FINAL REPORT

Review of methods to assess risk to human health from contaminated land

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IOM contract no: 611-00497
5.7 ANALYSIS OF UNCERTAINTIES
5.8 EXPOSURE TO MIXTURES
5.9 CONSULTANTS REPORTS
5.10 RISK COMMUNICATION AND COMMUNITY ENGAGEMENT
5.11 SPOSH
5.12 APPENDICES TO DRAFT GUIDANCE

Acknowledgements
Summary

This project was commissioned in order to assist in the clarification of what constitutes an unacceptable risk to human health from land contamination for the purposes of implementation of Part IIA of the 1990 Environment Protection Act. The aim was to develop new, practical and user-friendly guidance for LAs. The project has focussed on the scientific aspects of risk assessment and not the policy issue of the level of intake that is deemed to be unacceptable. It was intended that the output would include a short document providing high level guidance on health risk assessment with reference to existing published guidance and methodologies that have been identified as particularly relevant and helpful. This draft guidance is included as the final chapter to this report.

Human health risk assessment for hazardous substances involves characterisation of the hazard in terms of the quantities of the substances present, their toxicological properties and assessment of the potential exposure to the hazard. Risk is assessed on the basis of predicted exposure levels and the anticipated toxicological effects of those exposures based on any available information that links exposure to effect (exposure-response relationship). In undertaking risk assessments for contaminated land, the normal practice is to establish risk-based “assessment criteria” for individual contaminants at an early stage in the investigation. Measured contaminant concentrations are compared against these assessment criteria in order to determine whether a significant risk to health exists. The assessment criteria may be generic or site-specific. They are based on the potential for exposure to a given soil contaminant as a function of its concentration in soil and (for Part IIA) the predicted level of exposure above which the risk to health would be unacceptably high as determined from the contaminant’s toxicological properties. Under other regimes the assessment criteria would be based on the predicted exposure associated to give rise to no or minimal risk to health.

A review of the methods, guidance and tools available in the UK and internationally identified a wealth of information and guidance on health risk assessment for contaminated land. A similar tiered overall approach to health risk assessment is taken internationally based on the development of a conceptual model that identifies source, pathways and receptors. The preliminary risk assessment is largely desk based and reviews the potential for human exposure to soil contaminants in relation to the former history of the site or adjacent land. If the potential for significant risk is not excluded, a generic risk assessment is undertaken in which samples are collected and contaminant concentrations are compared with generic assessment criteria (GAC) appropriate to the generic land use based on generic assumptions about soil properties, pathways and receptors. If the potential for significant risk is not excluded, a detailed quantitative risk assessment (DQRA) is undertaken in which Site Specific Assessment Criteria (SSAC) are developed that take account of site specific conditions, exposure pathways and receptors. In addition measurements of contaminant concentrations in other media such as air and plant material may be made. The model that is most widely used in the UK for assessment is the CLEA model which is available as an easy to use spreadsheet application. No models or tools were identified that were superior to CLEA for application in Scotland. The supporting guidance developed by the Environment Agency is clearly written and well referenced. The main caveats are that the CLEA model and guidance do not prompt users to question the plausibility of assumptions about receptors, receptor behaviour and other factors influencing exposure in the context of an individual site nor is the user encouraged to investigate uncertainties and the sensitivity of the model outcomes to uncertainties in the data inputs and assumptions used. There is currently no readily available tool that would enable a probabilistic approach to be taken to estimating an SSAC that would provide information about upper and lower confidence limits. The LOM roadmap tool may be helpful in relation to Part IIA, but could be misleading, particularly if used by individuals with a limited or no toxicological background. SNIFFER have developed useful guidance on risk communication in relation to contaminated land that is also helpful. There are extensive sources of toxicological data, particularly the US EPA and ATSDR, that are probably under-utilised in Scotland. There is also useful information relating to exposure assessment published by US EPA that may be helpful in Scotland. There is a need to ensure that uncertainties are adequately explored and reported in relation to human health risk assessment and the development of an SSAC.

The outcome of consultation with local authorities (LAs) and other contaminated land professionals identified CLEA as the most widely used model. There is considerable variability in the tools available to individual LAs and the extent to which they are empowered to develop expertise in human health risk assessment. LAs with fewer contaminated land issues and little resource allocated to contaminated land strongly indicated a desire to have defined soil guidelines for SPOSH whereas LAs
that have major contaminated land issues and have developed extensive contaminated land expertise stressed the importance of site specific assessments. The main issues on which clearer guidance is required were identified as bioaccessibility, the toxicity of chemical mixtures, the assessment of chemicals such as lead for which the health information is based on blood levels rather than intakes, the use of tools such as the LQM road map approach and the potential use of structural activity analysis in risk assessment. Additionally, it was apparent from discussion with LA officers that most have no background in toxicology and that better guidance is required to assist those without technical expertise in toxicology in the interpretation of toxicological information and reference values. Concern was also expressed about the validity of “black box” risk assessments provided by consultants where it was often impossible for LA officers to verify the reported outcome of the assessment. The major issue identified by all LAs was the difficulty in determining "unacceptable intake" in relation to Part IIA rather than with the actual process of risk assessment. This issue cannot be resolved through simply improving the guidance available for undertaking human health risk assessment and the SG could consider developing a policy stance that would assist LAs in determining what constitutes an unacceptable risk.

It is difficult to determine what constitutes “acceptable risk” in other regulatory regimes. The levels of risk and safety factors incorporated in standards/limits intended to be protective of human health in other contexts are extremely variable. Relatively few bodies are explicit in the level of risk incorporated in standards/limits or in the extent to which the level set may be influenced by current levels and the costs and difficulties associated with reducing exposure. A number of air quality standards are set just below the reported lowest effects level or even at the lowest effects level in humans for health effects such respiratory irritation or small impacts on children's cognitive function whereas other air quality standards based on similar effects incorporate safety factors of between 5 and 20. UK air quality standards for carcinogens have generally been set at levels that are about 1000 times smaller than the modelled lowest effects level in workplace studies implying a cancer risk of between about 10^{-4} and 10^{-5}. The air quality objectives adopted in the UK are based on health-based standards but with some allowance for how readily that standard could be achieved, and are less protective than most people would imagine. Different air quality objectives apply in different parts of the UK reflecting the differences in air pollution climate and ease with which objectives can be met. Drinking water standards are based on World Health Organisation (WHO) guidelines from the 1990s and many of these have reduced and some have increased since the standards were incorporated into EU regulation. The action level for radon exposure in domestic properties equates to a lifetime cancer risk of about 3%, much higher than deemed acceptable under other regimes. It is approximately equivalent to the combined risk of accidental death in the home or in a road traffic incident at the time the action level was originally set. Workplace exposure limits (WELs) for carcinogens in the UK are typically associated with a lifetime cancer risk of about 1 in 1000 but many WELs for threshold substances are set at the lowest level or even above the lowest level that adverse effects have been observed in workers. The development of WELs does take account of the cost of implementation (and associated impact on employment) which can lead to a reduced level of protectiveness. The application of air quality or drinking water standards is based on individual substances and does not take account of the effect of mixtures as would be required for contaminated land.

One of the difficulties that the Scottish Government will face in defining "unacceptable risk" in policy is that contaminated land investigations do not lead to numerical estimates of risk or other measures of impact such as years of life lost. It would be theoretically possible to develop a benchmark dose approach for the assessment of toxic effects of any type of substance and define differing margins of exposure for effects of different defined severity. This would allow national definition of unacceptable but would require an undue level of toxicological expertise at LA level in order to implement it. One way forward would be to develop a national set of defined unacceptable intakes for commonly encountered contaminants. Four possible policy options were identified:

- Development of benchmark doses for common contaminants with policy guidance on the appropriate “margin of exposure” for different types of health endpoint;
- Setting soil concentration action criteria levels at a national level;
- Broadly adopting the new English Guidance on Part 2A; or
- Retaining the status quo with the possible provision of some supplementary guidance.
The supplementary guidance might address the conservatism in the CLEA model and how to derive appropriate exposure estimates for the purposes of Part IIA. Of the four options, the development of soil action levels or the adoption of the English guidance appear to be the least attractive. The disadvantages of developing soil action levels include the probable long timescale of implementation, cost and uncertainties of relevance at individual sites. Adoption of the English guidance does not offer any obvious advantages over the status quo and may have some disadvantages such as the suggestion that cost is considered at individual site level. The development of a benchmark dose/MoE approach to developing toxicological criteria and providing the basis for defining “unacceptable intake” could ease the process of site determination providing that a centrally held resource of BMDs was available to LAs rather than requiring this level of toxicological expertise at local level. The Scottish Government would have to invest in the development of a bank of BMD values for a range of contaminants. The fourth option of retaining the status quo but with the provision of some additional guidance would be much less costly for central Government but would lead to continued uncertainty of the definition of “unacceptable intake” and is unlikely to lead to progress in the Part IIA regime. It is also likely to be a more costly option at LA level.
### Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>ATSDR</td>
<td>US Agency for Toxic Substances and Disease Registry</td>
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<tr>
<td>ADI</td>
<td>Acceptable daily intake</td>
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<tr>
<td>BMD</td>
<td>Benchmark dose</td>
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<td>BMDL</td>
<td>Lower bound estimate of benchmark dose</td>
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<tr>
<td>BMD(_{10})</td>
<td>Dose estimated to give rise to a 10% incidence of effect</td>
</tr>
<tr>
<td>BMDL(_{10})</td>
<td>Lower bound estimate of dose estimated to give rise to a 10% incidence of effect</td>
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<tr>
<td>CLEA</td>
<td>Contaminated Land Exposure Assessment model and associated guidance</td>
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<tr>
<td>CL:AIRE</td>
<td>Contaminated Land: application in real environments</td>
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<tr>
<td>CCME</td>
<td>Canadian Council of Ministers for the Environment</td>
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<td>CLAG</td>
<td>Contaminated Land Advisory Group</td>
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<td>CIEH</td>
<td>Chartered Institute of Environmental Health</td>
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<td>CIRIA</td>
<td>Construction Industry Research and Information Association</td>
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<td>CSM</td>
<td>Conceptual Site Model</td>
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<td>DALYS</td>
<td>Disability adjusted life years</td>
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<td>DEFRA</td>
<td>Department for the Environment, Food and Rural Affairs</td>
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<td>DQRA</td>
<td>Detailed Quantitative Risk Assessment</td>
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<td>EA</td>
<td>Environment Agency for England and Wales</td>
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<td>ECHA</td>
<td>European Chemicals Agency</td>
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<td>EIC</td>
<td>Environmental Industries Commission</td>
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<td>EPAQS</td>
<td>Expert Panel on Air Quality Standards</td>
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<td>GAC</td>
<td>Generic Assessment Criteria</td>
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<td>HCV</td>
<td>Health Criteria Value</td>
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<td>HI</td>
<td>Hazard Index</td>
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<td>HPA</td>
<td>Health Protection Agency</td>
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<td>HPS</td>
<td>Health Protection Scotland</td>
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<td>HQ</td>
<td>Hazard Quotient</td>
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<td>HSE</td>
<td>Health and Safety Executive</td>
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<td>ID</td>
<td>Index Dose</td>
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<tr>
<td>IPCS</td>
<td>International Programme for Chemical Safety</td>
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<tr>
<td>JECFA</td>
<td>Joint Food and Agriculture Organisation/WHO Expert Committee on Food Additives</td>
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<tr>
<td>LA</td>
<td>Local Authority</td>
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<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effects Level</td>
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<tr>
<td>NOAEL</td>
<td>No Observed Adverse Effects Level</td>
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<td>µg</td>
<td>microgram = 0.001 mg = 0.000001 g</td>
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<tr>
<td>µgm(^{-3})</td>
<td>micrograms per metre cubed of air</td>
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<td>µg/l</td>
<td>micrograms per litre</td>
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<tr>
<td>mg</td>
<td>milligram = 0.001 g</td>
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<tr>
<td>mgm(^{-3})</td>
<td>milligrams per metre cubed of air</td>
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<tr>
<td>mg/l</td>
<td>milligrams per litre</td>
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<tr>
<td>mg/kg</td>
<td>milligrams per kilogram (=ppm)</td>
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<tr>
<td>MoE</td>
<td>Margin of Exposure – ratio of BMD(L) to estimated exposure</td>
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<tr>
<td>MRL</td>
<td>Minimal Risk Level</td>
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<tr>
<td>ng</td>
<td>nanogram = 0.001 µg</td>
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<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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<td>Part IIA</td>
<td>Part IIA of the 1990 Environmental Protection Act (Part 2A in English documents)</td>
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<td>ppm</td>
<td>Parts per million</td>
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<tr>
<td>RCEP</td>
<td>Royal Commission on Environmental Pollution</td>
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<tr>
<td>REACH</td>
<td>Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation)</td>
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<tr>
<td>RID</td>
<td>Reference Dose</td>
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<td>RIC</td>
<td>Reference Concentration</td>
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<td>RIVM</td>
<td>Dutch National Institute for Public Health and the Environment</td>
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<tr>
<td>SEPA</td>
<td>Scottish Environment Protection Agency</td>
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<tr>
<td>SG</td>
<td>Scottish Government</td>
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<tr>
<td>SGV</td>
<td>Soil Guideline Value</td>
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<tr>
<td>SNIFTER</td>
<td>Scottish and Northern Ireland Forum for Environmental Research</td>
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<tr>
<td>SPOSHE</td>
<td>Significant Possibility of Significant Harm</td>
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<tr>
<td>SSAC</td>
<td>Site Specific Assessment Criteria</td>
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<tr>
<td>SSL</td>
<td>Soil screening level</td>
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SCS  Soil contaminant standard
TDI  Tolerable daily intake
UF   Uncertainty factor
US EPA  United States Environmental Protection Agency
WHO  World Health Organisation
1 Introduction

1.1 INTRODUCTION

This report reviews the methods used for human health risk assessment for contaminated land and outlines a draft best practice guide intended to assist Local Authorities (LAs) in the task of assessing the human health risks associated with contaminated land.

1.2 BACKGROUND

It has estimated that approximately 67,000 sites (82,034 hectares, >1% of Scotland’s total land area) could be affected by land contamination (SEPA, 2009). In addition, nearly 11,000 hectares of urban land in Scotland is described as “derelict”. The potential for land contamination may be a significant deterrent to the redevelopment of this under-utilised resource. Under Part IIA of the Environmental Protection Act 1990 as implemented by the Contaminated Land (Scotland) Regulations (2000) LAs are required to identify any land in their area which poses an unacceptable risk to human health or the environment, with a view to remediation to make the sites suitable for their current use. Determination of a site as “contaminated land” requires an assessment of the risks posed to relevant receptors (people, water, designated ecological systems and property) and involves a complex scientific assessment of whether potential receptors will be exposed to sufficient levels of the contamination source to cause a significant possibility of significant harm (SPOSH). Uncertainties and inconsistencies around determining SPOSH have meant that the decision making process is slow and often unnecessarily costly as an individual site may undergo repeated investigation. The slow progress in determining contaminated sites may undermine the Scottish Government’s (SG’s) policy of promoting the re-use of brownfield land, prolong adverse environmental impacts of our past industrial legacy and adversely affect economic development. It has been suggested that the lack of clear and robust guidance has contributed to a reluctance of LAs to determine contaminated land. The uncertainties are also leading to inconsistencies in how sites are determined in different parts of Scotland and more widely across the UK. Participants at an Environment Protection UK/Scottish Government seminar held in August 2010 identified the uncertainties around what constitutes SPOSH and the inconsistencies in approach to determining SPOSH taken by different LAs and contaminated land consultants, as major issues. The output from a more recent SG workshop held in June 2011 concluded LAs were increasingly confident in assessing the level of risk, “having regard to expert opinion”. Any “expert opinion”, however, involves a value judgement and there is no explicit societal consensus embodied in SG policy on which to base this judgement. It was generally agreed that technical guidance was needed to underpin the existing Statutory Guidance. This project was commissioned in order assist in the clarification of what constitutes an unacceptable risk to human health from land contamination and to develop new, practical and user-friendly guidance for LAs. It was envisaged that the final output of the project would be a short document providing high level guidance with reference to existing published guidance and methodologies that have been identified as being particularly relevant and helpful. This project was focussed on the scientific aspects of risk assessment and not the policy issue of the level of intake that is deemed to be unacceptable. Some consideration has been given to the practicalities of defining SPOSH in relation to the outcomes of health risk assessments, particularly where the assessment process does not lead to the derivation of a quantitative risk estimate.

1.3 AIMS AND OBJECTIVES

Specific aims of the project were to:

- Examine how policy guidelines for unacceptable risk to human health have been developed using scientific knowledge, in particular toxicological data.
- Propose an approach for assessing what constitutes unacceptable risk to human health in line with the criteria for SPOSH, currently set out in the Scottish Statutory Guidance (especially Table B in Annex 3 chapter A of Paper SE/2006/44).

Consider existing regimes involving risk assessment where action is deemed appropriate on the basis of unacceptable risk, in the UK and internationally.

The specific research objectives for this project were as follows:

- Identify and assess national and international policies and regulations for environmental protection where the threshold for identifying contaminated land is based on assessing whether there are unacceptable risks to human health.
- Identify best practice and potential case studies.
- Assess their authority and robustness, and carry out a preliminary appraisal (including regulatory, impact and sustainability considerations) of their applicability; and consider whether they might be used in assessing risks in the SPOSH decision-making process of Part IIA in Scotland.

In practice, although the project did identify some examples of elements of “best practice” that have informed the development of the draft guidance outlined in Chapter 5, we did not identify suitable case studies to include as exemplars within the draft guidance. Factors that contributed to the difficulty in identifying suitable case studies include:

- The small number of investigated sites in Scotland where human health is the main issue;
- Difficulty of maintaining anonymity for Scottish case studies;
- Health criteria values have not been established or have been withdrawn for the specific pollutants involved and there is controversy as to exposure-response relationships;
- Variability in interpretation of existing statutory guidance; and
- The risk of an assessment level based on site specific circumstances being applied at other sites where exposures and risks are likely to be very different.

1.4 PROGRAMME OF WORK

Initially information was collected from various sources starting with an extensive internet search. We consulted with Scottish LAs and other contaminated land professionals in Scotland in order to find out what tools they currently use for human health risk assessment for contaminated land and whether/how these could be improved. We also consulted with the wider contaminated land community about the guidance, models and tools that are in use in the UK and internationally. Feedback was received from regulatory authorities in New Zealand, the US, Western Australia, New South Wales, the Netherlands and Canada. Although we contacted a wide range of contaminated land professionals in the UK, only two consultancy organisations provided substantive information about their approach. The information search identified a huge amount of relevant material including guidance and tools developed in the UK by regulators, researchers and consultancies and that developed by regulatory authorities elsewhere including the Dutch National Institute for Public Health and the Environment (RIVM), the US Environmental Protection Agency (EPA), Australian authorities (specifically in Queensland, New South Wales and Western Australia), Canada and the New Zealand Ministry for the Environment. The identified material was reviewed, taking account of differences in national contaminated land policy. The outcomes of the review were a summary of the available guidance and tools and an assessment of their usefulness and relevance in the context of contaminated land assessment in Scotland leading to an options appraisal. A draft guidance document (Chapter 5) was also prepared based on the outcomes of the review, the findings of the consultation with LAs and consultants and feedback from the project steering group.

1.5 REPORT ORGANISATION

Chapter 2 describes the outcome of the review of guidance, methodologies and, models and tools for human health risk assessment for contaminated land and Chapter 3 describes the outcome of the consultation with LAs and other contaminated land professionals. Chapter 4 discusses the relationship between the processes of human health risk assessment and the determination of SPOSH and reviews the approach to “acceptable risk” that is taken under other regulatory regimes. Chapter 4 includes an options appraisal that assesses the different approaches that the SG could consider in relation to developing new policy and guidance for human health risk assessment for contaminated land. Chapter 5 describes the intended contents of the draft guidance that is intended to arise as the end product of this project.
2 Methods review

2.1 INTRODUCTION

This chapter describes the process of human health risk assessment for contaminated land and the available tools. Guidance, methods and models from the UK, US, Netherlands, New Zealand, Canada and Australia were reviewed. The US EPA has generated the greatest volume of guidance and supporting resources and has undertaken the most research into links between soil quality, exposure and health. The Dutch have also been active undertaking research and have published extensively in English. Although the regulatory regime differs between countries, there is a common intention to bring land into use. In all of the regimes, the focus is on land being fit for purpose and proving that land does not represent an unacceptable risk to human health. The US EPA Brownfields guidance, for example, is focussed on the development of appropriate remediation plans to bring land into use at minimal cost. There are differences in the level of risk considered to be unacceptable and the level of ambition in relation to remediation work. In Canada, New Zealand and the US, action is required if a site is demonstrably causing adverse effects on human health and may be required if a detailed risk assessment indicates that modelled exposure levels are demonstrably higher than a site specific assessment level. There are also differences in the drivers for undertaking health risk assessments. In Canada, New Zealand and the Netherlands, human health risk assessment is undertaken when a change of land use is proposed whereas in the US and UK assessment follows the identification of land that may potentially be contaminated.

The overall approach taken to risk assessment is similar for all of the countries considered but one distinct difference between the UK and elsewhere is that human health and the water environment are treated separately in the UK. Drinking water standards are applied to both mains supplied and privately supplied drinking water in the UK that ensure the protection of human health from exposure to contaminants by this route. Consideration of the impact of land on the water environment is assessed but not as part of the human health risk assessment and specific tools are available for the assessment of risks to the water environment in the UK such as ConSim. In contrast, the approach to human health risk assessment for soils elsewhere takes account of potential contamination of the water environment and a range of possible exposure routes associated with water contamination.

2.2 GENERAL APPROACH

All authorities recommend a staged approach to risk assessment as outlined by the Environment Agency for England and Wales (EA) in its Model Procedures (CLR11):

- Preliminary risk assessment;
- Generic quantitative risk assessment;
- Detailed quantitative risk assessment (DQRA).

The Health Protection Agency (HPA) have published a brief descriptive guide to human health risk assessment for contaminated land that provides a useful overview of the process. It is generally acknowledged that risk assessment can be an iterative process with the detailed assessment leading to re-assessment of assumptions made in the earlier stages of the process.

