quantitative judgements where there is no evidence to draw upon.

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