2.3 CONCEPTUAL SITE MODEL

The first stage in site assessment outlined by all authorities is to establish a Conceptual Site Model (CSM). This is a description of the contaminants of concern, potential receptors, people in the case of health risk assessment, and the pathways by which receptors may be exposed to these contaminants. Receptors may include people living or working on a site or in areas affected by emissions from the site (eg windblown dust or groundwater contamination). The illustration below is

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5HPA (2009). A guide to land contamination for public health professionals
taken from guidance (SR3) developed by the EA\(^6\) and demonstrates the various routes by which people may be exposed to soil contamination in a residential scenario. The description of the receptors includes taking account of factors such as age that may affect exposure and vulnerability to contaminants. For example, the residential land use would include very young children who would not be present for (most) commercial land uses. Young children may have increased vulnerability to some types of toxin but may also have greater exposure to some types of contaminant, for example, as a result of greater hand to mouth contact and mouthing behaviours. The description of exposure pathways takes account of all relevant exposures resulting from dermal contact with, ingestion or inhalation of soil contaminants. These vary by land use, for example, as to whether the consumption of produce is a relevant route. In undertaking risk assessment, it is necessary to account for the potential impact of exposure to contaminants by all possible pathways. The CSM is used as a tool in preliminary risk assessment and to inform the design of more detailed quantitative assessments.

\[\text{Diagram of exposure pathways: Ingesting dust, ingesting soil, ingesting indoor dust and vapours, ingesting outdoor dust and vapours, rising vapours, tracking back of soil/dust from garden into home, rising vapours, wind-blow dust, plant uptake.}\]

2.4 PRELIMINARY RISK ASSESSMENT AND USE OF SOIL SCREENING VALUES

Under Part IIA, LAs are required to prioritise sites for investigation and focus their efforts on the sites that are most likely to represent a risk to health (or the environment) which implies a preliminary stage of risk assessment prior to the commencement of any site specific investigations. The Canadian Council of Ministers of the Environment (CCME) have developed a series of worksheets and a scoring system for the purposes of identifying and prioritising sites in Canada that would appear to offer an easily implemented, practical method of scoring sites in a consistent fashion in order to identify those requiring further work, although it is specific to Canadian circumstances\(^7\).

The preliminary site specific risk assessment generally starts as a desk-based study intended to identify whether past or current uses of the land are associated with a high risk of land contamination or whether there is other information that suggests the possibility of land contamination. If soil samples have been collected and analysed, measured concentrations of contaminants in soil samples are compared with generic soil screening levels (SSLs) – soil guideline values (SGVs) in the UK - that are intended to be highly protective of health. SGVs are intended as a starting point for evaluating long-term risks to human health and can be used as an indication of levels of chemical contamination in soil below which the long-term human health risks are considered to be tolerable or minimal. They are not intended as remediation targets.

The aim of the preliminary risk assessment is to establish whether pollutant-pathway-receptor linkages exist that could lead to harm to humans or the environment. If such a linkage exists, then it is

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appropriate to proceed to a Generic or Detailed Quantitative Risk Assessment as described in sections 2.6 and 2.7. Most regimes include a requirement to document the preliminary risk assessment and the reasoning underlying the termination of investigations at an early stage. Often the outcome of the preliminary risk assessment would be to conclude that better site characterisation data are required in order to make a more detailed assessment which would include a recommendation to collect (more) samples.

2.5 DERIVATION OF TOXICOLOGICAL REFERENCE VALUES

Overview

Extensive guidance has been developed to assist in the interpretation of toxicological data for the purposes of human health risk assessment. The UK and USA provide guidance on how to derive toxicological reference values from first principles whereas the New Zealand, Canadian and Australian advice is centred on the selection of appropriate toxicological reference values from national and international information sources. In the UK, the EA (2009) have produced guidance (SR2) for the development of health criteria values (HCVs) for the purposes of developing SGVs under its own programme or for the development of assessment criteria for other substances by others8. SR2 is, however, primarily a description of how HCVs are derived for those who use them rather than a manual to support the derivation by non-experts of site specific HCVs for contaminants for which HCVs are not available from the EA or other authoritative sources. The US EPA have probably undertaken the most research and produced the most guidance, although the documentation to support contaminated land investigations does not incorporate the most recent thinking of the US EPA on risk assessment9.

HCVs are intakes of individual chemicals present in soil that are believed to be tolerable or to pose minimal risk. They are based on a review of evidence from epidemiological studies of humans exposed in the workplace or wider environment to the substance of concern, experimental studies in animals and an understanding of the uptake, transport within the body, metabolism and mechanisms of toxicity of the substance. The process involves identification of the toxic effects associated with a substance and information about dose-response relationships and mechanism/mode of action and use of this information to derive a tolerable daily intake for each route of exposure. Both the bioaccessibility of substances from soil by different routes of exposure and the extent of exposure from non-soil sources may be taken into account in developing HCVs.

Threshold and non-threshold substances and benchmark dose

For the purposes of risk assessment substances are categorised as either having a threshold of effect or as being non-threshold, although the distinction can be blurred (see below). Currently “threshold” and genotoxic substances are typically treated differently in risk assessment for contaminated land although the UK Interdepartmental Group on Chemical Risks10 and the US EPA11 have recommended that a common approach is taken to risk assessment for both types of substance.

For substances regarded as having a threshold for toxic effects, the HCV is derived from a Tolerable Daily Intake (TDI) normally based on the no observed adverse effects level (NOAEL) or lowest observed adverse effects level (LOAEL) in animals or humans, although SR2 also describes the derivation of a benchmark dose, most usually the dose estimated to give to an incidence of effect 10% of subjects (BMD10). Most typically the 95th percentile lower bound estimate of BMD10, BMDL10.

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http://www.nap.edu/catalog.php?record_id=12209
is used in risk assessment. The advantage of the BMDL approach is that the NOAEL or LOAEL in an animal experiment is strongly dependent on the choice of dosing regime and may also be influenced by the number of animals (or for humans, volunteers or workers) involved in the study. As group size increases, so does the potential variation in susceptibility within the group and the apparent LOAEL is likely to reduce as group size increases. The use of a BMDL rather than NOAEL or LOAEL is likely to give a better measure of potency.

Genotoxic carcinogens are widely considered to have no threshold of effect; however, a better understanding of disease mechanism is leading to the recognition that there may be threshold levels of exposure below which key mechanisms are unlikely to come into play. This “practical threshold” might be the level of the active metabolite that is equivalent to endogenous levels present in the absence of exposure or some critical level of DNA or other cellular damage above which the body does not have the capacity to repair itself. The European Commission Scientific Committees have indicated that genotoxicity may have a threshold of effects but more research is needed. 12 If human data are available for non-threshold substances, the index dose (ID) should be based on a level at which there is no discernable cancer risk with the use of expert judgement to extrapolate to the wider population. Otherwise, SR2 indicates that the ID should be set at a level that is 0.01% of the lower bound estimate of BMDL10, ie the dose calculated to give rise to a 10% cancer incidence based on animal data. This equates to the calculation of a dose associated with a 10^{-5} cancer risk based on low dose linear extrapolation in which a cancer risk function is derived by assuming a linear dose-response between zero and BMDL10.

**Derivation and use of a benchmark dose**

The US EPA provide clearly written, documentation describing how to derive a benchmark dose for threshold or non-threshold substances and how to use low dose linear extrapolation in order to develop quantitative cancer risk estimates. 13,14 The US EPA approach is supported by the BMDS software which is free to download and easy to use. 15 It enables anybody to enter results from a toxicological experiment as reported in a published study and to derive a BMDL, BMDL0 or estimated dose associated with any other specified incidence of effect, that could then be used to inform risk assessment.

The use of a BMDL in risk assessment for carcinogens has been considered by the Department of Health's expert Committee on Carcinogenicity (COC). 16 The BMDL can be compared with modelled exposure levels in order to derive a Margin of Exposure (MoE). Guidance is provided on the interpretation of the size of the MoE indicating that a MoE of 10,000 indicates that an exposure to a carcinogen at this level is unlikely to be of concern. The COC have not issued a finalised statement on the issue and the approach is not completely accepted in the UK, probably because it involves risk quantification with its associated uncertainties. There is a strong preference in UK regulation for controlling exposures to carcinogens to be As Low As Reasonably Practicable (ALARP) because of the uncertainties in quantitative risk assessment. The problem with the ALARP approach, however, is that it may be difficult to prioritise actions and justify control measures in the absence of any quantitative assessment of benefit. The BMD/MoE approach to risk assessment for carcinogens has, however, been endorsed by a number of EU expert committees charged with ensuring consumer and public safety. 17 In a comprehensive review of risk assessment methodologies for carcinogens, these...
groups recommend that a BMD/MoE approach should be taken if sufficient data are available as determined on a case by case basis.

Allometric Scaling

The guidance for some regulatory regimes including that supporting the REACH\(^1\) Regulation which governs the supply and use of chemicals in the EU includes an additional stage of refinement in the derivation of health-based reference values for risk assessment. The REACH guidance indicates that it is appropriate to use an interspecies allometric scaling factor to allow for size dependent differences in metabolic rate (which affects the effective received dose of a substance, if expressed in terms of mg per kilogram bodyweight)\(^2\) (see section 4.1). SR2 does not describe the use of allometric scaling factors although these have been used in toxicological evaluations of substances by the US EPA, International Programme for Chemical Safety (IPCS) and other World Health Organization (WHO) committees.

Data sources and data evaluation

SR2 lists sources of toxicological information in an appendix. In addition to the US resources described below, these include the IPCS. The IPCS website is a vast resource developed in conjunction with the World Health Organisation (WHO) and others. The WHO has also published air quality and drinking water quality guidelines, although some of these are now a bit dated and more data have become available since they were last reviewed. SR2 notes that the conclusions of different expert groups in relation to an individual substance may be different but does not provide clear guidance on how to select the most appropriate values for use in the development of a HCV. SR2 provides limited guidance on data evaluation including the requirement to take account of mode of action, toxicokinetics (data describing the uptake, absorption, metabolism and elimination of a substance), dose metric and the assessment of background intake. It does not provide detailed guidance on how to assess study quality beyond indicating that previous reviews by appropriate expert groups are a good starting point, although for many substances such evaluations are not available and additionally previously published evaluations may predate important new evidence that should be taken into account.

The US EPA has developed specific guidance for toxicological review in relation to contaminated land under the superfund programme\(^3\). The Risk Assessment Guidance for Superfund (RAGS) part A\(^4\) provides a description of how to derive a reference dose for contaminated land assessment and also includes an updated hierarchical listing of toxicological data sources (US EPA 2003\(^5\)). More recent guidance is provided on the derivation of reference values for exposure by inhalation or dermal contact (US EPA, 2004\(^6\); 2009\(^7\)). In addition the US EPA IRIS database provides a comprehensive listing of toxicological reference values and cancer risk estimates for exposure to a wide range of substances by inhalation or ingestion together with clear supporting documentation (www.epa.gov/iris). Over the last decade, the US EPA has been harmonising the approach taken to risk assessment for carcinogens and non-carcinogens and moving towards adopting a common approach to threshold and non-threshold substances\(^8\). Recent evaluations by US EPA of both threshold and non-threshold substances have been based on a benchmark dose approach (see IRIS database). The US EPA has also been reviewing its approach to other aspects of developing references doses and concentrations including factors such as scaling from animal experiments to

\(^{18}\) Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation


\(^{20}\) http://www.epa.gov/oswer/riskassess/superfund_hh_characterization.htm


\(^{22}\) https://fortress.wa.gov/ecy/clarc/FocusSheets/httpwwwepagovoswerriskassessmentpdfhhmemo.pdf


humans, data quality criteria for studies to include in the determination and other issues relevant to evaluating toxicological data.

The US Agency for Toxic Substances and Disease Registry (ATSDR) which is primarily concerned with exposures associated with Superfund sites has developed detailed toxicological profiles for a large number of substances (www.cdc.gov/atsdr), each of which was comprehensive at the time of publication and some of which run to hundreds of pages. Some of the substance evaluations available from the IRIS database or ATSDR were undertaken over 20 years ago, however, and ideally a search should be undertaken to identify more recent additional information. An extensive quantity of further information and guidance on toxicological risk assessment that may be helpful in relation to specific sites is available from the US EPA website. This includes guidance on risk assessment for chemical mixtures in relation to Superfund sites, more recent updated generic guidance on risk assessment for chemical mixtures, the use of pharmacokinetic modelling for the risk assessment of mixtures and risk assessment for metals. It also includes specific guidance on risk assessment in relation to neurotoxicity, reproductive toxicity, developmental toxicity and mutagens, although some of these documents are quite old and may not reflect current US EPA thinking.

The New Zealand Guidance provides justification for the HCVs for contaminants for which SSLs have been derived but not a generic method of deriving them. For soil contaminants for which no New Zealand SSLs have been derived, guidance is provided on the choice of SSLs that are available from other jurisdictions. Health Canada (2004) describe the identification of appropriate toxicological reference values from Canadian sources (Health Canada) where possible or if no Canadian value is available from one of a list of internationally available sources of toxicological information and reference values. The Canadian Council of Ministers for the Environment (CCME, 2006) provide a more detailed guide to the interpretation of toxicological information, including how to develop reference values from primary data for substances lacking pre-existing reference values but refers the reader to reference values that have already been established by Health Canada. The draft Australian Guidance for health risk assessment (NEPM) is based on SSLs derived from toxicological reference values (TRVs) for which supporting documentation is provided. It does not provide guidance on how to derive a toxicological reference value for other substances.

2.6 GENERIC ASSESSMENT CRITERIA AND GENERIC QUANTITATIVE RISK ASSESSMENT

Overview

The split between generic and detailed quantitative risk assessment is fuzzy as the risk assessment process is frequently iterative. A similar approach is taken to generic risk assessment by the different national authorities in which Generic Assessment Criteria (GAC) are generated for a site on the basis

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http://www.epa.gov/raf/metalsframework/index.htm
http://www.ccme.ca/assets/pdf/sg_protocol_1332_e.pdf
of generic exposure assessments developed for generic land uses and based on defined toxicological criteria values. The different regimes include slightly different sets of generic land uses and vary in the number of exposure pathways that are included in the model. The risk assessment process involves comparison of measured soil concentrations against relevant GAC. Detailed guidance on the comparison of measurement data with assessment criteria is reviewed separately below (section 2.9). The EA highlight the need to consider data quality taking account of choice of sampling points, sampling method, sample handling and storage, sample preparation, analytical detection limit relative to SGV and analytical method quality assurance. The US EPA has published rather more extensive guidance on choosing a sampling strategy, data quality assessment and developing data quality objectives. The number of samples will depend on factors such as the size of the site and variability of contaminant concentrations.

**Generic Assessment Criteria**

SSLs or Generic Assessment Criteria (GAC) are generally developed by regulatory authorities for a small number of generic land uses and incorporate generic assumptions about source, pathways and receptors leading to human exposure including assumptions about soil and building properties and receptor behaviour. There is some variability in the complexity of the models used to generate the exposure component of the GAC derivation. The GAC derivation process is documented by each of the regulatory authorities that have developed GACs and also forms the basis by which site specific assessment criteria can be generated for standard land use scenarios. Although UK guidance indicates that a contaminant concentration below a SGV does not indicate that SPOSH is not present, in practical terms SGVs are set at such conservative levels, that such low contaminant concentrations could only represent SPOSH under extremely unusual conditions.

In the UK, the EA and Defra have developed SGVs for a relatively select group of 11 common contaminants. The SGV for lead, a widely distributed contaminant, has been withdrawn and those for some other contaminants have been revised since the original introduction of SGVs. The EA SGVs have been subject to extensive expert scrutiny and the process of deriving SGVs became bogged down through the failure to find a consensus view on individual substances. There are no plans to extend the current list of SGVs. An industry initiative led by the Environmental Industries Commission (EIC) and the Association of Geotechnical and Geoenvironmental Specialists (AGS) coordinated by CL:AIRE led to the development of Generic Assessment Criteria (GACs) for 35 substances using the methodology developed by the EA and based on the collation and review of physico-chemical data, toxicological data and information on background exposure for 44 contaminants for which SGVs were not available. Both the EIC/AGS/CL:AIRE GACs and LQM-CIEH GACs were subject to extensive internal peer review prior to publication and the EIC/AGS/CL:AIRE GACs were also reviewed by the Health Protection Agency (HPA) and EA, although these agencies did not review the underlying data. Neither the EIC/AGS/CL:AIRE nor the LQM-CIEH SSLs have been subject to the same degree of scrutiny as the

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40Arsenic, nickel, mercury, selenium, cadmium, benzene, toluene, ethylbenzene, xylene, dioxins, furans and dioxin like PBCs and phenol; http://www.environment-agency.gov.uk/research/planning/64015.aspx
41http://www.claire.co.uk/index.php?option=com_content&view=article&id=306&Itemid=91
422nd Edition – The ‘new’ LQM/CIEH Generic Assessment Criteria for Human Health Risk Assessment
SGVs developed by the EA and Defra. The involvement of a large number of professionals in their derivation provides some reassurance that they should be reasonably robust but users should take account of the underlying documentation when determining how much importance to attach to these values. In addition, to the EIC/AGS and LQM-CIEH initiatives, Atkins have developed the ATRISK Soil Screening Values (SSVs) for substances for which neither the EA nor the CIEH-LQM have set SSVs. The ATRISK SSVs and the supporting documentation are only available by subscription. It is claimed that the ATRISK values have been derived in accordance with the methods used to derive the EA SGVs but there is insufficient information in the public domain to enable an opinion on the process by which these values have been derived. It seems unlikely that they have had the same level of internal peer review as the EIC/AGS or LQM-CIEH SSVs but this does not mean that they are necessarily any less reliable. In general terms, any of these sources of SSVs provide a useful starting point for site investigation in the UK and are likely to be helpful in eliminating sites that are clearly not of concern for human health. A detailed review of the various published GACs that have been developed by LQM/CIEH, Atkins and the EIC/AGS was beyond the scope of this study.

Elsewhere, the US, Netherlands, New Zealand, Canada and Australia have developed SSLs for an extensive range of contaminants. These SSLs vary in the extent to which allowance is made for different soil types and local conditions. It would generally be argued that SSLs derived elsewhere in the world have little relevance to UK soils. In the absence of a specific UK SSL, however, this does not preclude their use at a very preliminary stage of investigation to help identify contaminants that are present at levels approaching or exceeding the SSL that may require further assessment. All of the national regimes reviewed provide supporting documentation for SSLs adopted at national level. Some of the individual substance reports may be helpful to the assessment of those substances.

The US EPA have developed generic SSLs for 110 chemicals but these are not intended to cover all known human exposure pathways or other site specific circumstances. The toxicological data and scenario assumptions for SSLs are outlined in supporting documentation. The US EPA have provided guidance that explains how SSLs should be used with reference to a conceptual site model and on the importance of comparing site specific circumstances with those assumed in the generic scenarios for which SSLs have been developed. It is also noted that SSLs may not be useful where they are lower than the background levels of a given contaminant which may or may not be harmful.

The Dutch SSLs have been developed for specific soil types representing different mixtures of sand and peat such as are found in the Netherlands. Values have been developed representative of background concentrations, maximum values for residential and industrial uses and levels at which intervention is required.

A review of Soil Screening Values (SSVs) in different EU countries published in 2007 provides a cautionary tale in relation to the use of SSLs from elsewhere. The SSVs in place for individual contaminants in different EU countries varied by over an order of magnitude, partly due to the regulatory differences between countries. Most of the countries involved in the survey were in the process of reviewing their SSVs. SSVs may be set to indicate soil concentrations that are negligible, provide a warning level and/or indicate potential unacceptable levels. Factors used in the development of SSVs that were highly variable between countries and had an important impact on the derived value included the exposure pathways considered such as the inclusion/exclusion of "indoor air exposure" and "consumption of home-grown vegetables"; the inclusion/exclusion of exposure sources that are not related to soil; and the choice of toxicological data sources. Factors that would have an important impact on the derived value but were not highly variable between countries were

43http://www.atrisksoil.co.uk/
47Dutch Ministry of Housing, Spatial Planning and the Environment: Into Dutch soils.
the large range of technical issues for which reference is made to national or international guidelines of more advanced countries. There was no clear relationship between the variation in national procedures for deriving SSVs and geographical and biological and socio-cultural variability across Europe. It was reported that many differences in SSVs were due to incidental reasons, like the period in which procedures were developed and the persons in charge of their development.

Generic quantitative risk assessment

The UK approach to generic quantitative risk assessment is based on the CLEA model and the supporting Updated Technical Guidance to CLEA (SR3)\textsuperscript{6}. The CLEA model is a spreadsheet based application for the estimation of exposure of adults and children to chemicals from soil sources over long periods of time. It is free to download and easy to use\textsuperscript{49}. In order to create GACs, drop down menus are used to select land use (residential with or without homegrown produce, residential lifetime exposure, allotment, allotment lifetime exposure or commercial), receptor (male or female, residential, allotment or commercial), soil type and end age class. In the next stage, chemicals can be selected from a drop down menu of 30 substances and before moving on to the results page which provides generic assessment criteria for those substances. Up to ten different pathways are included in the assessment:

- **Indoors** (includes exposure arising from tracked in soil from the garden) -
  - Dust ingestion;
  - Ingestion of contaminated vegetables and soil adhering to vegetables;
  - Skin contact with dust;
  - Inhalation of dust;
  - Inhalation of vapours (Johnson and Ettinger screening mode);

- **Outdoors** –
  - Soil ingestion (small children);
  - Skin contact with soil;
  - Inhalation of outdoor dusts (rate of contaminant release used in CLEA modelled with the US EPA air dispersion model AERMOD prime and annual mean dispersion factors for UK cities);
  - Inhalation of vapours (infinite source calculation – ASTM, 2000)

The CLEA model allows the user to proceed to a detailed site specific risk assessment by adding site specific data for individual chemicals including concentrations in soil gas, indoor or outdoor air, green, root or tuber vegetables, herb, shrub or tree fruit. This enables refinement of the model output to reflect site specific conditions.

SR3\textsuperscript{6} describes equations used for exposure assessment by each pathway and the data sources used in the development of generic variables for inclusion in the model and the reasoning behind the selection of specific values. Where possible these variables are based on studies of the UK population. The guidance lists the assumptions about people’s behaviour and building properties that are used to inform exposure estimation for the generic land uses. Information is provided about the physical characteristics of people that are relevant to exposure assessment (eg weight at different ages). Information about behaviours includes standard assumptions about time spent indoors, outdoors, soil and dust ingestion, fruit and vegetable consumption. The guidance also provides standard assumptions on dust and vapour inhalation inside and outside properties. In contrast to much of the international guidance that is available, there is no specific guidance on exposure from groundwater or surface water affected by contaminated land as this would be considered separately under the UK contaminated land regime. The document provides a useful and well referenced guide to exposure assessment although it is important to consider whether the exposure assumptions are relevant to the site in question and to be aware that for some issues such as indoor air quality, there is a considerable volume of published information that was not considered in the development of this guidance. In order to understand the site specific relevance of SGVs or GACs derived using CLEA, it is important to consider the relevance of the default parameters used in the model. This may require reference to cited source material and the wider literature (particularly the extensive guidance developed by US EPA) and as well as consideration of site specific factors in relation to receptors and factors affecting exposure (see detailed risk assessment below).

\textsuperscript{49}http://www.environment-agency.gov.uk/research/planning/40397.aspx
The exposure estimates are based on generic land use scenarios and derived for a hypothetical individual, whose aggregated exposure from all pathways is likely to be well above average. The exposure estimates are combined with HCVs to derive GACs that are highly protective of health. The slight downside of CLEA is that because the inner workings of the calculations are hidden and there is no need for familiarity with the underlying guidance, it is easy to use the model without questioning the relevance of the underlying assumptions.

The methodology used for generic risk assessment under the other regimes considered is similar to that used in the UK with some variations in the choice of generic land use for which exposure variables have been considered and the number of exposure pathways included. New Zealand for instance advocates a relatively cut down version whereas the US EPA have developed a more complex approach within their Soil Screening Guidance (SSG)\(^\text{50}\). The SSG is intended to provide a flexible, tiered approach to site evaluation and screening level development, similar to that incorporated in CLEA, but without the link with a supporting software package. The 1996 User's Guide provides details for implementing the simple, site-specific methodology for calculating site-specific SSLs for residential land use covering direct contact with contaminated soils, inhalation of volatiles and fugitive dusts and ingestion of groundwater. The method is underpinned by the toxicological reference values contained in the IRIS and HEAST toxicological databases maintained by the US EPA and values for the 110 chemicals for which generic SSLs were derived are included in the guidance, as well as relevant physi-chemical parameters. The guidance describes how to assess potential exposure by direct ingestion, dermal absorption, inhalation of volatiles and fugitive dusts, migration to ground water, mass-limit model development, plant uptake and intrusion of volatiles into basements (Johnson and Ettinger mode). The guidance also includes a chapter specifically on detailed modelling for groundwater and vapour concentrations. The 2002 paper, "Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites", contains methods for developing SSLs for non-residential land use and construction activities, new SSL equations for combined exposures via ingestion and dermal absorption and updated models of inhalation exposure. The guidance is of greater relevance to the US than the UK because of the separate consideration of the water environment in the UK. In addition, the CLEA guidance and model has been more recently updated.

None of the methodologies/guidance reviewed offered any clear advantage over the use of CLEA for the specific purposes of human health risk assessment.

2.7 DETAILED QUANTITATIVE RISK ASSESSMENT AND DERIVATION OF SITE SPECIFIC ASSESSMENT CRITERIA

Overview

For most of the regimes considered in this review, DQRA involves the derivation of site specific assessment criteria (SSAC). A different approach has been developed in the US where soil contamination levels are used to calculate a hazard index for threshold substances or a cancer risk estimate for non-threshold substances. It is probable that the US approach will be modified in the future to take account of changing approaches to chemical risk assessment in the US. In the UK, the CLEA model offers the most straightforward tool for undertaking DQRA but there is also an alternative spreadsheet based tool developed by SNIFFER (2003) that is designed to derive site SSAC for human health risk assessment\(^\text{51}\). The guidance that has been developed in New Zealand, Canada and Australia is well written, and although focussed on national circumstances (eg inclusion of national population characteristics and pathways of specific relevance to national circumstances), it largely overlaps with UK guidance. None of this guidance is supported by software tools similar to CLEA and it would be necessary to generate a spreadsheet to undertake the various calculations that are described. The US and Netherlands have undertaken a substantial volume of contaminated land research and independently developed risk assessment methodologies and supporting software packages that support a slightly different approach to DQRA. In practice, if the outcome of the generic

\(^{50}\) Soil Screening Guidance. http://www.epa.gov/superfund/health/commmedia/soil/

risk assessment is inconclusive, it is likely that additional samples will be collected, analysed and reviewed in relation to the GACs prior to developing SSACs, if appropriate.

**UK**

**CLEA**

The EA Model Procedures indicate that DQRA involves the development of site specific assessment criteria (SSAC) which essentially involves exploring each of the exposure pathways and modifying the generic assumptions used in the derivation of GACs in order to better reflect site conditions. This approach can be readily implemented using the CLEA model. When operated in “advanced mode”, the CLEA model enables the user to make temporary changes to the default input variables in relation to chemical data including adding extra chemicals, different tolerable daily intakes for each route of exposure, additional or different physico-chemical data and fractionation into different types of plant material. The user can also modify use and receptor information (eg soil and produce ingestion rates, time spent inside and outside) soils data (eg porosity, critical wind speed for dust pick up) and buildings data (eg size, area covered by hard covering, vapour ingress rates). There is considerable scope to fine tune the model parameters to better reflect site conditions and also to investigate the relative influence of different individual parameters on calculated SSACs for individual contaminants. The information provided in SR3 on the derivation of generic assessment criteria provides useful context in relation to investigating individual components of exposure pathways. The CLEA assumptions in relation to people’s behaviour have a significant impact on apparent exposure but there is a paucity of relevant UK data to support modification of these assumptions to fit site specific circumstances. In some instances a simple local survey such as the number of gardens with an active vegetable patch might be very informative.

**SNIFTER tool**

The SNIFTER tool is also designed for undertaking DQRA in the UK. It is based on the derivation of a Reference Intake for each contaminant and a soil equivalent intake for each exposure pathway. For local effects (eg respiratory irritation), the SSAC is focussed on relevant route of exposure and for systemic effects, the SSAC takes account of all routes of exposure. Dermal exposure is included or screened out as appropriate. Downloadable excel worksheets are provided for the calculation of intake of organic or metal contaminants by different routes for standard land uses, taking account of soil and substance properties. For example, an algorithm is provided to estimate plant uptake for the purposes of estimating the intake of the consumption of contaminants in homegrown produce based on soil density, organic carbon-water fractionation, the fraction of organic carbon in soil and soil water content by volume. There is no database of chemical parameters and toxicological reference doses and chemical/physical parameters for contaminants need to be derived from other sources. The guidance assumes that toxicological reference values will be derived from the HCVs published by the EA and Defra and does not provide guidance on the derivation of reference values for other substances.

For standard land uses, the first step is to collect input data – mean and tolerable daily intakes for threshold ingestion and inhalation effects, Index Dose for non-threshold effects, organic carbon/water co-efficient (\(K_{oc}\)), mass of organic fraction in soil, Henry’s Law co-efficient (H), Effective Diffusion Coefficient (\(D_{eff}\)), volumetric soil vapour and water content, bulk soil density and to the check skin permeability coefficient and dermal absorption. The second step is to select land use which fixes the Exposure Duration, Averaging Time, Childhood Factor, Exposure Frequency and Time-Averaged Body Weight. The third step is to select the relevant exposure pathways and the fourth step is to calculate reference intake. The fifth step is to calculate the soil equivalent intake for each exposure pathway using default values such as time-averaged soil and dust ingestion rate, time-averaged vegetable consumption rate, homegrown fraction of vegetables consumed and vegetable soil concentration factor. These default values are largely the same as those used in the original version of the CLEA model. The sixth step is to calculate the assessment subcriterion for each exposure pathway and the final step is to calculate overall SSAC based on the subcriteria. The process for non-standard land uses is similar but requires the identification of exposure pathways and allows for alteration of the default parameters to reflect site specific circumstances. The guidance describes how to modify standard assumptions on exposure factors to reflect site specific conditions.
Information about undertaking a check of the importance of dermal exposure for a given contaminant at an individual site is provided in one of the appendices to the report.

The SNIFFER tool is less user-friendly and less sophisticated than the most recent version of CLEA and considers fewer exposure routes and is unlikely to the model of choice for most users. The SNIFFER (2003) report, however, does describe the output of an analysis of the sensitivity of the model output to variations in the input parameters which provides a useful background to the uncertainties associated with the use of the SNIFFER (or other) models. This analysis indicated that parameters used in deriving the Reference Intake such as averaging time and reference dose have a vast effect on pathway-specific Assessment Sub Criteria and the SSAC. In addition, variability in published values of contaminant parameters such as $K_{oc}$ have a significant effect on SSAC and site specific values should be used where possible. Site specific factors that have an important impact on SSAC include pH, depth to contamination, soil organic matter content, air and water filled porosity, width of contaminant source zone and wind speed. For the individual exposure pathways, the use of different algorithms to calculate exposure affected the value of the SSAC.

**Deterministic versus probabilistic models**

The SNIFFER model and the current version of the CLEA model are deterministic models meaning that single estimates of each input parameter are entered into the model to generate a single point estimate of exposure. Given that reasonable worst case assumptions are used for each input parameter, there is the potential to substantially over-estimate exposure (and risk) as a result of the multiplication of a number of worst case assumptions. The choice of model assumptions in CLEA has been modified to reduce the risk of vastly over-estimating estimating exposure, but is designed to provide an overall reasonable worst case estimate of exposure. It is difficult to judge how “reasonable” the estimate may be, although for an individual site, the model user can test the importance of individual assumptions on model output. An earlier version of CLEA was based on a probabilistic model in which information about the variability of the input variables was used to generate a probability distribution for the exposure estimates generated in the model (ie median estimate, 95th percentile estimate etc). The difficulties with this approach were that there was little information about the probability distribution for many of the input variables (eg variability in individual habits) and the greater level of complexity required in the calculation process made the spreadsheet very unstable.

**LQM Roadmap**

The LQM Roadmap package is also available to support DQRA that is specifically undertaken for the purposes of Part IIA. The following section is based on a detailed discussion about the tool with Paul Nathanail of LQM. The LQM Roadmap tool is focussed on the toxicological component of DQRA. The Roadmaps provide for plots for 18 common contaminants that comprise comprehensive dose-response charts (for oral, dermal and inhalation pathways as appropriate) showing the range of doses that correspond with observed health effects in humans and animals. Severity of effect is plotted against dose and the user can interrogate each point on the graph to examine the underlying data. The intention is that users can decide how close to the Lowest Observed Effects Level does an intake have to be in order to considered unacceptable, taking account of the severity of the effect. The input data has been subject to review and meets the quality standards set by LQM. Although the graphical output is very helpful, the approach does have some serious limitations:

- Intakes by inhalation are treated as systemic exposures (mg/kg/day) even where effects are on the respiratory system and the relevant dose metric would be a concentration in air;
- No attempt has been made to scale for interspecies differences;
- No allowance has been made for differences in exposure duration; and
- It doesn’t take account of the size of the study population.

The use of scaling factors to allow for size-related differences in metabolism between species is common practice in toxicology and it is surprising that LQM have not adopted the allometric scaling factors advocated in the guidance for undertaking chemical safety assessments under the REACH Regulation. It is also surprising that they have not based their assessment of inhalation toxicology on concentrations for effects on respiratory system which is also common practice in toxicology. The

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52\[http://www.lqm.co.uk/roadmaps/index.html\]
duration of exposure is important as the results of animal experiments demonstrate that the LOAEL in lifetime (2 year) studies in rodents is typically much lower than in subchronic (13 week experiments) and the severity of effects is usually greater. The size of the study population is important as there are genetic differences between people or animals, even for animals of the same strain that lead to differences in susceptibility. Generally, the larger the study, the more representative it is likely to be of the wider population and the greater the likelihood of including some susceptible individuals who may respond at a very low level of exposure. This may affect any allowance made by the user for interindividual differences in the determination of unacceptable exposure. More generally, it should be borne in mind that where data exist describing the responses of different species to a single substance in a single assay, there are real and demonstrable differences between the species in their response. Caution should be applied in the interpretation of the LOAEL determined in an experimental system in terms of human exposure.

**Bioaccessibility**

Bioaccessibility is being increasingly taken into account during DQRA in the UK. The CLEA and SNIFFER models have facilities to include bioavailability (CLEA) or bioaccessibility (SNIFFER) in the derivation of SSACs. Bioaccessibility is the term used to describe the proportion of a contaminant in soil that is actually absorbed by a human receptor. For example, if an insoluble metal compound is ingested, a substantial proportion of the metal may pass through the human digestive system without being absorbed. Bioavailability describes the proportion of an ingested metal that is absorbed by the digestive tract. The bioaccessibility of many substances is reduced by the presence of other substances in soil and is also related to particle size and surface area.

Various experimental test systems have been developed in order to assess the bioaccessibility of contaminants in soils in order to inform the development of SSACs. These include the Physiologically Based Extraction Test (PBET) that replicates the chemical but not microbiological conditions in the stomach and small intestine. This test has been widely used in the UK. The EA (2007) sponsored an interlaboratory comparison of in vitro bioaccessibility measurements for arsenic, lead and nickel in soil. The study found variability in the results reported by different UK laboratories and differences between the results reported by UK and overseas laboratories. The variation in results was probably due to methodological differences. The study also noted the absence of validation against in vivo measures of bioaccessibility and the likelihood that in vitro methods under-estimate in vivo uptake.

The BARGE Unified Method (UBM) has been derived from the Dutch RIVM physiologically based in vitro extraction test and has been calibrated against in vivo data. A recent interlaboratory trial of the UBM test, however, found substantial interlaboratory differences in reported results for the tested metals – arsenic, cadmium and lead.

There is no formal guidance on how to incorporate bioaccessibility data into DQRA but the CIEH (2009) have produced a professional practice note. The science of assessing bioaccessibility is still at a developing stage and there are substantial uncertainties in the data provided by current laboratory tests. Care is required in the interpretation of experimental data as experimental conditions will not completely replicate conditions in the human digestive system and the bioaccessibility of inhaled contaminants or contaminants in contact with the skin is very different from that following ingestion. In addition, the absorption of ingested substances is influenced by age and diet. It is also important to consider the chemical speciation of the contaminant of interest in the exposure on which the HCV is based. For example, many metals are more readily absorbed from soluble rather than


insoluble compounds and may exert an apparently greater toxicity when administered to animals in a soluble rather than insoluble form. Particle size can have a substantial influence on bioavailability, partly because smaller particles have larger surface to volume ratios and are likely to dissolve more quickly but also because particle size governs the fate of inhaled particles. Particles less than about 5 \(\mu\)m in diameter are able to penetrate to the gas exchange region of the lung where high rates of blood flow to the alveoli may help to give rise to substantially greater levels of absorption than for ingested particles. While bioaccessibility data are likely to be helpful to understanding potential risk and to become increasingly important in Part IIA determinations, the CIEH highlight a number of potential pitfalls: insufficient samples tested, use of literature rather than site specific values, application to routes of exposure other than ingestion or to other substances, mixing of samples of different soil types, poorly documented test procedures, tests not conducted for relevant concentrations of contaminants and inappropriate use of statistics.

Other models

A number of commercially available software packages are used in the UK to support DQRA for human health risks in addition to the CLEA, SNIFFER and LQM models. These have been primarily developed to support contaminated risk assessment in the Netherlands (RISC 3) and US (RBCA and RISC 4 and 5). The US packages include more sophisticated approaches to modelling contaminant behaviour in water and air than employed by CLEA and the relative contribution of these pathways to overall exposure will vary by contaminant. However the RBCA and similar RA tools don’t consider / treat the water environment in all the ways required by Part IIA (although they can be adapted to some extent) and the UK ConSim tool is likely to be more appropriate for assessing the water environment risks in Scotland. Detailed modelling of the water environment is rarely likely to be directly relevant to human health risk assessment in the UK as drinking water is separately regulated. Detailed modelling of vapour release may be relevant to more volatile contaminants. These packages are discussed further below in relation to the relevant national regimes.

New Zealand

The Ministry for the Environment (2011) has provided guidance on Site-specific Risk Assessment intended to support practitioners deriving, site-specific soil guideline values that if accepted by the relevant territorial authority, become legally binding for the particular piece of land\(^56\). Site-specific assessment is required where the current site use, or intended site use, does not fit within any of the generic exposure scenarios such that the selection of the most relevant generic soil contaminant standards (SCS) would under-estimate actual human exposure. Site specific assessment is not normally considered appropriate for uses that fit within a particular generic exposure scenario for which national SCS guidelines have been developed.

The approach taken to DQRA in New Zealand is similar that in the UK in that it follows the same overall methodology as that used to generate GACs and national standards but allows individual components to be modified take account of site specific circumstances. This may include changes to:

- The toxicological reference values for the chemical of concern, particularly in relation to chemical speciation and bioaccessibility;
- Assumptions about receptors including the physical characteristics of those receptors (eg, weight, skin areas) and their behaviour (frequency and duration on the site, lifestyle);
- The exposure (intake) estimates, such as which exposure pathways actually exist or whether other exposure factors are realistic for the particular situation.

The implied flexibility is, however, ambiguous as later the guidance states that any factors may be changed except the contaminant toxicity, the dermal absorption factor, the averaging time for non-threshold substances and the assumption of 100% oral bioaccessibility. These restrictions are likely to lead to the generation of highly conservative SSACs. This is consistent with the regulatory regime in

New Zealand which does not require inspection of potentially contaminated sites unless the owner wishes to apply for consent for change of use or to otherwise disturb the soil.57

The development of a suitable conceptual site model describing the contaminants of concern, exposure pathways (and any barriers) and receptors is described in earlier Ministry of Environment Guidelines.58 The equations used to assess exposure set out in the 2011 guidance are the same as those used in the UK, US, Netherlands and elsewhere, but the New Zealand guidance indicates that the main sources of exposure to contaminants are through soil ingestion, produce consumption and dermal exposure. It screens out other potential routes of exposure as being of minor importance. The relative importance of these versus other routes of exposure in the UK is likely to be different given that many households do not grow any of their own food and tracked in soil has been identified as a potentially important source of exposure to soil contaminants in indoor air. The inclusion of fewer pathways in the overall assessment of exposure would be expected to give rise to lower predicted levels of exposure than with the CLEA model, although the New Zealand guidance implies that this should not make a significant difference to exposure levels. Plant uptake levels are identified as a major source of uncertainty and the user is advised to make measurements where possible.

Canada

Health Canada (2004) provide a description of how SSLs are derived that is also intended to support the development of SSACs.53 The guidance describes the identification of appropriate toxicological reference values and how the exposure pathways and receptors identified for generic scenarios may be adapted for site specific circumstances. The guidance also describes how to calculate exposure by each pathway for an individual class of receptor. The relevant exposure calculation equations are provided in text and together with tabulations of receptor characteristics such body weight, inhalation rate, soil, water and food ingestion rates, skin surface area by body part, time spent indoors etc. These data are specific to the Canadian population. The exposure pathways considered include several that are specific to North America such as the consumption of wild game. CCME (2006)34 published a more detailed protocol for developing SSLs that includes much more detailed consideration of different potential exposure pathways and a guide to the interpretation of toxicological information, including how to develop reference values from primary data for substances lacking pre-existing reference values. Although these documents are likely to be helpful in understanding Canadian SSLs, they are unlikely to be particularly useful in the Scottish context.

Australia

The Australian approach is based on the development of GACs that take account of site-specific pathway linkages to avoid being unnecessarily conservative. Where these GACs are exceeded, the DQRA involves a more detailed investigation of exposure pathways that may include collection of additional data, such as soil vapour sampling, ambient air sampling, analysis of dust and biological monitoring. New draft guidance59 provides a useful succinct description of how to undertake an exposure assessment that is largely based on US EPA guidance. The draft NEPM emphasises the importance of ensuring that the assessment is not excessively conservative, since this is likely to lead to unnecessary health concerns and over-remediation. It is recommended that due account is taken of:

- Average and high-end estimate (e.g. upper 95th percentile or maximum) contaminant concentrations;
- The appropriate sensitive exposed population for the conceptual site model;
- Assumed behaviours that give plausible high-end exposure estimates;
- Exposure by several pathways;
- Fate and transport models (e.g. vapour intrusion) which provide estimates of the amount of contamination that reaches the exposed populations.

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57 Resource Management (National Environmental Standard for Assessing and Managing Contaminants in Soil to Protect Human Health) Regulations 2011; 2011/361
In principle, the derivation of SSACs would also take account of bioavailability, bioaccessibility and metal speciation. Overall the draft NEPM is well written, refers extensively to the relevant international literature and may provide useful background material in relation to planning and undertaking risk assessments in Scotland. The draft NEPM is, however, designed for the Australian regulatory regime and there is no supporting software.

Netherlands

The Netherlands have developed CSOIL, a risk assessment tool similar to CLEA, that exists as a series of linked spreadsheets. A version for free download is available on the internet but it is unclear whether this is the most recent version as I was unable to locate a "homepage" for the model. The download package includes a user’s guide and the underlying formulae are detailed by Brand et al (2007). This report provides a clear description (in English) of the model and the factors to consider in exposure modelling and standard input parameters for different scenarios. It does not provide documentation for the derivation of the various receptor input values such as contact frequency or soil ingestion rates. The main exposure pathways considered by CSOIL are:

- Exposure through soil ingestion (mainly relevant for immobile contaminants);
- Exposure through crop consumption (mainly relevant for mobile contaminants);
- Exposure through inhalation of indoor air (mainly relevant for volatile contaminants).

Additionally, exposure through the inhalation of soil particles, dermal uptake via soil, groundwater consumption and inhalation of air during showering may contribute to the exposure. The model is based on default settings for different contaminants that can be adjusted by the user as appropriate. As with CLEA, the user can start with a standard land use scenario and assumptions and then adapt these assumptions to meet the site specific conditions. The model may be used to specifically examine exposure/contact with: soil, air, crops and drinking water.

The model concept consists of three main parts:

- Description of the behaviour of the compound in the soil and the partitioning over the soil phases;
- Transfer processes and parameterisation of the different exposure routes (direct and indirect);
- Quantification of the lifetime average exposure

The input parameters are divided into:

- Compound-specific input parameters; mainly physico-chemical properties e.g. $K_{ow}$;
- Site and soil properties, related to potential exposure e.g. pH;
- Exposure parameters which describe the receptor characteristics and behaviour e.g. breathing volume or ingestion frequency.

Site specific parameters include mean depth of contamination, air permeability of soil, depth of groundwater table, height of the capillary transition boundary and crop characteristics. Soil characteristics include volume fraction air, water and soil, fraction of organic carbon, clay, pH and temperature. Exposure characteristics largely include the same parameters as CLEA with some additional parameters such as exposure during showering. The model takes account of bioavailability assessed using a standard in vitro test system. In addition to CSOIL, the Dutch have developed the VOLASOIL model has been developed to assess effects on indoor air quality as a function of type and positioning of the contaminants, building and soil characteristics, and groundwater depth. The SEDISOIL exposure model is used to assess relevant pathways for sediments such as exposure via fish consumption, dermal uptake when swimming and the ingestion of water and particulate matter when swimming.

The CSOIL spreadsheet package has an entry page similar to that in CLEA and takes the user through a series of spreadsheets. The model can be used to calculate predicted human exposure based on soil concentrations of specified contaminants with the potential to refine these estimates by adding site specific data describing concentrations of the contaminants in other media (similar to the facility in CLEA). The model can also be used to determine the maximum tolerable concentration of a contaminant based on the Dutch criteria. The software draws on Dutch toxicological reference values and chemical parameters and it is not clear how to modify the database to enter toxicological and chemical parameters of choice. The toxicological reference values are visible (within protected cells) within the series of spreadsheets, so in principle it would be possible to adjust the output of the model to take account of different toxicological reference values. The input pages take the user through identification of a generic exposure scenario or a user defined scenario. In the user defined scenario it is possible to define the

- Daily intake soil (year average);
- Fraction consumption root crops or potato from own garden (from total);
- Fraction consumption leafy crops or vegetables from own garden (from total);
- Consumption amount root crops or potato;
- Consumption amount vegetables of leafy crops;
- Time spend indoors (year average);
- Time spend outdoors (year average);
- Exposure time soil contact indoor;
- Exposure time soil contact outdoor;
- Exposure via drinking water.

The user then selects the relevant exposure pathways to be included in the assessment. The next screen allows the user to define site specific soil characteristics: clay and organic matter contents, crawl space height, depth of crawl space, contamination depth, pH, dry bulk density, volume fraction of soil, water and air, ventilation rate of crawl space and contribution of crawl space to indoor air. Default parameters are used, if site specific data are not available. The user selects the contaminants of interest and has the option of entering contaminant concentrations in soil, soil air, soil water, crawl space air, indoor air, leafy crops, potato or root crops and in drinking water. CSOIL then calculates the exposure for a human receptor via different routes and provides a “risk index”. Alternatively if site specific receptor, exposure pathways and soil characteristics are entered, the model will calculate a maximum tolerable soil concentration for the contaminant based on the Dutch criteria.

A commercially available model - RISK INTEGRATED SOFTWARE FOR CLEAN-UPS RISC-HUMAN 3.1 (Version 3.1) – is a development of the CSOIL model intended to estimate human exposure to contaminants within soil, groundwater and sediment. CIEH\(^{62}\) indicate that RISC 3.1 allows the creation of subsites with different land uses and includes a sophisticated vapour model with a number of conceptual models although the default receptor parameters and exposure scenarios database are not consistent with UK data and the chemicals parameter database does not include UK HCVs.

The CSOIL and RISC models have been developed specifically within the Dutch context and some of the exposure routes included would have limited relevance in the Scottish context. In particular, the water environment would be considered separately in Scotland and some routes of exposure such as swimming in inland waters would be of little relevance here, even if not covered by separate legislation. In addition, Dutch soils are generally very different from soils in Scotland and the relative availability of contaminants and potential for exposure is very different, although it should be possible to take account of this in using the software. Overall, however, it would seem much easier to use CLEA for undertaking DQRA in Scotland than trying to adapt the use of CSOIL.

US EPA

Overview

The US EPA have developed extensive guidance to support site specific risk assessment (RAG Part A and associated guidance)\(^{20,21}\). The basic approach is similar to that developed elsewhere but described in considerably more detail. The guidance describes how to calculate uptake by different exposure pathways and routes and how to derive appropriate toxicological reference values for exposure by different routes. This includes the development of cancer risk estimates, although more recent US EPA guidance advocates a benchmark dose approach\(^{13}\). As with the Dutch guidance, a wider range of exposure routes is considered than in CLEA with a greater emphasis on the water environment. One key difference in relation to toxicological reference values is that the US guidance deals with inhalation exposure in terms of exposure concentrations rather than as systemic intake as mg/kg/day. Scientifically, this is a better approach for contaminants that primarily impact on the respiratory system.

Probabilistic modelling

The original approach to risk assessment for Superfund sites was deterministic in which reasonable worst case assumptions were used for each input parameter, giving rise to the potential to substantially over-estimate risks as a result of the multiplication of a number of worst case assumptions. More recently a probabilistic approach has been developed in which a probability distribution, rather than single value, is specified for one or more variables and a Monte Carlo simulation is executed by repeatedly selecting random values from each of these distributions and calculating the corresponding exposure and risk\(^6\). The resulting predicted typical and reasonable worst case estimates would be expected to be considerably more realistic than those generated by traditional deterministic methods because they take account of all the various combinations of variability possible within the system. The guidance describes how frequency information for input parameters such as human body weight or surface area by age or adults’ consumption of drinking water can be used to derive a probability function suitable for use in a Monte Carlo simulation. This is subject to site specific or other relevant data being available for each of the input variables, although point estimates may be used for variables where no information is available. Although probabilistic methods of risk assessment offer the potential to provide much more robust reasonable worst case estimates than traditional point estimates, the software is not currently available to enable LAs to adopt this approach for routine site assessment. In addition, there is a paucity of information about the distribution of input values for most variables which greatly reduces the potential robustness of the model outputs.

Risk assessment for mixtures

The US EPA has also developed guidance on risk assessment for chemical mixtures that is relevant to contaminated land investigation\(^25\). For threshold substances describes how modelled intakes of contaminants can be compared with reference values to derive a hazard quotient (HQ) for each contaminant that can be summed to derive a hazard index (HI). Generally if the HI is less than unity risks are considered to be adequately controlled. For non-threshold substances, it may be appropriate to sum the estimated risks. Although neither the use of neither hazard indices nor cancer risk estimates are supported in the Scottish regulatory context, they do provide pragmatic tools to assist decision making, particularly where a mixture of contaminants are present. More recent US EPA guidance\(^26\) describes methods for using whole-mixture data on a toxicologically similar mixture, methods for incorporating information on toxicological interactions to modify a HI, and generalised procedures for mixtures involving classes of similar chemicals. This guidance is potentially useful in a Scottish context, but its implementation requires a background in chemical risk assessment. Subsequent guidance describes the use of pharmacokinetic modelling for assessing the interactions of substances and their metabolites in the body\(^64\). Pharmacokinetic modelling involves modelling the absorption and metabolism of substances and the transfer of substances and their metabolites


\(^{24}\) US EPA (2009). Considerations for Developing a Dosimetry-Based Cumulative Risk Assessment Approach for Mixtures of Environmental Contaminants

27
through different compartments in the body (e.g., digestive system, systemic circulation, liver, brain, etc). It is a tool that enables the modelling of the received dose at target organs, but requires substantial input data from experimental systems. The guidance is supported by a free software modelling tool\(^{65}\). Given that pharmacokinetic modelling requires substantial input data that are unlikely to be available in the public domain for most contaminants of interest, it is not an approach that is likely to be useful in the context of risk assessment for contaminated land in Scotland.

The US EPA Exposure Factors Handbook\(^{66}\) has been developed to support all areas of human health risk assessment and provides a comprehensive resource that describes the outcome of investigations of exposure and uptake to contaminants by all routes of exposure and all the related behavioural factors that influence exposure. For example, it details the outcomes of multiple investigations of activity patterns (such as sleeping, time spent indoors, outdoors, and on various activities), eating patterns, food and water consumption, height, weight, body surface area, quantities of dust ingested, adhering to skin, and many other parameters. It is an extremely useful resource for anybody developing an exposure model from first principles for a specific exposure scenario as well as being a useful reference document when reviewing the plausibility of generic assumptions incorporated into models such as CLEA.

**Supporting software**

The US EPA risk assessment guidance documentation is supported by a freeware programme—the *Spatial Analysis and Decision Assistance software tool (SADA)*\(^{67}\). SADA is intended to provide comprehensive risk assessment tools in a spatial modelling environment that can be used to perform human health risk assessment calculations for one or more contaminants. Users have complete control over all toxicological data, physical properties, and land use/pathway exposure parameters and the software is intended to support a risk based characterization from a preliminary initial sample design through a final feasibility study. In addition, SADA allows users to import their own site or region specific screening or decision threshold values separately from SADA’s own risk modelling tools. SADA provides a full human health risk assessment module and associated databases. The risk models follow the EPA’s Risk Assessment Guidance for Superfund (RAGS) and can be customized to fit site specific exposure conditions. The generic land use scenarios in SADA are residential, industrial, agricultural, recreational and excavation. The exposure routes are ingestion, inhalation, dermal contact, external (radionuclides) and food consumption. SADA comes with a toxicological profiles data base that contains all toxicological/physical properties for over 1000 contaminants from the Risk Assessment Information System based on IRIS and HEAST and an exposure/scenario parameters database. Each database is produced in Microsoft Access and can be readily modified by the end user. SADA can be linked to geospatial tools and used to inform the design of sampling strategies. The example data entry screens provided in the model description suggest that the software is likely to be easy to use and a reference on the homepage to an upcoming training course in Sweden, indicates that it is clearly used in mainland Europe. The SADA model would appear to be potentially a very powerful tool that is designed to be used in conjunction with GIS software. It has the drawback, however, of being a deterministic rather than a probabilistic model such it retains the uncertainties associated with estimation of reasonable worst case exposure. SADA could offer a substantial advantage over CLEA for large and complex sites, where the mapping facility would allow clear demarcation of areas of potential concern for different contaminants. It allows for the investigation of the impact of small modifications in assessment criteria on the area and volume of soil to be targeted for remediation and can aid in assessing the cost effectiveness of different remediation strategies based on different trigger levels. SADA is unlikely to offer a substantial advantage over CLEA in relation to the relatively small sites that are typically the subject of Part IIA investigations.


\(^{67}\) [http://www.tiem.utk.edu/~sada/index.shtml](http://www.tiem.utk.edu/~sada/index.shtml)
Other US-based tools

At least two commercially available US-based software packages designed for human health risk assessment of contaminated land sites are used to a small extent in Scotland:

- RBCA (risk-based corrective action) tool kit for chemical releases\(^68\), and
- Risk integrated software for clean-ups - RISC (Version 4.0 now updated to version 5.0)\(^69\)

RBCA is designed to meet the requirements of the ASTM Standard Guide for Risk-Based Corrective Action (E-2081) and is intended for use in Tier 1 and 2 evaluations for chemical release sites. The software combines contaminant transport models and risk assessment tools to calculate baseline risk levels and derive risk-based cleanup standards. Exposures are modelled for residential, commercial, and user-defined receptors arising from groundwater, surface water, surface soil, outdoor air and indoor air, taking account of groundwater ingestion, surface water recreational contact and fish consumption, combined direct contact with surface soils (incidental ingestion, dermal absorption, inhalation of vapours and particulates, and consumption of homegrown vegetables) and outdoor and indoor inhalation of vapours emanating from soil or groundwater sources. Fate and transport models have been developed for all exposure pathways for petroleum hydrocarbons (including TPH), metals, chlorinated solvents, pesticides, and other substances based on an array of default transport parameters for various soil types. Models integrated within the software include:

- Soil and groundwater source depletion
- ASTM and US EPA (SSG) outdoor air volatilization
- Johnson & Ettinger and Groundwater Mass Flux indoor air models
- ASTM soil leaching model, with decay options
- Dual-equilibrium desorption
- Point-source air dispersion
- Domenico groundwater solute transport, with decay options

The software includes a database of default physical, chemical, toxicological and regulatory parameters for over 600 of chemicals, including organic solvents, petroleum hydrocarbons (including TPH fractions), pesticides and metals. The user is able to specify default toxicological parameters from published sources in the USA, Netherlands, and UK. Although RBCA may also be used to assess risks to the water environment, it does not address all the pathways required under Part IIA.

RISC (version 5.0) is an updated version of software developed by BP to provide a standardised approach to soil and groundwater risk assessment through fate and transport modelling. It is a highly sophisticated model that is designed for use in the US regulatory and physical environment. As with RBCA, care is needed to ensure that input parameters are adjusted to reflect Scottish conditions and that the sensitivity of model outcomes to different input parameters is investigated and understood. The supplier’s website indicates that RISC is designed to:

- Estimate human health risk from exposure to contaminated media,
- Estimate risk-based clean-up levels in various media,
- Perform simple fate and transport modelling, and
- Evaluate potential ecological impacts to surface water and sediment.

It includes a customizable chemical database with more than 100 chemicals, the ability to calculate additive risk due to multiple pathways, compound and receptors (such as a resident exposed as both a child and an adult) and Monte Carlo capabilities for probabilistic risk evaluation. The exposure pathways in RISC include:

- Ingestion of soil
- Dermal contact with soil
- Ingestion of groundwater

\(^{68}\)http://www.groundwatersoftware.com/rbca_tool_kit.htm
• Dermal contact with groundwater
• Inhalation in the shower
• Inhalation of outdoor air
• Inhalation of indoor air
• Ingestion of surface water
• Dermal contact with surface water

Sources of exposures are also considered include water used for gardening but not for indoor usage and crops grown in contaminated soil (with plant uptake model), human exposure from vapours in groundwater, airborne particulate emissions and sediment.

Fate and transport models in RISC include

• Johnson and Ettinger indoor air model
• Volatilisation from groundwater to indoor and outdoor air
• Outdoor box model
• Unsaturated zone model
• Saturated zone model.

The key drawback with the RBCA or RISC model from a UK perspective is that they are designed for use in the US where the key factors driving human exposure to soil contaminants and the underlying regulatory regime are different. For example, both windblown dust and the water environment are likely to be of less importance for exposure in a UK context, and the UK regulatory regime considers human health and the water environment separately in relation to soil reflecting the separate regulation of drinking water quality. In using either tool to model human exposure for a Scottish site, care would be needed to include only relevant sources of exposure and to ensure that any inherent assumptions about human behaviour or building characteristics were appropriate. Other than the potential to access a large quantity of useful input data for a wide variety of substances, it is not immediately apparent that either tool would be more helpful than CLEA for the purposes of risk assessment. There is a trade off between the sophistication of modelling packages versus the increased uncertainty introduced by the increased level of assumption required to achieve that sophistication, particularly in relation to relevance to the Scottish environment. Key assumptions may be buried deep within the software rather than being explicit. As with any package, the sensitivity of model outcomes to input parameters should be investigated and reported and taken into account when using the model predictions in the context of risk assessment.

Conclusions

In terms of ease of use, the CLEA model is clearly the model of choice as the user is presented with an entry screen to guide them through a small number of input screens. The model provides the opportunity to explore the impact of different input variables on risk estimates giving a relatively robust status to the resultant risk assessment. In most circumstances, the output from CLEA is likely to provide a robust basis for decision making in Scotland, providing appropriate input variables are entered for contaminants and relevant pathways are considered. The current version of CLEA model is easier to use and more sophisticated than the older SNIFFER model and is likely to be the preferred model for most sites. There are likely, however, to be some circumstances when the CLEA output will generate SSACs that overlap with measured soil contaminant levels and the basis for decision making is unclear. In that instance, a LA may wish to experiment with the use of different models including the SNIFFER model which is specific to the UK context but may not be as well informed as the newer CLEA package.

None of the internationally available tools for DQRA offer clear advantages over the CLEA or SNIFFER models. The CLEA and SNIFFER models have the advantage of being directly relevant to UK conditions and are supported by free software. In particular, they are designed to support separate assessment of risks to human health and the water environment that is consistent with the Scottish regulatory regime.

In using the CLEA model, it is important to examine the underlying assumptions outlined in SR3 in relation to the specific site in order to be certain that they are appropriate and to have an awareness of how varying individual parameters may impact on the SSAC derived. This can be achieved
relatively easily by varying the input parameters in the model in the advanced use mode. It is also important to be aware that exposure research is a very active field and that a search of the internet is likely to reveal further information relevant to assessing exposure by ingestion, inhalation or dermal contact such as new information linking outdoor soil concentration data to indoor exposure parameters. In taking account of more recent research findings, it is important to consider their likely reliability and their relevance to conditions in Scotland. The reliability of the findings will be a function of study design including factors such as the method of observation, number of observations and number of individuals.

The most difficult aspect of using models such as CLEA is adjusting the input variables to generate reasonable worst case exposure estimates that do not vastly over-estimate probable exposure levels. The extent to which it is appropriate to investigate model sensitivity and input assumptions will depend on site circumstances. If soil contaminant concentrations are well below the SSAC based on default assumptions in CLEA, there would be little to justify further investigation. Finally, neither CLEA nor SNIFER are designed for health risk assessment for asbestos and there are currently no published tools for undertaking human health risk assessment for asbestos contaminated sites.

Other models are not specific to the UK context and care is required to ensure that the input variables employed are relevant to the UK rather than the US, Netherlands or elsewhere. When the CLEA model fails to provide a clear basis for decision making, it would be better to re-evaluate the input variables from a site specific perspective rather than experimenting with a different model. It may be necessary to collect more measurement data to better understand the potential for exposure. This might involve collecting further soil samples, investigating contaminant levels in homegrown food, measurements of indoor air quality and analysis of house dust.

2.8 UNACCEPTABLE INTAKE

UK (including Scotland) government guidance

Scotland

The lack of clear advice on how to decide how much is too much in relation to Part IIA has become a major issue in contaminated land management in the UK. The UK guidance on undertaking a DQRA using the CLEA model\(^4\) does not specifically link the process with the determination of SPOSH. The 2006 Scottish statutory guidance for Part IIA\(^2\) is not particularly helpful in relation to the definition of SPOSH: SPOSH for human health effects arising from the intake of a contaminant, or other direct bodily contact with a contaminant (exposure) exists, if the amount of the pollutant in the pollutant linkage that a human receptor in that linkage might take in or to which a human might otherwise be exposed, as a result of the pathway in that linkage, would represent an unacceptable intake or exposure, assessed on the basis of relevant information on the toxicological properties of that pollutant. LAs are encouraged to take account of:

- the nature and degree of harm;
- the susceptibility of the receptors to which the harm might be caused; and
- the timescale within which the harm might occur, taking into account any evidence that the current use of the land will cease in the foreseeable future.

Defra: new Part 2A guidance

Defra have made a number of attempts to improve the guidance available to LAs south of the border. The new draft Part 2A guidance in England includes extensive text on the determination of SPOSH in England\(^7\), but this is phrased in terms that allow for a wide variability of interpretation. Defra indicates that number-based risk thresholds have not been set because of the uncertainties in deriving risk estimates and, because of the variability in site conditions, the likelihood that any limits would be precautionary and catch a lot of land unnecessarily. The Impact Analysis for the new guidance states

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that excessive caution should be avoided because of the potential negative impacts of regulatory intervention including:

- Public anxiety over possible health risks and effects on house prices, property blight, and high levels of inconvenience and disruption while sites are investigated;
- Stress related health impacts that might outweigh any health benefits of investigating and remediating land where there is only a low/hypothetical risk;
- Risks associated with mobilisation of contaminants during remediation works; and
- The costs to individuals, businesses and the taxpayer.

Significant harm to human health is defined as death; life threatening diseases (e.g. cancers); other diseases likely to have serious impacts on health; serious injury; birth defects; and impairment of reproductive functions in line with the Scottish and earlier Defra guidance. It is indicated, however, that the potential for lesser harm to be indicative of more serious harm following long term exposure should also be considered. In deciding whether or not a particular form of harm is significant, the LA should consider the impact on the health, and quality of life, of any person suffering the harm; and the scale of the harm and take account of the broad objectives of Part IIA. In deciding whether or not SPOSH exists, the LA should first understand the possibility of significant harm from the relevant contaminant linkage(s), the strength of evidence underlying the risk estimate and the associated uncertainties. Whether the possibility of significant harm being caused is determined as significant depends on whether the risk is sufficiently high to justify regulatory action to reduce it.

English LAs are now required to categorise land using the following criteria as part of the determination process:

- Category 1: There is an unacceptably high probability, supported by robust science-based evidence, that significant harm would occur if no action is taken to stop it.
- Category 2: There is a strong precautionary case for considering that the risks from the land are of sufficient concern that the land poses SPOSH but where there is little or no direct evidence that similar land, situations or levels of exposure have caused harm before.
- Category 3: The case for category 2 cannot be made.
- Category 4: There is no risk or that the level of risk posed is low.

Categories 1 and 2 encompass land which is capable of being determined as contaminated on the grounds that a significant possibility of significant harm to human health exists or is likely to exist. Categories 3 and 4 encompass land which is not capable of being determined on such grounds. In making its decision on whether land falls into Category 2 or Category 3, the LA is required to consider the likely direct and indirect health benefits and impacts of regulatory intervention, what remediation is likely to involve, how long it would take, what other benefits it would be likely to bring, whether the benefits would outweigh the financial and economic costs and any impacts on local society or the environment from taking action that the authority considers to be relevant. If the LA cannot decide whether or not SPOSH exists, it should conclude that the legal test has not been met and the land should be placed in Category 3. Sites where soil contaminant levels are below relevant SGVs are likely to fall within Category 4 but the Impact Analysis indicates that SGVs/GACs are excessively cautious and should not be used to distinguish Category 4 sites. It is intended that new generic Category 4 screening levels (C4SLs) will be developed. These would necessarily have to incorporate a degree of caution whereas the C3/C4 boundary at a specific site could be assessed by a DQRA.

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71 Impact assessment - Simplification of the contaminated land regime
72 Defra call for proposals SP1010
The SG Contaminated Land Advisory Group (CLAG) commented on an earlier version of this guidance73 and expressed concern that the implied greater flexibility for individual LAs to decide what constitutes significant harm would lead to greater potential for inconsistency. CLAG also indicated that factors such as socio-economic or environmental factors should not be included in the consideration of SPOSH as this would introduce inconsistency (between regulators and areas) and the approach suggested deviates from the “risk based” regime that was originally intended. From a health perspective, however, it is worth noting that socio-economic factors have a considerably greater impact on health and life expectancy than exposure to environmental pollution at levels that are likely to arise in the UK. The health impacts of soil contamination in the UK have not been quantified but the Defra research study SP100274 did not find evidence linking land contamination in the UK to adverse health effects or clear evidence from elsewhere that adverse effects are likely. A study undertaken in Belgium found that that there were adverse mental health effects associated with land contamination but these were related to a lack of community consultation and disbelief in the need for remediation rather than the nature and levels of contamination present75. The health effects of air pollution are better quantified and it is thought that exposure to air pollution in the UK leads to an average loss of life expectancy of about 8 months76. In comparison the Health Life Expectancy (HLE) of males in the most deprived 10% of the Scottish population was 22.5 years shorter than for those in the least deprived 10% (2009-10) and for females the difference was 22.1 years. Males in the most deprived decile experience 21.3 years in ‘not good’ health compared with 12.1 years in the least deprived decile. For females the figures are 24.9 years compared with 11.6 years in the least deprived decile76.

CLAG also expressed concern about the arbitrary exclusion of background levels of contaminant from consideration. The local “background” could include high levels of pollutants in an urban area and even where contaminants arise from natural geological features, they could still be present in soil at levels that could potentially be harmful to health. In practice, however, if there is no evidence of a health problem associated with “background” levels of contamination, it would be difficult to argue that the associated exposure to the contaminant was unacceptable.

_Earlier Defra guidance_

Earlier Defra (2008) guidance77 had indicated that:

For substances with an SGV, the more the SGV is exceeded, the more likely it is to be SPOSH.

SPOSH is unlikely to exist at concentrations close to SGVs.

In some cases, land with concentrations of contaminants which marginally exceed an SGV (say, up to a few times the SGV) might give rise to SPOSH if, for example, the receptor is particularly sensitive; or if further assessment finds that exposure is higher than that estimated in the generic SGV; or if there is little uncertainty in the underlying toxicology and HCV. In other cases an SGV may be exceeded by tens of times and there might be no SPOSH (e.g. if further assessment found that exposure was much lower than that estimated using the generic SGV).

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73 Public consultation on changes to the contaminated land regime under Part IIA of the Environmental Protection Act (1990): Consultation questions response form: Contaminated Land Advisory Group (CLAG) members; submitted by Francis Brewis, SG
In an Annex to the 2008 guidance Defra stated “The Government considers that an excess lifetime cancer risk of 1 in 100,000 based on suitable human cancer data would be an appropriate approach for setting HCVs (Health Criteria Values) for soil contaminants based on “minimal risk””. This view however has not been subsequently endorsed by Defra or other government agencies. The 2008 guidance followed an earlier circular intended to provide clarification of the definition of SPOSH that lacked sufficient precision to be readily applicable. This circular indicated SPOSH existed for human health effects arising from the intake of, or other direct bodily contact with, a contaminant, if the amount of the pollutant in the pollutant linkage in question would give rise to an unacceptable intake, assessed on the basis of relevant information on the toxicological properties of that pollutant. The assessment was to take account of the likely total intake of, or exposure to, the substance or substances of concern from all sources including the pollutant linkage in question, the relative contribution of the pollutant linkage in question to the likely aggregate intake and the duration of intake or exposure resulting from the pollutant linkage in question. It was indicated that the question of whether an intake or exposure to a toxic substance is unacceptable is independent of the number of people who might experience or be affected by that intake or exposure.

The SG Short Life Working Group (SLWG) which reviewed the Defra (2008) guidance concluded that there was no need to adopt and issue the Defra document in Scotland given that statutory guidance in Scotland adequately defined the definition of contaminated land and that the Defra approach (in a number of ways) appeared inconsistent with that adopted in Scotland.

**Other UK guidance**

The CIEH guidance on land for housing is not specific to health or Part IIA but does provide some practical guidance on rating risks of differing severity, although this stops short of providing a clear definition of SPOSH. Annex 4 to the guidance provides guidance on what may be considered severe, medium, mild or minor consequences where highly elevated concentrations likely to result in significant harm to human health is categorised as a severe consequence and non measurable impact on human health is categorised as a minor consequence. Likelihood is defined as shown below.

**High likelihood:** There is pollutant linkage and an event would appear very likely in the short term and almost inevitable over the long term or there is evidence at the receptor of harm of pollution.

**Likely:** There is pollutant linkage and all the elements are present and in the right place which means that it is probable that an event will occur. Circumstances are such that an event is not inevitable, but possible in the short-term and likely over the long term.

**Low likelihood:** There is pollutant linkage and circumstances are possible under which an event could occur. However, it is by no means certain that even over a long period such an event would take place, and it is less likely in the shorter term.

**Unlikely:** there is pollutant linkage but circumstances are such that it is improbable that an event would occur even in the very long term.

An earlier CIEH (2006) publication sought to provide guidance on determining unacceptable intake, specifically in relation to toxicological information. This publication is not particularly helpful in that it highlights the substantial discretion that LAs can exercise without providing authoritative guidance on what might be considered reasonable. The guidance also requires a degree of toxicological expertise to implement, particularly as it is inaccurate in its description of what constitutes a tolerable daily intake, omitting to note the substantial margin of safety that is normally used to derive a TDI from a no effects level in animals. The guidance is helpful to the extent that it highlights that an intake exceeding

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79Scottish Government: Report on the Short Life Working Group; 16th April 2009 – provided by Francis Brewis, SG  
80CIEH 2006. The determination of contaminated land: deciding what is an “unacceptable intake”  
http://www.cieh.org/policy/determination_contaminated_acceptable.html
the TDI or a potential lifetime cancer risk exceeding $10^{-5}$ may not be unacceptable, but the burden of responsibility for deciding how much above the TDI is placed on the LA. For non-threshold substances, the guidance does present a precedent for permitting calculated risks to be as high as $10^{-4}$.

In practice, where LAs have difficulty in determining whether SPOSH exists, they are likely to collect more samples in order to refine their model of contaminant distribution and examine the exposure parameters used in the CLEA model in order to generate SSAC. They may also re-evaluate the toxicological information. In particular, they may wish to determine unacceptable intake as being higher than that used in the determination of generic HCVs. This may include reducing the size of the uncertainty factor where the HCV is based on a threshold effect or, for non-threshold substances, setting a higher risk level than that associated with the HCV (e.g. a lifetime cancer risk of $10^{-4}$ rather than $10^{-5}$). The LQM roadmap approach may be helpful in assisting LAs in the development of SSACs for threshold contaminants that incorporate much smaller margins of safety (uncertainty factors) than traditionally incorporated in the setting of health based limits for environmental exposures. As described above, however, some care is required with the LQM approach, as the roadmaps do not incorporate interspecies scaling factors that could substantially affect apparent dose, some apparently minor health effects (e.g. respiratory irritation) are the precursors of serious disease (e.g. disabling respiratory illness), the approach taken to dose for inhaled substances is inappropriate for effects on the respiratory system and the visual portrayal of the information does not clearly separate data in relation to differing periods of experimental exposure (typically 1, 3 or 24 months in toxicological assays).

**Criteria applied elsewhere**

The Dutch are unusual in that they have specified criteria against which land can be compared and the decision made to remediate. The Dutch Intervention levels for soils are based on the human toxicological Maximum Permissible Risk (MPR) level and or the ecotoxicological risk limit, depending on which gives the lower concentration in soils. For threshold substances the MPR is based on the NOAEL. Uncertainty factors are used in order to ensure that sensitive subpopulations are protected. Typical factors of x10 for interspecies, x10 for intraspecies variability are combined with factors to allow for extrapolation from short term to long term exposure and/or route to route extrapolation. An additional factor may be applied to take account of reliability of the database. The overall approach is similar to that used to derive HCVs in the UK or Reference Doses/Concentrations or Minimal Risk Levels in the US. The Dutch intervention levels for carcinogens are set to be equivalent to an increase in lifetime cancer risk of $10^{-4}$. The intervention values are intended to be based on realistic rather than worst case estimates of exposure and are therefore likely to be less conservative than SGVs or GACs deriving using CLEA that are intended to represent a reasonable worst case. For an intervention value to be exceeded, a minimum of 25 m$^3$ of the soil volume in the case of earth or sediment contamination, or 100 m$^3$ pore saturation soil volume in the case of groundwater contamination, must be higher than the intervention value for at least one substance.

Some individual US states have specified the upper bounds of acceptability for concentrations of specific soil contaminants. Under the other regimes considered, however, there is a strong emphasis on site specific decision making, usually in consultation with stakeholders. The US EPA have developed guidance on the development of risk based remediation goals for Superfund sites based on a hazard index of less than unity and a target cancer risk of less than one in $10^6$. The guidance is not particularly informative in the context of Part IIA.

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2.9 COMPARISON OF MEASURED DATA WITH ASSESSMENT CRITERIA

Detailed guidance has been developed in the UK by the CIEH. The approach under all the regimes considered is conveniently summarised in the New Zealand guidance: it is not envisaged that occasional SCS exceedances would necessarily trigger a site-specific assessment (or management action or remediation), rather the site should be assessed on the basis of average exposure over appropriate exposure (averaging) areas, taking into account any hotspot contamination, as necessary.

In the UK, CIEH/CL:AIRE (2008) published guidance describing how statistical techniques can be used in the comparison of measured concentrations of contaminants in soil against some, user defined, ‘critical concentration’ or indicator of risk. The guidance approaches this in the contexts of establishing whether land is suitable for a new use under the land use planning system or falls within the scope of Part IIA (see Figure 2.1). Issues addressed include whether there are sufficient, representative data available to apply statistical tests in a meaningful way, what statistical methods should be used and the confidence level at which statistical tests should be conducted. It is suggested that under Part IIA, there is a requirement to demonstrate that there is a 95% probability that the true population mean soil concentration falls above the critical concentration whereas in the planning scenario, the statistical test is to demonstrate that there is a 95% probability that the true population mean falls below the critical concentration (note that the x axis is shifted in the two graphs shown in Fig. 2.1 and the critical concentration is the same in both cases). Unlike the “planning scenario”, a decision on a Part IIA assessment can be based on the balance of probability.

Figure 2.1: Illustration from the CIEH (2008) guidance demonstrating the difference between evaluation of soil samples in relation to the planning regime versus Part IIA.

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http://www.cieh.org/policy/guidance_soil_contamination.html
The US EPA have developed rather more detailed guidance on developing data quality objectives and setting the criteria for decision making in relation to contaminated land (specifically Superfund sites). This guidance is intended to cover the whole process of site investigation and has been developed in order to optimise the level of data collection undertaken in order to ensure that there are sufficient data to support a decision but avoiding unnecessary effort and cost. The guidance covers clarification of the study objective, determining the most appropriate data to collect, determining the appropriate sampling strategy and specification of the tolerable limits on decision errors which will determine the quantity and quality of data required to support the decision. The description of setting decision criteria is useful in the context of Part IIA and in planning DQRAs but it does not equate to a clear instruction manual of what to do.

2.10 RISK COMMUNICATION AND STAKEHOLDER INVOLVEMENT

The determination of contaminated land in Scotland is a LA responsibility and there is no regulatory requirement to involve stakeholders in the decision process. The findings of research undertaken in Belgium, however, indicates that risk communication and stakeholder participation in consultation on the management of risks arising from contaminated land plays an important role in reducing stress and associated mental health issues in communities concerned about land contamination. UK guidance on risk communication and community engagement in relation to soil contamination is available together with guidance on risk communication in other contexts. Generally environmental decision making in the UK does not involve any community engagement and there are no mechanisms by which local communities can become involved other than in the context of commenting on planning applications. In contrast, in both the US and Australia, there is a non-mandatory but specific requirement to involve local communities that has led to the development of guidance on community engagement and risk communication that is specific to contaminated land. Community engagement is presented in guidance as an integral part of the process of risk assessment and the development of remediation plans in the US for both “Superfund” and “Brownfield sites”. In Australia, community engagement is encouraged but not prescribed. Although there is no formal community engagement in Part IIA decisions, risk communication is an important issue. Contaminated land officers and/or consultants engaged by LAs will require to engage with stakeholders including elected representatives, council officers and those directly affected by the decision.

The SNIFFER (2010) report on risk communication for contaminated land and the associated summary leaflet provide lots of sensible advice on good risk communication in the UK context. This

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includes designing a strategy that identifies stakeholders, defines the message to be communicated and the method of communication and takes account of local community issues. Various suggestions are provided on how to engage with communities with advice on key issues including building and maintaining trust, openness and transparency, acknowledge of people’s concerns and awareness of historical issues. The guidance indicates that communication should start as early as possible and involve as many people as possible and highlights the importance of making stakeholders feel involved in the process. Practical tips on risk communication in a wider context are provided by the Risk and Regulatory Advisory Council. Previously the HPS (2008) had provided guidance on risk communication in a more generalised context. Key rules are to keep the message:

- Simple – frightened people don’t want to hear big words
- Timely – frightened people want information immediately
- Accurate – make it direct; frightened people won’t grasp nuances
- Relevant – give action steps and answer specific questions
- Credible – use empathy and openness to achieve credibility
- Consistent – keep messages consistent, but qualify areas of uncertainty where there may need to be a change to the message, as changes are unsettling and will be scrutinised closely for their significance.

In order to communicate risk successfully, the messenger must avoid being paternalistic and be participatory, inclusive, empathetic, non-patronising, caring and non-judgmental. They should also be honest and open, competent with expertise in the relevant areas, including risk communication, credible and genuine and consistent.

None of the recent UK advice on risk communication provides clear instruction on how to explain the magnitude of risk to nontechnical stakeholders.

The Department of Health (1997) guidance on communicating about risks to public health was based on the results of empirical research on reactions to risk and took account of the role of risk communication in the decision making process. The guidance outlines what influences trust, which types of risk are most likely to be seen as unacceptable or outrageous, how information about probabilities may be understood or misunderstood, and why comparisons between different risks are sometimes misleading. In addition, the role of the media in determining which potential risks become major public “issues” is discussed. It is recommended that risk communication is initiated earlier rather than later and has clear objectives that are kept under review. Policy must be agreed internally prior to communicating to stakeholders and the outcomes of risk communication should be evaluated. The guidance does provide some information about the risk of death from various causes, although it cautions about the need to be careful in making comparisons. It also discusses issues around the uncertainties in risk estimation.

US EPA have developed guidance on community involvement in Superfund Risk Assessments as a supplement to RAGS A. The aim of the guidance is to provide the site team--risk assessor, remedial project manager (RPM), and community involvement coordinator--with information to improve community involvement in the risk assessment process. It is stated that early involvement of local...
communities can substantially reduce community anxieties in relation to potential risks and build confidence in the outcome of the risk assessment. It also ensures the risk assessment addresses issues of concern to the community and generates buy-in to the outcome. The guidance provides good practice guidelines for both Superfund staff and community groups to facilitate working together, describes different routes of engagement (such as interviews, small group meetings, workshops, public meetings, open sessions, public notices, co-operative working groups and/or community liaison groups) and identifies where, within the framework of the human health risk assessment methodology, community input can augment and improve EPA's estimates of exposure and risk. Other US EPA guidance is also available on risk communication: a 2007 publication entitled risk communication provides some good practical advice on communication that overlaps with the guidance developed by SNIFFER\textsuperscript{91}.

The draft Australian NEPM includes a schedule specific to community engagement and risk communication\textsuperscript{92} that is based on 3 principles:

- No assessment of site contamination should commence until an evaluation has been made regarding the probable need, nature and extent of community consultation for the project;
- Interaction with the community is not simply a technical process but requires skills in listening and communicating and should be a two-way process;
- Community consultation is essential for sites with contentious issues, particularly where the contamination at the site has the potential (or the perceived potential) to have an impact on any stakeholder.

Community engagement is required where the assessment or remediation of the site may affect the amenity of the locality, for example, by way of temporary noise, odour emissions or dust, where a high level of contamination has the potential to affect the adjacent community, or the contaminant types are controversial, where the site is near residential areas or particularly sensitive receptors and/or vulnerable sub-populations such as childcare centres, schools or nursing homes, where the site or locality has a controversial history or its development is controversial for political, economic or social reasons.

The guidance provides information on a large number of different ways in which community engagement may be conducted and a long list of “dos and don’ts” in relation to risk communication.

Overall there is plenty of well written, practical advice on community engagement and risk communication. The key component in risk communication that would appear to be missing from available guidance relates to the expression of the magnitude of risk.

2.11 CONCLUSIONS

This review identified a wealth of information and guidance on health risk assessment for contaminated land available from sources in the UK and elsewhere. The overall approach taken to health risk assessment is similar internationally and no models or tools were identified that were superior to CLEA for application in Scotland. The supporting guidance developed by the EA is clearly written and well referenced. The LQM roadmap tool may be helpful in relation to Part IIA, but could be misleading, particularly if used by individuals with a limited or no toxicological background. SNIFFER has developed useful guidance on risk communication in relation to contaminated land that is also helpful. There are extensive sources of toxicological data, particularly the US EPA and ATSDR, that are probably under-utilised in Scotland. There is also useful information relating to exposure assessment published by US EPA that may be helpful in Scotland. The major drawback with CLEA and other currently available models and tools is that they provide a point estimate of an appropriate SSAC and conceal the range of uncertainty that actually exists. There is currently no readily available tool that would enable a probabilistic approach to be taken to estimating an SSAC that would provide


information about upper and lower confidence limits. There is a need to ensure that uncertainties are adequately explored and reported in relation to human health risk assessment and the development of an SSAC.
3 Outcome of consultation with local authorities and other UK contaminated land specialists

3.1 INTRODUCTION

The aims of the consultation were to establish what methods and guidance are currently used for human health risk assessment for contaminated land in Scotland, the good aspects and deficiencies of these methods and guidance, what was desired by way of new guidance and also to potentially identify examples of good practice that could inform improved guidance.

Several different approaches were taken to engagement with Scottish local authorities (LAs) and others with a professional interest in contaminated land issues in Scotland. An e-mail questionnaire was sent to the individual identified as the “contaminated land officer” at all 32 Scottish LAs. In most cases the individual was identified through communication with the LA. In addition we also circulated the questionnaire via the Scottish Contaminated Land Forum (SCLF) in the belief that most people with a professional interest in contaminated land in Scotland are likely to be members of SCLF. Meetings were held with the East and West Pollution Liaison Group Contaminated Land subgroups.

The questions asked were:

1. What guidance/methods do you currently employ in determining the human health risks associated with contaminated land?

2. What guides your choice of guidance/methods?

2. Which guidance/methods would they recommend to others for use in determining the human health risks associated with contaminated land?

   What features of this guidance/method are particularly helpful and why?
   What improvements could be made to this guidance/method?

3. What are the shortcomings of existing guidance/methods?

   Which aspects of existing guidance/methods are
   Poorly explained?
   Impractical? (and why)
   Difficult to implement? (and why?)

   What aspects of the process of health risk assessment are missing from existing guidance?

4. In an ideal world, what would you desire of a new guide to the assessment of human health risks associated with contaminated land?

5. Have you determined any sites in your area as contaminated or not contaminated in relation to human health?

6. Is it possible to have copies of the documentation that describes how the available evidence was used to determine whether or not SPOSHE existed in relation to human health and how existing guidance was used in the decision process?

3.2 GUIDANCE/METHODS/MODELS USED CURRENTLY

Most LAs indicated that their approach to health risk assessment is based the Scottish Statutory Guidance on Part IIA, guidance issued by the EA and CLEA. Several LAs indicated that their first stage of assessment is based on the use of GACs published by the EA (SGVs), LQM/REHIS, EIC/AGS/CL:AIRE and ATKINS (ATRisk) and two LAs referred to the Dutch values. Most of the LAs indicated that they use the CLEA software to derive SSACs. Generally LAs undertake an initial generic risk assessment based on GACs followed by a detailed risk assessment using tools such as
CLEA when required. Several LAs referred to RISC and RBCA and one LA referred to the SNIFTER worksheets. Most LAs clearly interpret the statutory requirement to base their assessment on authoritative information sources as limiting them to UK sources, and the EA guidance, in particular. Relatively few LAs indicated that they made reference to other authoritative sources such as the WHO, US EPA, ATSDR or RIVM. Other reasons for using CLEA include relevance in the UK context, ease of use, availability (free to download) and compliance with EA guidance. A number of the LAs use the CLAIRE/CIEH guidance on the statistical analysis of soil data and comparison with assessment criteria. Several LAs cited cost as a barrier to the use of tools such as RBCA, RISC or the LQM roadmaps.

3.3 BENEFITS OF EXISTING GUIDANCE/METHODS/MODELS

The use of CLEA is believed to be consistent with the requirements of the Statutory Guidance. It is also available (free), easy to use, relevant in the UK context and allows ready calculation of SSACs based on HCVs. The values generated by CLEA are conservative and there is a high level of confidence in the protectiveness of SSACs generated by CLEA.

3.4 DISADVANTAGES OF EXISTING GUIDANCE/METHODS/MODELS

There is a lack of clarity in existing guidance as to what constitutes SPOSH and the existing tools do not assist LAs in determining whether SPOSH exists. Virtually all the LAs indicated that a clearer, more readily applicable definition of what constitutes SPOSH is required combined with appropriate tools that would enable them to determine whether SPOSH exists at a site. It was identified as a major failing of CLEA and similar tools that they are designed to calculate highly protective assessment criteria which may be appropriate to the planning regime but are not designed for the derivation of assessment criteria based on unacceptable intakes/exposures. In addition, a number of LAs have indicated that “unacceptable” should be defined at SG level and not devolved to individual LAs. There was a concern the determination of SPOSH is not necessarily consistent between different local authority areas. One LA expressed concern about remediation goals being set at unnecessarily low levels and the adverse impact on sustainable development associated with undertaking unnecessary remediation work.

Some LAs indicated concern about the relevance of the guidance and data from non-UK sources to contaminated land risk assessment in the UK. Concern was also expressed at the level of technical expertise required to make best use of resources or interpret guidance and data from different sources. A typical contaminated land officer is unlikely to have the level of toxicological expertise and knowledge assumed by some guidance.

3.5 LOCAL AUTHORITIES’ REQUIREMENTS OF ANY NEW GUIDANCE

The over-riding requirement of LAs is for clear, workable guidance on the meaning of SPOSH that can be practically applied at individual sites. By implication, the definition of SPOSH and the methods used for risk assessment will need to be co-ordinated in order to ensure that the outcome of the risk assessment can be interpreted in relation to SPOSH. A number of LAs indicated that it would be desirable to have defined numbers representing unacceptable intake or unacceptable soil concentrations for individual pollutants that could be used as the basis of determining sites. The guidance must be designed to support a transparent, defensible decision process.

Other issues identified by LAs for which better guidance is required include bioaccessibility, the toxicity of chemical mixtures, the assessment of chemicals such as lead for which the health information is based on blood levels rather than intakes, the use of tools such as the LQM road map approach and the potential use of structural activity analysis in risk assessment.

3.6 OTHER COMMENTS

There are differences between LAs and individual contaminated land officers in how they approach contaminated land in relation to planning and Part IIA. In most LAs, planning and Part IIA would be dealt with by a single individual or team but these functions may be separated in larger LAs. Several LA officers expressed concern about the time and resource available to assess contaminated land risk assessment under the planning process and the associated risk of development projects.
becoming Part IIA sites. In particular, officers commented that they were presented with human health risk assessments for contaminated land under the planning regime that were essentially “black boxes”. Consultants provide a report that describes the results of an assessment using a tool such as RBCA without outlining the underlying assumptions or providing other information that would enable the LA to make an informed decision as to whether the model conclusions are appropriate to the site. There is no mechanism by which LA officers can validate the reported findings and a fundamental lack of trust in the ability of the planning regime to deliver land remediation. There was some concern that consultants were “risk assessing” away potential human health issues when providing supporting documentation for planning applications and selecting models that gave the desired results rather than properly assessing the risk to human health. There was a sense that some developers are not taking adequate precautions in relation to human health when building on brownfield sites.

LAs lack confidence in declaring sites as contaminated where their judgement is open to legal challenge and most sites that have been declared under Part IIA have either been owned by the LA and/or the LA has had a grant to undertake the remedial works. Under these circumstances, LAs are unlikely to be under such intense scrutiny as if the determination had led to another organisation or individual paying for remediation.

It is unclear whether remediation requirements under the planning regime are consistent between LAs. There is an impression that many developers are trying to minimise the remediation undertaken during the development process and taking an approach to contaminated land that is similar to that required under Part IIA. Equally other developers and/or other LAs may be achieving remediation to much higher standards than is really required to ensure adequate protection of health. One LA expressed concern, that if inadequate remediate standards are agreed for a site, then the costs of subsequent re-assessment and further remediation are substantial. This fear may drive some LAs towards demanding unnecessarily stringent remediation goals. In contrast other LAs may accept lower standards of remediation as a result of political pressure in relation to job creation and the removal of derelict land.

3.7 CONCLUSIONS

The major issue identified by LAs was the difficulty in determining “unacceptable intake” in relation to Part IIA rather than with the actual process of risk assessment. Most LAs seem satisfied with the CLEA model as a tool for risk assessment. There is considerable variability in the tools available to LA officers and the extent to which they are empowered to develop expertise in human health risk assessment. LAs with fewer contaminated land issues and/or limited resource allocated to contaminated land strongly indicated a desire to have defined soil guidelines for SPOSH whereas LAs that have major contaminated land issues and have developed extensive expertise in contaminated land stressed the importance of site specific assessments. In terms of the scope of this project, the main issues on which clearer guidance is required were identified as bioaccessibility, the toxicity of chemical mixtures, the assessment of chemicals such as lead for which the health information is based on blood levels rather than intakes, the use of tools such as the LQM road map approach and the potential use of structural activity analysis in risk assessment. Additionally, it was apparent from discussion with LA officers that most have no background in toxicology and that better guidance is required to assist those without technical expertise in toxicology in the interpretation of toxicological information and reference values.

3.8 LOCAL AUTHORITY EXPERIENCE IN PART IIA DETERMINATIONS

Several LAs offered case studies where sites had been declared or remediation work required in order to remove a potential risk to human health associated with raised levels of soil contamination. Key issues that are apparent from these studies are:

- The necessity to collect sufficient samples to be able to properly characterise the extent of contamination;
- The potential impact of considering bioaccessibility on apparent risk;
- The effect of local circumstances on exposure; and
- The desirability of setting a local HCV incorporating a higher level of risk than the EA SGVs under some circumstances.
The issue of sample numbers and coverage is key to decision making with many DQRAs arising as the result of findings in one or two samples. LAs provided several examples of sites or areas within sites that were initially identified as exceeding GACs on the basis of a small number of samples, where the apparent exceedance disappeared when a larger number of samples was investigated in order to provide a better statistical basis for decision making. An example was also provided where the collection of further samples from a school playground constructed on the site of an old tannery merely confirmed that the SGVs for multiple substances were exceeded by substantial margins across a large area and remediation was advised without any further risk assessment being undertaken, as it seemed unlikely that the results of a DQRA would lead to a different conclusion.

LAs take a variable approach to adjusting exposure estimates to take account of local circumstances and it is not clear that the approach taken is entirely consistent with the statutory guidance which requires the land to be suitable for its designated use. For example, it is probably not appropriate to discount home grown produce as a source of exposure where people have gardens simply because current residents in the area do not grow their own food. It may be appropriate to factor in the small size of gardens where this is likely to limit the consumption of home grown produce to levels well below those assumed in CLEA. One LA had undertaken a survey of allotment users in order to refine their risk assessment by taking account of the age distribution of those spending time on the allotment, the duration spent on the allotment each week and the quantity of produce consumed. In another assessment, this LA had taken account of how residents used garden space in its assessment. This LA and another LA had undertaken analysis of plant material grown on affected soils in order to improve the input information to the DQRA. The other LA had also undertaken DQRA for an allotment site and were able to eliminate nickel from further consideration as some of the exceedances of the GAC were at too great a depth to be of concern (>1m) and the other exceedances of the GAC were lower than a SSAC developed using a lower ingestion rate that was believed to be more realistic for allotment users.

Two examples were provided where the LA had developed an alternative HCV as a starting point for deriving a SSAC. In one case, two lead hot spots were identified at an allotment site and an SSAC of 1200 mg/kg was developed on the basis of a lower ingestion rate and different toxicological basis from that used to derive the then current EA GAC of 450 mg/kg. The justification for using a different toxicological assessment based on excess lifetime cancer risk was justified on the basis that the use of blood lead concentration of 10 ug/dL as the basis of the SGV was not appropriate in the context of Part IIA. For one of the hot spots, the allotment was not currently used for growing vegetables and there was no exposure through consumption of vegetables. For the other plot, the exceedance occurred at a depth of 0.6 m and although exposure via plant uptake was unlikely, the possibility could not be eliminated. A further 10 samples were collected at 5 locations distributed over the plot at depths of up to 0.5 m in order to better establish the likelihood of significant plant uptake occurring. The lead content of these samples was well below 450 mg/kg (the SGV) and it was determined that SPOSH was not present.

In another case, a LA set a local HCV for benzo(a)pyrene (BaP) that incorporated a higher level of risk than associated with non-threshold carcinogens for which the EA has set SGVs. The LA officer invested considerable time in investigation of the (now withdrawn) index dose developed by EA on the basis of the World Health Organization (WHO) drinking water guideline for ingested BaP and the air quality standard recommended by Defra’s Expert Panel on Air Quality Standards (EPAQS) and in developing an understanding of the Benchmark dose/Margin of exposure (MoE) method of risk assessment for carcinogens described in SR28. On the basis of his findings he recommended a SSAC based on an HCV that incorporated a smaller MoE than the index dose but was still believed to represent a lifetime cancer risk of less than 10⁻⁶. This was supported by reference to the documentation supporting the WHO drinking water recommendation that indicated that member states could multiply or divide by 10 to generate standards equating to a risk of 10⁻⁶ or 10⁻⁸ as appropriate to their circumstances. In addition the CIEH (2006)50 had indicated that 10⁻⁶ might represent an appropriate benchmark for “unacceptable intake” which equates to the level of risk incorporated in the maximum permissible soil standards in the Dutch regime. It was also noted in relation to the control of lung cancer risks associated with radon in the UK, that the HPA considers that there is a low individual risk associated with exposure levels below 100 Bqm⁻³ despite evidence that exposure to 100 Bqm⁻³ for 30 years is associated with a 5-31% increase in lung cancer risk.
Two LAs who discussed issues of risk communication had encountered several different issues which
highlight the complexities to community and stakeholder engagement in the context of Part IIA. Where
an elderly resident has spent most of their life living at a property that is under investigation by LA,
little credibility is given to the possible health risk associated with garden soil as the individual in
question is a healthy octogenarian. In contrast, where people are living in poor quality council housing
where land contamination has been identified as a reason for demolition and redevelopment, they are
likely to be very co-operative and positive about the prospect of being re-housed. Problems can arise
where gardens are determined and remediated on an individual basis such that some properties
effectively have a free garden make over whereas others not requiring remediation are left
unimproved.

The case studies, although defensible in a local context, were not developed as examples of best
practice for the purposes of illustrating the draft guidance because:

- They were based on contaminants for which interpretation of the toxicology is controversial
  (eg lead, benzo(a)pyrene);
- The assumptions in the exposure assessment may have been appropriate in a local context
  but appear to be at odds with statutory guidance; and/or
- The LA was not required to demonstrate beyond doubt that SPOSH existed for human health
  as funding was available for remediation.

It was also difficult to provide a sufficiently robust but short description of any case study that would
be without risk of the “good practice” being illustrated being misapplied elsewhere (eg SSACs being
treated as GACs). In addition, sites were likely to be identifiable within the relatively small
contaminated land community in Scotland which would potentially expose individual LAs to undue
scrutiny in relation to past decisions.
4 Discussion and conclusions

4.1 AVAILABILITY OF GUIDANCE AND TOOLS TO UNDERTAKE HUMAN HEALTH RISK ASSESSMENT FOR CONTAMINATED LAND

CLEA

The CLEA model provides an easy to use tool for calculating SSACs that can take account of site specific measured data as well as site specific assumptions. The CLEA model is based on an extensive body of research, is endorsed by UK Government Agencies and is widely respected. The number of contaminants for which reference data are available within the CLEA software is restricted, but in practice covers many of the contaminants that are most commonly encountered in significant (relative to background) quantities and that are likely to be most influential in risk assessment. Lead is a notable exception. The withdrawal of some of the HCVs that were originally derived by the EA (lead and benzo(a)pyrene) has led to a vacuum in relation to developing toxicological reference values for these substances. If UK regulators have seen fit to withdraw their recommendations, it is not possible for LAs to have confidence in recommendations made by other authoritative bodies, such as WHO or the US EPA, that have not been subject to recent scrutiny and review. In general terms, an imperfect HCV is likely to be more protective of health than no HCV (and therefore no underpinning of any risk assessment). As an analogy, IOM’s experience of the regulation of workplace exposure to hazardous substances, the absence of a workplace exposure limit (WEL) for a substance is usually interpreted by employers to mean that there is no need to control exposure, even where the substance is highly toxic. The absence of a WEL may be due to inadequate data being available to determine a safe level of exposure or the number of people thought to be exposed in the UK being too small to justify the development of a limit. An absence of an HCV may similarly be interpreted to imply an absence of risk or requirement to undertake further investigation.

The gaps in the existing guidance are in relation to approaches to determining unacceptable intake. The guidance and models are inherently conservative being based on toxicological reference values that are set with substantial margins of safety and over-estimates of exposure. The CLEA model is based on assumptions about receptors and their behaviour that are likely to give estimated exposures that exceed typical exposures for the majority of individuals. Although the revised CLEA model has reduced the size of individual factors leading to estimated exposures, the resultant estimate is still likely to be higher than the 95th percentile (reasonable worst case) exposure that would be measured, if direct measurement of soil-related exposure was possible.

Toxicological reference values

Existing UK guidance (SR28) describes how toxicological reference values are derived but does not provide the tools to enable an individual without toxicological experience to critically review the assumptions underlying existing reference values or to develop reference values in the absence of an existing HCV. SR2 is focussed on deriving a reference (safe) intake rather than identifying the intake that is unacceptable. There is no authoritative guidance that would empower LAs to develop criteria for unacceptable intakes that incorporate a higher cancer risk or smaller margin of safety than a reference intake. Such approaches require an understanding of the basis of the estimated cancer risk estimate or uncertainty factor used in derivation of individual HCVs and the appropriate level of toxicological expertise is unlikely to be available in most LAs. Guidance is required from the SG as to the extent to which LAs may wish to adjust these factors in the assessment of an individual site, while taking adequate account of uncertainties in the underlying toxicological database, particularly in relation to interindividual and interspecies variability in susceptibility to individual substances. Further guidance is required on the level of risk or margin of safety that might be acceptable under different circumstances (see below).

Other issues with SR2 are that it treats dose expressed as mg/kg as being equivalent between species and translates inhaled doses to a systemic dose as mg/kg. These approaches can have a substantial impact on the apparent toxicity of substances and are out of line with current regulatory thinking in Europe. The incorporation (or not) of interspecies dose scaling to take account of size related differences in metabolism makes a significant difference to the dose used as a starting point in deriving a toxicological reference value. International agencies have taken different approaches to interspecies scaling at different times and this has contributed to the variability of reference values set...
by different organisations. Table 4.1 illustrates how the use of the scaling factors described in guidance for undertaking chemical safety assessments for the REACH Regulation\(^\text{19}\) would affect the calculation of a human equivalent dose to use as a starting point for risk assessment. The conversion of inhaled doses to intake as mg/kg/day means that the estimated dose for small children is relatively greater than for adults (Table 4.2). This is appropriate for substances with systemic effects but not for substances that act directly on the respiratory system for which concentration is probably the most relevant exposure metric and the guidance developed for the purposes of implementation of REACH indicates that no interspecies scaling is required\(^\text{19}\). It may also be unnecessarily precautionary to compare the modelled dose received by a toddler against a reference dose derived on lifetime exposure.

**Table 4.1:** Species and human equivalent doses for systemic exposure based on the allometric scaling factors outlined in the guidance to support implementation of the REACH Regulation\(^\text{19}\).

<table>
<thead>
<tr>
<th>Species</th>
<th>Dose equivalent to 1 mg/kg in humans</th>
<th>Human dose equivalent to 1 mg/kg in other species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Rat</td>
<td>4</td>
<td>0.24</td>
</tr>
<tr>
<td>Mouse</td>
<td>7</td>
<td>0.14</td>
</tr>
<tr>
<td>Hamster</td>
<td>5</td>
<td>0.20</td>
</tr>
<tr>
<td>Guinea pig</td>
<td>3</td>
<td>0.33</td>
</tr>
<tr>
<td>Rabbit</td>
<td>2.4</td>
<td>0.42</td>
</tr>
<tr>
<td>Monkey</td>
<td>2</td>
<td>0.50</td>
</tr>
<tr>
<td>Dog</td>
<td>1.4</td>
<td>0.71</td>
</tr>
</tbody>
</table>

**Table 4.2:** Comparison of inhalation intake of a contaminant present at a concentration of 1 ugm\(^{-3}\) in air over a 24 hour period for different ages and genders (based on parameters tabulated in SR2\(^\text{8}\)).

<table>
<thead>
<tr>
<th>Age class</th>
<th>Body weight kg</th>
<th>Inhalation volume m(^3)/day</th>
<th>Intake ug/kg/day associated with continuous exposure to 1 ugm(^{-3})</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>1</td>
<td>5.6</td>
<td>6.9</td>
<td>8.5</td>
</tr>
<tr>
<td>2</td>
<td>9.8</td>
<td>10.5</td>
<td>13.3</td>
</tr>
<tr>
<td>8</td>
<td>25.3</td>
<td>25.4</td>
<td>12.4</td>
</tr>
<tr>
<td>12</td>
<td>41.3</td>
<td>40.2</td>
<td>13.4</td>
</tr>
<tr>
<td>18</td>
<td>70.9</td>
<td>82.7</td>
<td>12</td>
</tr>
</tbody>
</table>

**Exposure assessment**

There are some minor gaps in the existing UK guidance relating to exposure assessment. The CLEA model description, SR3\(^\text{6}\), indicates that assumptions about receptors and receptor behaviour at an individual site should be reviewed but does not encourage users to consider the plausibility of default assumptions. Little advice is provided on how site specific information could be collected and there is no encouragement to look for new information that might lead to some adjustment to exposure parameters (e.g., reference to sources of exposure information such studies indexed in the free to access US National Institutes of Health database, PubMed, or the exposure research programme of the US EPA). SR3 does discuss uncertainties and does identify the major sources of uncertainty for generic scenarios but provides little advice on the investigation of site specific uncertainties.

**4.2 USING EXISTING TOOLS IN THE ASSESSMENT OF SPOSH: APPLES AND Pears**

There appears to be an overwhelming consensus among LAs that the SG should define SPOSH, specifically unacceptable intake, at national level in terms that can be unambiguously applied at local level. There is less consensus as to whether the definition should be numerically based. It is difficult to see how ambiguity can be eliminated without the use of quantification but the output of human health risk assessments for contaminated land does not typically provide explicit numerical risk
estimates. Typically site specific assessment criteria (SSAC) are derived for the concentrations of individual contaminants in soil. SSACs for non-threshold carcinogens may incorporate some quantified element of risk whereas those for threshold substances incorporate variable margins of safety without any explicit investigation of risk. In other contexts, risk assessments may describe health impact in terms of a quantified predicted change in the lifetime risk of death, serious disease or less serious endpoint, of years of life lost or disability adjusted life years (DALYs) which take account of years of life lived with disease as well as premature mortality. Although regulatory regimes in the Netherlands, North America and elsewhere have developed numerical definitions of risk acceptability in terms of lifetime mortality risk, this approach does not take account of the extent to which death from a certain cause will shorten life expectancy. For threshold substances, national and international authorities have generally identified a threshold for effects and then factored in various uncertainty factors to derive a criteria value that is several orders of magnitudes smaller than the lowest dose known to give rise to adverse effects in animals. Although various standard schemes have been developed for uncertainty factors, such as that described in the guidance for undertaking chemical safety assessments for the purposes of REACH \textsuperscript{18}, all of these schemes incorporate a degree of expert judgement. UK regulators have not adopted quantitative risk assessment as a tool in decision-making for non-threshold substances. There has been some use of the assessment of life years gained in UK policy development, for example, in the development and updating of the National Air Quality Strategy \textsuperscript{93}. 

4.3 ASSESSMENT OF IMPACTS IN TERMS OF DEATHS AVOIDED OR LIFE YEARS GAINED

The calculation of health impacts in terms of deaths avoided or Disability Adjusted Life Years gained is increasingly used to inform regulatory decision making. DALYs are a superior measure to deaths avoided but their calculation requires information about potential shortening of life and years lived with disease associated with different causes of death as well as information about background mortality rates by age class. Neither the calculation of deaths avoided nor life years/DALYs gained have ready application in the management of contaminated land. If risk estimates were used to estimate DALYs associated with an individual site, the estimated impact is likely to be small relative to the cost of remediation, although the risk associated with the exposure might be viewed as significant by society (eg greater than the risk of death in a road traffic accident). Potentially, if national remediation targets were to be set for individual pollutants, the calculation of DALYs gained might be informative but the estimate would be subject to large uncertainties and skewed by the location and areas of affected land which would potentially affect the numbers of people that might benefit.

Although the formal calculation of benefits is complex, it is possible to make an approximate estimate that may be informative during the early stages of evaluating a regulatory policy. For example, if land remediation is undertaken to allow the construction of 50,000 homes that eventually have an average occupancy of 100,000 people, remedial work to reduce the lifetime risk of cancer from 1 in 1000 to 1 in 10,000 would result in the avoidance of about 1 death per year, whereas a further reduction in risk would result in the avoidance of about 1 death in every decade. It is also possible to make an order of magnitude estimate of benefits in terms of life years gained based on the output of impact analysis undertaken for other policies. The impact analysis for UK National Air Quality Strategy estimated that 1% change in mortality rate equated to 5,974,449 years over a 100 year period for England and Wales for a starting population of 51,646,891\textsuperscript{93}, or roughly 42 days per person per year. Although age specific mortality rates in Scotland are slightly different, the UK data provide an indication of impact that can be used to assess the potential benefits of interventions that would reduce the all cause mortality risk by a given percentage. A more refined analysis of the reduction in health risk and associated benefits could be made at a later stage in the decision making process, if appropriate. While these approaches are not informative at individual site or LA level, they may be helpful to SG policy makers charged with developing national policy on soil contamination including a definition of SPOSH.

4.4 POTENTIAL USE OF A “MARGIN OF EXPOSURE” APPROACH TO DEVELOP NATIONALLY APPLICABLE DEFINITIONS OF UNACCEPTABLE INTAKE

Currently the approach that Defra and the EA have taken to establishing HCVs has been different for threshold and non-threshold substances but as discussed in section 2.5 above, it would be possible to develop a common approach in which toxicological data is used to derive a benchmark dose. This would enable a national approach to the level of risk considered to be unacceptable for different types of health endpoint. It would be possible to use this approach to quantify risks associated with exposure at an individual site or to set SSACs based on toxicological reference values derived for pre-agreed levels of risk. The reference value approach offers a philosophical advantage as it can be based on the concept of “Margin of Exposure” as described below and avoids some of the uncertainty involved in making risk estimates. In addition toxicological reference values equating to “unacceptable risk” could be established at national level and SSACs could be established prior to sample collection or completion of sample collection. In contrast, risk estimation can only be conducted following sample analysis and risk estimates may need to be updated in light of further sample analysis.

One of the major drawbacks with the traditional way of identifying a threshold level of effects in studies of humans or animals is that the apparent threshold may be strongly dependent on the study design (section 2.5). In principle, it would be better to use experimental data to predict the dose associated with a 10% response (ED$_{10}$), usually referred to as the Benchmark Dose (BMD$_{10}$). This approach takes account of all of the data rather than just the lowest dose and ED$_{10}$ is less sensitive to population size and dosing regime than NOAELs and LOAELs. It has been widely adopted for risk assessment for carcinogens and is now also recommended for use for threshold substances by the UK Interdepartmental Group on Chemical Risk Assessment and the US EPA. It is also the approach that I would recommend on the basis of 20 years of experience of undertaking toxicological assessments because of the difficulty of comparing studies with different dosing regimes, proportions of animals affected at the LOAEL, durations and endpoints assessed. The calculation of BMD enables a more confident assessment of the relative risks of different health endpoints arising. Although there are uncertainties in the calculation of the BMD arising from the choice of statistical models available, US EPA guidance describes how to select the most appropriate model for a given dataset.

For the purposes of risk assessment, exposure is usually assessed against the lower bound (95th percentile) estimate of BMD$_{10}$, referred to as BMDL. Modelled exposures can be compared against the BMDL and the ratio of the BMDL to the modelled exposure is referred to as the Margin of Exposure (MoE). The larger the MoE, the smaller the potential risk. The DH Committee on Carcinogenicity (CoC) produced the ranking of risk shown in Table 4.3 in relation to the MoE for carcinogens where the BMDL$_{10}$ is based on animal data. There is no guidance for where the BMDL$_{10}$ is based on human data and therefore associated with less uncertainty but it is arguable that a lower MoE might be tolerated than where the BMDL is based on animal data. In addition, it seems likely that a smaller MoE would be appropriate in relation to determining unacceptable (<10,000) than in relation to setting target risk levels to be met under the planning regime. The CoC guidance relates to cancers. If a similar approach was used for a less serious (less unacceptable) endpoint, then a smaller MoE would seem appropriate.

Table 4.3: Terminology used by the CoC to describe differing levels of risk as assessed using a BMD and MoE approach

<table>
<thead>
<tr>
<th>MoE</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10,000</td>
<td>May be a concern</td>
</tr>
<tr>
<td>10,000-1,000,000</td>
<td>Unlikely to be a concern</td>
</tr>
<tr>
<td>&gt;1,000,000</td>
<td>Highly unlikely to be a concern</td>
</tr>
</tbody>
</table>

It is possible to use the BMDL to estimate risks at low levels of exposure using linear extrapolation and this was the approach that was traditionally taken by the US EPA. This method assumes that there is a linear relationship between the origin (dose and effects =0) and the BMDL$_{10}$. An MoE of 10,000 corresponds approximately to a $10^{-5}$ risk. The advantage of reporting an MoE over a risk estimate is that the MoE does not incorporate any assumptions about the shape of the dose-response curve at low doses, even although the MoE may be used in a way that implies a linear dose response relationship. Software for calculating BMD or BMDL is available free from the US EPA website as described in section 2.5. In principle, the SG could group health outcomes by severity and then define
the MoE required for each group of health outcomes with some additional guidance as to how MoE might be adjusted to take account of uncertainties in the data (for example, human versus animal data or failure to meet some pre-defined quality criteria).

4.5 ASSESSMENT OF THE POTENTIAL UTILITY OF USING A MOE APPROACH TO DEVELOP COMPARABLE RISK INFORMATION FOR DIFFERENT TYPES OF CONTAMINANT AND EFFECT

The development of health based standards derived from BMDL10 with different margins of exposure for effects of differing severity offers a mechanism by which SPOSH can be defined at a national level and I have been unable to think of a scientifically defensible alternative. The development of an MoE approach to assessing SPOSH, however, is highly unlikely to represent a practical method by which LA contaminated land officers or most contaminated land consultants could derive criteria values for individual pollutants because of the level of familiarity with toxicological data and concepts that is required. It may be an approach that the SG wish to consider at national level in order to derive a set of health-based values representing unacceptable intake for commonly encountered contaminants. For many of these contaminants, the key toxicological data will already have been reviewed by regulatory authorities in the UK or elsewhere, and/or by WHO. These organisations will have addressed issues such as study quality and it should be relatively simple to select suitable data sets from which BMDL values can be derived. It is also relatively easy to set criteria for the inclusion of other studies in development of an appropriate BMDL (eg those published since the most recent authoritative review). A policy decision would be required on how to select the critical effect/BMDL combination where several choices are available and guidance would also be needed on the selection of the most appropriate BMDL where several studies have investigated the same effect but reported different results. For some contaminants it would be appropriate to set separate criteria values where adults and children have very differing susceptibilities and there are foreseeable circumstances where children are highly unlikely to be exposed on a regular basis (for example, land designated for industrial use). In principle, the development of HCVs specific to Part IIA at a national level in Scotland could present a highly cost-efficient approach (in terms of overall public spend) to defining SPOSH and increase the consistency of site determination in Scotland. In practice, the experience of the EA and Defra south of the border suggests that it can be difficult to gain consensus on appropriate HCVs, partly due to differing approaches to risk management adopted by different bodies. For example, the HPA being charged with health protection take a highly precautionary approach in the development of assessment levels for soil contaminants as demonstrated by their assessment of benzo(a)pyrene94. This is not consistent with the approach employed under other regulatory regimes as discussed in section 4.6 below, where account has been taken of current levels of exposure and the options for exposure reduction. The HPA’s approach is, however, compatible with the outcomes of recent civil litigation in relation to asbestos where liability can be attributed where asbestos exposure has occurred, regardless of the size of that exposure and likely impact on health. Overall, although we would recommend that the SG are proactive in developing HCVs specific to Part IIA, we recognise that such a move would be out of step with developments elsewhere in the UK. There is a significant risk that the HPS and the SG take different views on risk acceptability and unacceptable risk that could either prevent HCVs being agreed or lead to HCVs being set at levels of risk well below what the courts would consider to be unacceptable. The problem of human health risk assessment for environmental pollutants becoming bogged down as a result of failure to reach consensus is not unique to the UK as US EPA risk assessments take many years or even decades to complete9.

4.6 TOLERABLE RISK

Overview

Tolerable risk is not rigidly defined within the UK regulatory regime as it reflects a balance of social and economic pressures. The level of risk viewed as tolerable in different areas of regulation, within individual areas of regulation and standard setting and in relation to other sources of voluntary and involuntary risk is highly variable. The section reviews the process of setting environmental quality standards, previous advice on acceptable risk in relation to contaminated land and the levels of risk

associated with air quality, drinking water, radon and occupational exposure limits and incorporated into the guidance for undertaking Chemical safety Assessments for the purposes of REACH.

Royal Commission on Environmental Pollution

The RCEP reported on the process of setting environmental quality standards in 1998 and their report is useful in the context of considering tolerable risk. The RCEP stressed the importance of involving the public in decision making that affects them and recommended that decisions on tolerable risk should be societal decisions and not made in isolation by a panel of experts. It stated that “Bodies setting environmental standards must operate in an open and transparent way with adequate opportunities for those outside an institution, especially those with a particular interest in a given decision, to contribute fully to the decision-making procedure.”

The RCEP emphasised the importance of determining dose-effect relationships for the effects of substances and identified two issues in relation to scientific assessment:

- Is the science well done, and uncertainties and limitations in the data properly recognised?
- Does the science provide a firm basis for policy decisions?

The RCEP stressed the importance of transparency and balance in presenting the underlying scientific basis of an assessment including uncertainties in the scientific evidence, the rationale for any methods used to cope with variability and uncertainties (for example, any safety or uncertainty factors used) and the assumptions implicit in their use. It was noted that a single answer (especially a single number) may give a spurious impression of accuracy. Risk assessments should indicate whether risks are especially high for people in certain localities, age groups or occupations, or people with certain medical conditions or genetic predisposition, and characterise as far as possible the respective perceptions of the risks held by relevant groups, the meanings the risks will have for them, and their views about the tolerability of the risks. Where possible quantitative risk information should be provided. Where data are available and the processes sufficiently understood, direct comparison between options may be useful in informing decisions. The RCEP believed that new approaches would be developed towards managing environmental exposures including greater use of economic instruments and various forms of self-regulation and that these were likely to become increasingly important in environmental decision making.

Guidance for contaminated land

The criteria by which land is deemed to be contaminated and the associated risk levels (where numerical definitions have been provided) are described above in section 2.8. The HCVs derived by Defra and the EA are regarded as representing levels of exposure associated with zero risk for threshold substances and minimal risk for carcinogens. The use of uncertainty factors (UFs) in setting an HCV is intended to reduce risks for the wider population to (close to) zero. Given a typical group size of ≤50 animals in a toxicological study or ≤100 individuals in a workplace study, the actual risk associated with the NOAEL could be in the region of 1-5%. The UFs applied are typically of the order of 100-1000, implying a potential risk of between 0.001 to 0.05% for a health endpoint that could have a serious impact on an individual’s activities and/or life expectancy. In considering carcinogens, SR2 and the guidance produced by DEFRA (2008) indicates that:

“The Government considers that an excess lifetime cancer risk of 1 in 100,000 based on suitable human cancer data would then be an appropriate approach for setting HCVs (Health Criteria Values) for soil contaminants based on “minimal risk”. These levels are broadly consistent with similar risk levels applied in the UK and internationally for the protection of health from chemicals in other environmental media.”

The guidance notes, however, that it may not be able to provide risk estimates to this level of detail. It is probable that the HCVs for some non-threshold substances are more protective (in terms of fatal risk) than those set for threshold substances.

The Dutch Intervention levels for soils are based on the human toxicological Maximum Permissible Risk (MPR) level and or the ecotoxicological risk limit, depending on which gives the lower concentration in soils. The overall approach for threshold substances is similar to that used to derive HCVs in the UK or Reference Doses/Concentrations or Minimal Risk Levels in the US, although the UFs may be smaller. The Dutch intervention levels for carcinogens are set to be equivalent to an increase in lifetime cancer risk of $10^{-4}$. The intervention values are intended to be based on realistic rather than worst case estimates of exposure and may be less conservative than SGVs or GACs derived using CLEA. The Dutch target values are intended to represent a sustainable soil quality at which the functional properties of the soil for humans and plant and animal life would be fully recovered. Most soils in relatively unpolluted areas in the Netherlands (the 95th percentile concentration) should meet the target values.

**Air Quality**

The UK air quality objectives are intended to reduce the impacts of air pollution on human health but the short term objectives are less protective than the air quality standards on which they are based and permit pollution levels to exceed the standards on a small number of occasions each year. The annual mean air quality objectives are intended to benefit health through lowering exposures rather than representing a “safe” level of exposure. Different objectives have been set in different parts of the UK reflecting differences in air pollution climate and the levels that are achievable. Scotland has cleaner air than London and has set objectives at much lower levels in order to achieve an equivalent improvement in air quality. Air quality guidelines and standards are applied to individual substances and do not take account of the potential effects associated with exposure to a mixture.

The development of air quality standards by Defra’s Expert Panel of Air Quality Standards (EPAQS) involved consideration of the available information for each substance by a group of experts and a series of discussions leading eventually to a consensus. Each member of the panel led on writing different sections of the reports which were then peer reviewed by the group. The 24 hour standard for PM$_{10}$, set by EPAQS, was estimated to be associated with an increased risk of emergency hospital admission on a high pollution day of about 1 in a million. The short term standards for sulphur dioxide (15 minutes), nitrogen dioxide (1 hour) and ozone (8 hours) were set with reference to findings in human volunteer experiments and were believed to be levels at which the risk of respiratory symptoms in most individuals including those with asthma would be very small. The standards of 100,150 and 50 ppb for sulphur dioxide, nitrogen dioxide and ozone respectively were based on lowest effects levels of <250, 200 and 80 ppb in experiments. The UFs are small, but the sulphur dioxide and nitrogen dioxide standards were based on the basis of experiments in people with asthma who were anticipated to be particularly sensitive to effects. The standards for polycyclic aromatic hydrocarbons, arsenic, nickel and chromium were based on the threshold concentration for the reported development of cancer following workplace exposure with UFs of x10 for conversion from a LOAEL to a NOAEL, x 10 for the difference between workplace and lifetime exposure and x10 to allow for a greater range of susceptibility in the general population. The standard for beryllium was based on the NOEL for beryllium related disease in the workplace with UFs of x10 and x10 to allow for extrapolation to lifetime exposure and the general population. The

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97 I was a member of EPAQS and was involved in developing standards for halogens, hydrogen halides and some metals and metalloids.


52
short term standards for the halides and hydrogen halides were based on experimental findings of respiratory effects in human volunteers. An UF of 5 was used where the lowest effects level was relatively well established whereas a large UF of 10 was applied where there was greater uncertainty. Increased awareness of the risks of long term adverse effects following acute exposure to respiratory irritants (irritant-induced asthma or reactive airways dysfunction syndrome) may have contributed to the larger UFs than in the earlier determinations for sulphur dioxide, nitrogen dioxide and ozone. The long term standards for iodine and fluorine were based on the threshold of effect in humans. In both cases there is a relatively small gap between the intake that is beneficial and that which is harmful. A UF of 10 was allowed for fluorine where the receptor of most concern is children. A UF of only 5 was allowed for iodine as effects were extremely small at the LOAEL. Overall, the approach taken to the setting of air quality standards was consistent with the approach taken to developing HCVs for soil contamination with the exception of the short term standards for sulphur dioxide, nitrogen dioxide and ozone which are less protective than those set for other substances. Although EPAQS took account of quantitative cancer risk assessment in setting standards, standards were based on LOAELs and the use of safety factors rather than a stated quantified level of risk.

The WHO has not set air quality standards for non-threshold substances including airborne particles for which exposures should be reduced regardless of existing background levels (WHO, 2005). The older Air Quality Guidelines for Europe (2000) provide estimates of the concentrations of various carcinogens in ambient air that would be associated with lifetime cancer risks of $10^{-4}$, $10^{-5}$ or $10^{-6}$ for lifetime exposure but do not indicate which level should be incorporated into regulation. This is also the approach taken for non-threshold carcinogens within the US EPA IRIS database. The air quality standards outlined for threshold substances by WHO (2000) and reference concentrations derived by US EPA in the IRIS database are based on NOEALs or LOAEALs divided by an UF and incorporate variable levels of protectiveness. Generally the protectiveness of standards has increased though time so that guidelines and reference values that were last reviewed in detail in the 1970s or 1980s are likely to be less protective than those set in the last decade. The protectiveness also depends on the perceived severity of effect and on the individual judgements of the committee members involved in deriving the standards. Table 4.4 describes the criteria underlying some of the WHO guidelines set for threshold substances. UFs vary from zero, when no factor has been applied to allow for interindividual variability to 100 for a guideline based on animal data. Although UFs take account of the severity of effect, they are not consistent between substances. The guideline for carbon monoxide, for example, is set at about half the LOAEL in healthy individuals which might exceed the LOAEL in more susceptible individuals. The guideline for formaldehyde is set at the LOAEL for respiratory irritation and the guideline for lead is set at a level where effects on children’s IQ would be small rather than at a NOAEL. The mercury guideline exceeds the level associated with possible adverse effects on immune function. In contrast, the guideline for respiratory irritation associated with vanadium based on workplace findings incorporates an UF of 20. The UFs for the manganese and toluene guidelines based on possible neurotoxicity were 50 and 30 respectively based on workplace findings. The UF for the hydrogen sulphide guideline set to prevent eye irritation is 100, to allow for an apparently steep exposure response function. Since the WHO (2000) air quality guidelines were published, there has been much greater recognition of the potential for repeated respiratory irritation to give rise to irreversible long term respiratory disease.

105 EPAQS (2009). Addendum to guidelines for halogens and hydrogen halides in ambient air. Defra and the Devolved Administrations
Table 4.4: Examples of uncertainty factors (UFs) used in the derivation of air quality guidelines by the WHO (2000)\(^{107}\).

<table>
<thead>
<tr>
<th>Substance</th>
<th>Air quality guideline</th>
<th>Reasoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon disulphide</td>
<td>100 μgm(^{-3})</td>
<td>The LOAEL for carbon disulphide in workplace studies was about 10 μgm(^{-3}), believed to be equivalent to a concentration in the general environment of 1 mgm(^{-3}). An UF of 10 was selected to allow for the expected variability in the susceptibility of the general population giving a guideline value of 100 μgm(^{-3}). If carbon disulphide is used as the index substance for viscose emissions, odour perception is not to be expected when carbon disulphide peak concentration is kept below one tenth of its odour threshold value, i.e. below 20 μgm(^{-3}). Based on the sensory effects of carbon disulphide, a guideline value of 20 μgm(^{-3}) (averaging time 30 minutes) is recommended.</td>
</tr>
<tr>
<td>Hydrogen sulphide</td>
<td>0.15 mgm(^{-3})</td>
<td>The LOAEL is 15 mgm(^{-3}) for eye irritation with serious eye irritation at 70 mgm(^{-3}). An UF of 100 was recommended because of the steep dose-response curve. A single report of changes in haem synthesis at a hydrogen sulphide concentration of 1.5 mgm(^{-3}) was noted. In order to avoid substantial complaints about odour annoyance, hydrogen sulphide concentrations should not be allowed to exceed 7 μgm(^{-3}), with a 30-minute averaging period.</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>0.1 mgm(^{-3})</td>
<td>The lowest concentration that has been associated with nose and throat irritation in humans after short-term exposure is 0.1 mgm(^{-3}), although some individuals can sense the presence of formaldehyde at lower concentrations. UF = 0.</td>
</tr>
<tr>
<td>Tetrachloroethylene</td>
<td>0.25 mgm(^{-3})</td>
<td>Given the limitations of the weight of the epidemiological evidence, and the uncertainty of the relevance to humans of the induction of tumours in animals exposed to tetrachloroethylene, the derivation of a guideline value is at present based on non-neoplastic effects. On the basis of a long-term LOAEL for kidney effects of 102 mgm(^{-3}) in dry-cleaning workers, a guideline value of 0.25 mgm(^{-3}) is calculated. In deriving this guideline value, the LOAEL is converted to continuous exposure (dividing by a factor of 4.2, 168/40) and divided by an UF of 100 (10 for use of an LOAEL and 10 for intraspecies variation). An alternative calculation was made based on the LOAEL in mice of 680 mgm(^{-3}), and using an UF of 1000 to yield a guideline value of 0.68 mgm(^{-3}).</td>
</tr>
<tr>
<td>Toluene</td>
<td>0.26 mgm(^{-3})</td>
<td>The LOAEL for effects on the central nervous system from occupational studies is approximately 332 mgm(^{-3}) (88 ppm). A guideline value of 0.26 mgm(^{-3}) was established by dividing by 4.2 to adjust for continuous exposure and an UF of 300 (10 for inter-individual variation, 10 for use of a LOAEL rather than a NOAEL, and an additional factor of 3 given the potential effects on the developing central nervous system). Peak concentrations should be kept below the odour detection threshold level of 1 mgm(^{-3}) as a 30-minute average.</td>
</tr>
<tr>
<td>Lead</td>
<td>0.5 μgm(^{-3})</td>
<td>Critical effects include elevation of free erythrocyte protoporphyrinin adults and cognitive deficit, hearing impairment and disturbed vitamin D metabolism in children. A critical level of lead in blood of 100 μg/l was proposed based on population studies yielding group averages. Currently measured &quot;baseline&quot; blood lead are probably in the range 10–30 μg/l, the threshold for adverse effects of lead in populations of young children is 100–150 μg/l. 1 μg lead per m3 air contributes approximately 19 μg/l blood lead in children and about 16 μg/l in adults. To allow for uptake by other routes, it is assumed that 1 μg lead per m3 air would contribute to 50 μg/l blood lead. At least 98% of an exposed population, including preschool children, should have blood lead levels ≤100 μg/l implying the median blood lead level should be ≤54 μg/l. On this basis, the annual average lead level in air should not exceed 0.5 μgm(^{-3}); UF = 0.</td>
</tr>
<tr>
<td>Manganese</td>
<td>0.15 μgm(^{-3})</td>
<td>Based on neurotoxic effects observed in occupationally exposed workers, and using the benchmark approach, an estimated NOAEL (the lower 95% confidence limit of the BMDL5) of 30 μgm(^{-3}) was obtained. A guideline value for manganese of 0.15 μgm(^{-3}) was derived by dividing by a factor of 4.2 to adjust for continuous exposure and an UF of 50 (10 for interindividual variation and 5 for developmental effects in younger children).</td>
</tr>
</tbody>
</table>

54
### Substance | Air quality guideline | Reasoning
--- | --- | ---
**Mercury** | 1 μgm⁻³ annual mean | The LOAELs for the neurotoxic effects for mercury vapour are around 15–30 μgm⁻³. Applying an UF of 20 (10 for variable sensitivities in higher risk populations and, on the basis of dose–response information, 2 to extrapolate from a LOAEL to a likely NOAEL), a guideline for inorganic mercury vapour of 1 μgm⁻³ was established which should also protect against mild renal effects caused by cationic inorganic mercury but may not prevent effects on the immune system.

**Vanadium** | 1 μgm⁻³ 24 hours | The LOAEL for respiratory effects in workers exposed to vanadium is 20 μgm⁻³, since the observed effects on the upper respiratory tract were minimal at this concentration, and a susceptible subpopulation was identified, a protection factor of 20 was selected.

**Carbon monoxide** | 100 mgm⁻³ (90 ppm) for 15 minutes 60 mgm⁻³ (50 ppm) for 30 minutes 30 mgm⁻³ (25 ppm) for 1 hour 10 mgm⁻³ (10 ppm) for 8 hours | Severe hypoxia due to acute carbon monoxide poisoning may cause both reversible, short-lasting neurological deficits and severe, often delayed neurological damage. Impaired coordination, tracking, driving ability, vigilance and cognitive performance occur at blood COHb levels as low as 5.1–8.2%. In apparently healthy subjects, maximal exercise performance has decreased at COHb levels as low as 5%. In controlled human studies involving patients with coronary artery disease, mean post-exposure COHb levels of 2.9–5.9% (corresponding to post-exercise COHb levels of 2.0–5.2%) have been associated with a significant shortening in the time to onset of angina. In healthy subjects, endogenous production of carbon monoxide results in COHb levels of 0.4–0.7%. During pregnancy, elevated maternal COHb levels of 0.7–2.5%, mainly due to increased endogenous production, have been reported. The COHb levels in non-smoking general populations are usually 0.5–1.5%, owing to endogenous production and environmental exposures. To protect non-smoking, middle-aged and elderly population groups with coronary artery disease from acute ischaemic heart attacks, and to protect the foetuses of non-smoking pregnant women from hypoxic effects, a COHb level of 2.5% should not be exceeded. The guideline values were derived to ensure that the COHb level of 2.5% is not exceeded, even when a normal subject engages in light or moderate exercise.

### Drinking water guidelines

The European Drinking Water Directive (Council Directive 98/83/EC) sets out drinking water standards for 48 microbiological and chemical parameters that were largely based on the then current WHO drinking water guidelines. Many of these have subsequently been revised with some values increasing and others decreasing. The WHO (2009) have published guidance on developing drinking water guidelines. Microbial risk assessment requires information on dose response, risk of illness following infection, disease burden (DALYs per case) and the fraction of the population that is susceptible to infection. For threshold chemicals, a tolerable daily dose (TDI) is calculated from the BMDL, NOAEL or LOAEL for the effect considered to be most biologically significant, by dividing by an UF. The drinking-water guideline value (GV) is then calculated from the TDI as:

\[
GV = \frac{(TDI \times bw \times P)}{C}
\]

Where bw is the body-weight; C is the daily consumption of drinking-water and P is the fraction of the TDI allocated to drinking-water.

For threshold chemicals, the TDI covers total intake from all sources. It is, therefore, necessary to allocate a proportion of the TDI to drinking-water to derive a guideline value. There is considerable discretion in the UF$s$ that may be applied:

- Interspecies variation (animals to humans): 1 – 10
- Intraspecies variation (individual variations): 1 – 10

---

Adequacy of studies or database: 1 – 10
Nature and severity of effect: 1 – 10

Lower UFs may be used, for example, for interspecies variation when humans are known to be less sensitive than the animal species studied. Situations in which the nature or severity of effect might warrant an increased UF include foetal malformation or effects related to possible carcinogenicity.

For compounds considered to be non-threshold chemicals, cancer risks are typically estimated using a conservative linear non-threshold model and dose is based on body weight. The guideline value recommended is the concentrations in drinking-water associated with an estimated upper bound (e.g. 95th percentile value) excess lifetime cancer risk of $10^{-5}$ (i.e. one additional cancer per 100,000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years).

The microbiological standards applied in the UK are for “indicator species” – *Escherichia coli*, a marker of human or animal faecal contamination, *clostridium perfringens*, a marker of remote or historic faecal contamination and total colony counts – a general assessment of bacterial content. The standards for the two markers of faecal contamination are set at zero which equates to a very low level of risk, although the absence of indicator species does not preclude the possibility that some pathogens may be present. For total colony counts the standard is “no abnormal change”.

Some examples of the standards set for chemical parameters and the underlying reasoning outlined in the WHO documentation are shown in Table 4.6. The guidelines for carcinogens roughly equate to an estimated lifetime cancer risk of $10^{-5}$ for individual substances but incorporate varying degrees of uncertainty. Guidelines for threshold substances incorporate variable UFs. The guidelines for nitrate and lead are approximately equivalent to LOAEL in children, the guideline for copper is just below the LOAEL in adults for gastrointestinal effects and the guideline for nickel incorporates an UF of 10-40 but does not take account of nickel sensitised individuals. The guideline for chromium is set at an apparently arbitrary level. Drinking water guidelines are applied to individual substances and do not take account of the potential effects associated with exposure to a mixture.

**Table 4.6: Examples of drinking water guidelines developed by the WHO applied in the UK**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
<th>Risk/UF associated with limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>10 ug/L</td>
<td>The maximum likelihood estimates, using a linear extrapolation, for bladder and lung cancer for populations in the USA exposed to arsenic at concentrations of 10 μg/l in drinking-water are 12 and 18 per 10 000 population for females and 23 and 14 per 10 000 population for males.</td>
</tr>
<tr>
<td>Chromium</td>
<td>50 ug/L</td>
<td>There are no adequate toxicity studies to provide a basis for a NOAEL. The guideline was first proposed in 1958 for hexavalent chromium, based on health concerns, but was changed to total chromium because of analytical difficulties.</td>
</tr>
<tr>
<td>Copper</td>
<td>2 mg/L</td>
<td>The IPCS concluded that the upper limit of the acceptable range of oral intake in adults is uncertain but is likely in the range of several, but not many, milligrams per day in adults based on the acute gastrointestinal effects of copper and to provide an adequate margin of safety in populations with normal copper homeostasis; Staining of laundry and sanitary ware occurs at copper concentrations &gt;1 mg/l and copper imparts an undesirable bitter taste to water at &gt;2.5 mg/L; higher levels cause discoloration of water.</td>
</tr>
<tr>
<td>Lead</td>
<td>10 ug/L</td>
<td>The guideline value was based on a JECFA PTWI, which has since been withdrawn on the basis that there does not appear to be a threshold for the key effects of lead and the PTWI was not protective. Based on the dose–response analyses, JECFA estimated that the previously established PTWI of 25 μg/kg body weight is associated with a decrease of at least 3 IQ points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. These changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population.</td>
</tr>
</tbody>
</table>

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Chapter 12: Chemical factsheets
Radon

One of the LA respondents reviewed exposure to radon as an example of risk acceptance for an involuntary exposure. Radon is a natural radioactive gas emitted from uranium that occurs naturally in all rocks and soils. The average lifetime exposure of the population to all sources of ionising radiation (natural plus man-made) may be associated with an additional risk of fatal cancer of about 1% compared with a life-time risk of cancer of about 20-25% from all causes. The HPA has estimated that radon accounts for half of the total annual radiation dosage of most UK residents. Levels of radon exposure are variable across the UK and people with high exposures may have increased risks of developing lung cancer. The HPA has advised that indoor radon above an Action Level of 200 Bqm⁻³ should be reduced and have identified a target level of 100 Bqm⁻³. The HPA has estimated that the risk of lung cancer associated with lifetime exposure to radon at the action level of 200 Bqm⁻³ is about 1 in 30. Most UK homes have fairly low radon levels, with an average of about 20 bm³⁻ but levels in some parts of the country may be more than 10 times higher. HPA advises householders with radon between the Target Level and the Action Level to seriously consider reducing their radon levels in some parts of the country may be more than 10 times higher. HPA advises householders about 1 in 30 the risk of lung cancer associated with lifetime exposure to radon at the action level of 200 Bqm⁻³.

The 200 Bqm⁻³ action level is based on a statement made by the National Radiological Protection Board in 1990 and replaced an action level of 400 Bqm⁻³ set in 1987. The action level was revised in the light of new risk estimates that showed that the lung cancer risk at the 200 Bqm⁻³ action level was equivalent to the risk that had previously been estimated to exist at 400 Bqm⁻³. At the time the 400 Bqm⁻³ action level was set, the associated lifetime lung cancer risk was estimated to be 2.5% and

### Table: Risk/UF associated with limit

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
<th>Risk/UF associated with limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nickel</td>
<td>20 ug/L</td>
<td>The guideline value 12 μg/kg body weight is close to the acute LOAEL for provocation of Ni-induced skin reactions in nickel sensitised individuals based on total exposure from drinking-water and taking account of 10- to 40-fold higher absorption from drinking-water on an empty stomach than from food. A general toxicity value of 130 μg/l based on a NOAL for reproductive toxicity and an UF 100 was also determined from a well conducted two-generation study in rats but this may not be sufficiently protective of nickel sensitised individuals.</td>
</tr>
<tr>
<td>Bromate</td>
<td>10 ug/L</td>
<td>A health-based value of 2 μg/l is associated with the upper-bound excess cancer risk of 10⁻³. A similar conclusion may be reached through several other methods of extrapolation, leading to values in the range 2–6 μg/l.</td>
</tr>
<tr>
<td>Fluoride</td>
<td>1.5 mg/L</td>
<td>Epidemiological evidence indicates that higher concentrations carry an increasing risk of dental fluorosis and that progressively higher concentrations lead to increasing risks of skeletal fluorosis. The value recommended for artificial fluoridation of water supplies is usually0.5–1.0 mg/l. The protective effects of fluoride increase with concentration up to about 2 mg/l; the minimum concentration required for protection is of about 0.5 mg/l.</td>
</tr>
<tr>
<td>Nitrate</td>
<td>50 mg/L</td>
<td>Nitrate (bottle-fed infants): In epidemiological studies, methaemoglobinemia was not reported in infants in areas where nitrate in drinking-water was consistently &lt;50 mg/l; 97% of cases have been associated with concentrations &gt;44.3 mg/l.</td>
</tr>
<tr>
<td>Vinyl Chloride</td>
<td>0.5 ug/L</td>
<td>Derived by linear extrapolation by drawing a straight line between the dose, determined using a pharmacokinetic model, resulting in tumours in 10% of animals in rat bioassays involving oral exposure and the origin (zero dose) to determine the intake associated with the upper-bound risk of 10⁻³ and assuming a doubling of the risk for exposure from birth.</td>
</tr>
</tbody>
</table>

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111 From HPA webpage outlining health issues associated with non-occupational exposure to radon http://www.hpa.org.uk/Topics/Radiation/UnderstandingRadiation/UnderstandingRadiationTopics/Radio n/
112 From HPA webpage outlining action and target levels for radon in dwellings http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733807197#radon_target_level
believed to be equivalent to the combined risk associated with dying prematurely in a road accident or in an accident at home. The 200 Bqm$^{-3}$ action level was also equivalent to the limit recommended by the WHO in 1987. Current (2010) annual death rates from land transport accidents in England and Wales (ie for the majority of the UK population) are 5 per 100,000 for men and 1.6 for women compared with 12.5 and 4.1 per 100,000 in 1991$^{114}$. The equivalent lifetime risk for men based on the 2010 rate would therefore be about 0.4% and for women about 0.05%. In 2010, land transport related deaths accounted for 50 of 198 accidental deaths in men and 16 of 101 accidental deaths in women. This suggests that the overall lifetime risk of accidental death is about 1%, much less than the lifetime cancer risk associated with the radon action level.

It is estimated that 3.3% of lung cancer deaths in the UK in 2006 (about 1 in 516 of all deaths) were attributable to radon and most radon-related deaths are associated with relatively low radon exposures$^{115}$. The cost of installing measures to prevent radon exposure in all new houses in high radon areas was approximately £100/household in 2007 compared with an estimated avoidance of health care costs associated with lung cancer of £248/household, indicating that the measure would be highly cost effective. It would also be cost effective to install basic preventative measures in all new housing both within or outside of high radon areas. The benefits would not be immediate as overall risk levels related to lifetime exposure. The current policy of targeting existing houses with elevated radon levels has less potential to prevent lung cancer and is not cost-effective.

**REACH**

For threshold substances, the REACH guidance for undertaking chemical safety assessment$^{18}$ sets out the UFs that should be applied in deriving a Derived No Effects Level (DNEL) based on a NOAEL, LOAEL or BMD derived from animal studies (Table 4.5). For non-threshold substances such as carcinogens, a Derived Minimum Effect Level (DMEL) is established, although the REACH process is supposed to lead to the eventual withdrawal of carcinogens, mutagens and reproductive toxins (CMRs) from use in the EU. The REACH guidance indicates that DMELs should be based on quantitative risk estimates, where possible (ie sufficient data are available). The DNEL or DMEL is effectively the exposure limit for either general population or workplace exposure. The DNELs derived for workplace exposure are likely to be associated with considerably lower levels of risk than associated with traditional exposure limits (see below). The REACH registration process requires registrants to demonstrate that human exposure to a substance associated with the use(s) for which it is registered will be below the relevant DNEL (for substances produced or imported into the EU at volumes of $\geq 10$ tonnes per year. For general population exposure, it is required that the DMEL is set at a level equivalent to a lifetime risk of $10^{-6}$ whereas for workplace exposure, the DMEL is set to be equivalent to a lifetime risk of $10^{-5}$. It is uncertain how effectively REACH will be enforced as the regime is heavily dependent on self-regulation and supply chain pressure.


$^{115}$Gray A, Read S, McGale P, Darby, S (2009). Lung cancer deaths from indoor radon and the cost effectiveness and potential of policies to reduce them. BMJ; 228a3110
**Table 4.5:** Default assessment factors for the purposes of deriving a DNEL

<table>
<thead>
<tr>
<th>Assessment factor – accounting for differences in:</th>
<th>Default value</th>
<th>Default value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>systemic effects</td>
<td>local effects</td>
</tr>
</tbody>
</table>
| Interspecies                                      | AS<sup>a</sup>  
- correction for differences in metabolic rate per body weight  
- remaining differences | 2.5 | 1<sup>b</sup> |
|                                                   |               |               |
| Intraspecies                                      |               |               |
| - worker                                          | 5             | 5             |
| - general population                              | 10<sup>c</sup> | 10<sup>c</sup> |
| Exposure duration                                 |               |               |
| - subacute to sub-chronic                         | 3<sup>b</sup> | 3<sup>b</sup> |
| - sub-chronic to chronic                          | 2<sup>c</sup> | 2<sup>c</sup> |
| - subacute to chronic                             | 6             | 6<sup>b</sup> |
| Dose-response                                     |               |               |
| - issues related to reliability of the dose-response, incl. LOAEL/NAEL extrapolation and severity of effect | 1<sup>d</sup> | 1<sup>e</sup> |
| Quality of whole database                         |               |               |
| - issues related to completeness and consistency of the available data | 1<sup>d</sup> | 1<sup>e</sup> |
| - issues related to reliability of the alternative data |               |               |

<sup>a</sup> AS – factor for allometric scaling (see Table R. 8-3)  
<sup>b</sup> Caution should be taken when the starting point is an inhalation or diet study  
<sup>c</sup> Not always covering for very young children; see text for deviations from default  
<sup>d</sup> See text for deviations from default  
<sup>e</sup> Special consideration needed on a case-by-case basis  
<sup>f</sup> for effects on skin, eye and GI tract via simple destruction of membranes  
<sup>g</sup> for effects on skin, eye and GI tract via local metabolism; for effects on respiratory tract

**Risk tolerability in the workplace**

Traditionally, the tolerable upper bound of risk tolerability in relation to death from workplace exposures is $10^{-3}$ (HSE 1992<sup>116</sup>). Although more recent guidance (eg HSE, 2001<sup>117</sup>) has avoided explicitly quantifying tolerable risk, $10^{-3}$ is still implicitly regarded as the upper bound of tolerability for lifetime risks of mortality arising from workplace causes. The 2001 HSE guidance also implies however that the tolerable risk for death from cancer is likely to be lower than for death from other causes because of the specific dread that is associated with cancer. Workplace exposure limits (WELs) applied in the UK incorporate variable levels of risk as the limit setting process is heavily influenced by the beliefs about the concentrations in workplace air that are achievable. WELs are set by a tripartite group involving employers’ representatives, trade unions and the regulator (HSE) and the process is influenced by the desire to protect jobs. There is a difficult balance between the risks of possible ill health associated with exposure at work compared with those arising from unemployment. The Regulatory Impact Assessments (RIAs) undertaken for WELs set before the decision to defer completely to the EU in relation to new WELs, incorporated an analysis of the costs of achieving different levels of controls versus the estimated monetised benefits in terms of serious illness or deaths avoided. This enabled identification of the level of exposure control that gave the maximum return in terms of health benefit versus cost of implementation. The RIA published for respirable crystalline silica is a good example in which the risks of silicosis and cancer associated with each of 4 candidate WELs were calculated and the risk estimates used to calculate the number of cases

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avoided at each candidate WEL\textsuperscript{118}. Benefits were monetised in line with the then current Treasury advice and took account of pain, grief and suffering, medical costs and costs of lost production. The value assigned to life for cancer deaths was based on the Department of Transport’s Value for a Prevented Fatality (VPF) but was doubled because of the particular dread that is associated with cancer. The costs of implementation took account of the differing control measures required to reduce exposure to below each of the candidate WELs plus related costs such as increased monitoring costs. The estimated total costs versus benefits over a 60 year period are shown below (Table 4.7). The limit was set at 0.1 mgm\textsuperscript{-3}, a level that was believed to be achievable. It was believed that a lower limit was too costly to implement in relation to health benefit and was likely to lead to a significant number of business closures.

Table 4.7: Summary of costs and benefits associated with setting the WEL for respirable crystalline silica at different levels as used to inform the RIA and development of the current WEL

<table>
<thead>
<tr>
<th>Candidate WEL</th>
<th>0.3 mgm\textsuperscript{-3}</th>
<th>0.1 mgm\textsuperscript{-3}</th>
<th>0.05 mgm\textsuperscript{-3}</th>
<th>0.01 mgm\textsuperscript{-3}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total costs</td>
<td>£ million</td>
<td>£ million</td>
<td>£ million</td>
<td>£ million</td>
</tr>
<tr>
<td>5.1-5.3</td>
<td>638-650</td>
<td>3453-3603</td>
<td>12024-14663</td>
<td></td>
</tr>
<tr>
<td>Total benefits</td>
<td>39.4 – 78.8</td>
<td>209-414</td>
<td>340-671</td>
<td>515-1015</td>
</tr>
</tbody>
</table>

Quantitative risk assessment has not been used for setting WELs for carcinogens in the UK but is used elsewhere in the EU\textsuperscript{119}. In the Netherlands, the target is to reduce the additional risk of cancer to <10\textsuperscript{-6} per substance per year (one extra death from cancer each year per million exposed employees). OELs for these substances are reviewed every 4 years in order to assess whether any additional measures are available to reduce exposure. In Poland, risk levels for OELs of between 10\textsuperscript{-3} and 10\textsuperscript{-5} have been deemed socially acceptable. For an individual substance, the decision making body chooses one of two proposed OELs based on risk levels of 10\textsuperscript{-3} and 10\textsuperscript{-5}. Germany has recently developed an approach to deriving OELs for carcinogens based on quantified risks. Three risk bands are identified (high, medium and low) and these are linked to substance-independent control measures that are graded according to risk band. The upper limit (tolerable) (additional) cancer risk for workplace exposure for 8 hours/day, 240 days/year over 40 years was set at 4:1000 and the lower limit (acceptable risk) was set at 4:10,000, to be achieved by 2018. An interim target of 4:10,000 to be achieved by 2013 has also been set. In deriving these limits, the risks of a fatal work accident (3:1000 to 4:10,000, depending on occupation) and of a non-smoking adult developing lung cancer (about 4:1000) were taken into account. Under REACH\textsuperscript{19}, the DMEL (effectively the WEL) for workplace exposure to carcinogens should equate to an estimated cancer risk of 10\textsuperscript{-5}.

There has been a general reduction in the level of risk considered acceptable for workplace standards over the last 50 years as living standards and overall health status have improved and people no longer accept an increased risk of illness as an inevitable consequence of employment in particular industries. There has also been a concurrent reduction in exposure levels but this is largely the result of increased automation and better process design. The reduction in exposure levels has been paralleled by a reduction in workplace exposure limits (Figure 4.1).

In conclusion, WELs are set to reduce workplace exposure to hazardous substances but are not necessarily set at levels where no adverse effects would be anticipated following 40 years exposure at work to a threshold substance or where the increase in lifetime cancer risk would be less than 1 in 1000. Although WELs are not fully protective, there are still substantial benefits in reducing exposures, as evidenced by the substantial reduction in the number of cases of pneumoconiosis among coal miners following the introduction of limits to reduce exposure to dust in coal mines, even although the estimated risk of developing disabling disease at the limit was between 1 and 5% at the

\textsuperscript{118} HSE. A Regulatory Impact Assessment (RIA) on proposals to reduce the UK Occupational Exposure Limit for Respirable Crystalline Silica (RCS) http://www.hse.gov.uk/ria/chemical/reduceoccexp.pdf

time the limits were set. The results of more recent studies of the adverse effects of exposure to dust in workplace air on respiratory health would suggest that actual risks of developing disabling disease are considerably higher than was believed when the limits were originally set.

Figure 4.1: Reduction in the workplace Threshold Limit Value (exposure limit) recommended by the American Conference of Governmental Hygienists through time.

IGHRC Review of the use of uncertainty factors in UK Government chemical risk assessment

The IGHRC (2003) reviewed the use of uncertainty factors in the setting of health-based exposure standards by different parts of UK Government. With the exception of workplace exposure limits, the IGHRC reported that there was a surprising degree of consistency in the approach taken for different types of chemical hazard between different UK Government bodies and also with international good practice, despite the separate development of risk assessment methodologies (Table 4.8). They concluded that the uncertainty factors used were appropriate and in line with wider evidence relating to interindividual and interspecies differences in susceptibility to chemical agents. The IGHRC noted the potential for new methodologies such as probabilistic risk assessment, in vitro testing and pharmacokinetic modelling to replace the use of uncertainty factors in the future but recommended that the existing uncertainty factors used in decision making were retained and used at present.

122 American Conference of Government Industrial Hygienists (2005). Criteria Documents for Threshold Limit Values (updated annually and available from ACGIH)
Table 4.8: Default uncertainty factors used in UK Government chemical risk assessment (NS – not
specified, NA – not applicable)

<table>
<thead>
<tr>
<th>Chemical sector</th>
<th>Animal to human factor</th>
<th>Human variability factor</th>
<th>Quality or quantity of data factor</th>
<th>Severity of effects factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food additives and contaminants</td>
<td>10</td>
<td>10</td>
<td>2–10</td>
<td>1–10</td>
</tr>
<tr>
<td>Agricultural pesticides</td>
<td>10</td>
<td>10</td>
<td>2–10b</td>
<td>2–10</td>
</tr>
<tr>
<td>Non-agricultural pesticides</td>
<td>10</td>
<td>10</td>
<td>2–10</td>
<td>2–10</td>
</tr>
<tr>
<td>Veterinary products</td>
<td>10</td>
<td>10</td>
<td>2–5</td>
<td>2–10</td>
</tr>
<tr>
<td>Air pollutants</td>
<td>10</td>
<td>10</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Industrial chemicals</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Consumer products</td>
<td>10</td>
<td>10</td>
<td>&gt; 2 or greater</td>
<td>&gt; 2 or greater</td>
</tr>
<tr>
<td>Drinking water contaminants</td>
<td>1–10</td>
<td>1–10</td>
<td>1–10</td>
<td>1–10</td>
</tr>
<tr>
<td>Soil contaminants</td>
<td>1–10</td>
<td>1–10</td>
<td>1–10</td>
<td>1–10</td>
</tr>
<tr>
<td>Medical devices</td>
<td>1–10</td>
<td>1–10</td>
<td>1–100</td>
<td>–</td>
</tr>
<tr>
<td>Human medicines</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Risk comparison

Although current guidance advises against making comparisons of different types of risk, it is a useful way of conceptualising the size of a calculated risk against more familiar risks. The Department of Health (1997) provided a useful tabulation of common risks (Table 4.8).

Table 4.9: Department of Health terminology for differing levels of risk

<table>
<thead>
<tr>
<th>Term</th>
<th>Risk estimate</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>&gt;1 in 100</td>
<td>First year of life, in Glasgow 1855 1 in 8.</td>
</tr>
<tr>
<td>Moderate</td>
<td>1 : 100 to 1 : 1,000</td>
<td>Smoking 10 cigarettes/day, 1 in 200</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All natural causes for 40 year old, 1 in 850</td>
</tr>
<tr>
<td>Low</td>
<td>1 : 1,000 to 1 : 10,000</td>
<td>All kind of violence and poisoning, 1 in 3,300</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Influenza, 1 in 5,000, Road accidents, 1 in 8,000 (recent estimate 1 in 16,000)</td>
</tr>
<tr>
<td>Very low</td>
<td>1 : 10,000 to 1 : 100,000</td>
<td>Leukaemia, 1 in 12,000, Accidents; at home, 1 in 26,000; at work, 1 in 43,000</td>
</tr>
<tr>
<td>Minimal</td>
<td>1 : 100,000 to 1 : 1,000,000</td>
<td>Railway accident, 1 in 100,000</td>
</tr>
<tr>
<td>Negligible</td>
<td>1 : 1,000,000 to 1 : 10,000,000</td>
<td>Hit by lightning 1 in 10,000,000, Radiation leak from nuclear plant 1 in 10,000,000</td>
</tr>
</tbody>
</table>

The HSE (2001) also provide a large number of helpful examples of low probability risks of mortality associated with everyday life in the UK (Table 4.10).
Table 4.10: Annual risk of death for various UK age groups in 1999

<table>
<thead>
<tr>
<th>Population Group</th>
<th>Risk as annual experience</th>
<th>Risk as annual experience per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death from any cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entire population</td>
<td>1 in 97</td>
<td>10309</td>
</tr>
<tr>
<td>Men aged 65-74</td>
<td>1 in 36</td>
<td>27777</td>
</tr>
<tr>
<td>Women aged 65-74</td>
<td>1 in 51</td>
<td>19607</td>
</tr>
<tr>
<td>Men aged 35-44</td>
<td>1 in 637</td>
<td>1569</td>
</tr>
<tr>
<td>Women aged 35-44</td>
<td>1 in 838</td>
<td>1012</td>
</tr>
<tr>
<td>Boys aged 5-14</td>
<td>1 in 6907</td>
<td>145</td>
</tr>
<tr>
<td>Girls aged 5-14</td>
<td>1 in 8696</td>
<td>115</td>
</tr>
<tr>
<td>Death from specific causes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>1 in 387</td>
<td>2584</td>
</tr>
<tr>
<td>Injury and poisoning</td>
<td>1 in 3137</td>
<td>319</td>
</tr>
<tr>
<td>All types of accidents/other external causes</td>
<td>1 in 4064</td>
<td>246</td>
</tr>
<tr>
<td>Road accident</td>
<td>1 in 16800</td>
<td>60</td>
</tr>
<tr>
<td>Lung cancer caused by radon in dwellings</td>
<td>1 in 29000</td>
<td>34</td>
</tr>
<tr>
<td>Gas incident (fire, explosion, carbon monoxide)</td>
<td>1 in 510000</td>
<td>20</td>
</tr>
<tr>
<td>Lightning</td>
<td>1 in 1870000</td>
<td>0.5</td>
</tr>
<tr>
<td>Death at work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths in employees</td>
<td>1 in 125000</td>
<td>8</td>
</tr>
<tr>
<td>Deaths in self employed</td>
<td>1 in 50000</td>
<td>20</td>
</tr>
<tr>
<td>Mining, quarrying of energy producing materials</td>
<td>1 in 9200</td>
<td>109</td>
</tr>
<tr>
<td>Construction</td>
<td>1 in 17000</td>
<td>59</td>
</tr>
<tr>
<td>Extractive and utility supply industries</td>
<td>1 in 20000</td>
<td>50</td>
</tr>
<tr>
<td>Agriculture, hunting, forestry, inland fishing</td>
<td>1 in 17200</td>
<td>58</td>
</tr>
<tr>
<td>Manufacture of metals and metal products</td>
<td>1 in 340000</td>
<td>29</td>
</tr>
<tr>
<td>Deaths associated with specific activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal death in pregnancy – per pregnancy</td>
<td>1 in 8200</td>
<td></td>
</tr>
<tr>
<td>Surgical anaesthesia – per operation</td>
<td>1 in 185000</td>
<td></td>
</tr>
<tr>
<td>Scuba diving – per dive</td>
<td>1 in 200000</td>
<td></td>
</tr>
<tr>
<td>Fairground rides – per ride</td>
<td>1 in 834000000</td>
<td></td>
</tr>
<tr>
<td>Rock climbing – per climb</td>
<td>1 in 320000</td>
<td></td>
</tr>
<tr>
<td>Canoeing – per outing</td>
<td>1 in 750000</td>
<td></td>
</tr>
<tr>
<td>Hang-gliding – per flight</td>
<td>1 in 116000</td>
<td></td>
</tr>
<tr>
<td>Rail accident per journey</td>
<td>1 in 43000000</td>
<td></td>
</tr>
<tr>
<td>Air accident per journey</td>
<td>1 in 12500000</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

It is difficult to determine what constitutes “acceptable risk” in other regulatory regimes. The levels of risk and safety factors incorporated in standards/limits intended to be protective of human health in other contexts are extremely variable. Few bodies are explicit in the level of risk incorporated in standards/limits or in the extent to which the level set may be influenced by current levels and the costs and difficulties associated with reducing exposure. Some air quality and drinking water standards are set just below or at the reported LOAEL for effects such as small impacts on children’s cognitive function whereas others based on similar effects incorporate safety factors of between 5 and 20. The UK air quality standards and drinking water standards for carcinogens are associated with an approximate lifetime cancer risk of between about $10^{-4}$ and $10^{-5}$. The air quality objectives adopted in the UK are based on the health-based standards but with some allowance for how readily that standard could be achieved. The action level for radon exposure in domestic properties equates to a lifetime cancer risk of about 3% which is much higher than that associated with standards set under other regimes. When the action limit for radon was developed in 1990, it was believed to be associated with a similar mortality risk to that associated with accidental death in a traffic accident or in the home. The risks of accidental death have reduced over the last 2 decades and the lifetime risk is probably now around 1% for accidental deaths from any cause or about 0.2-0.3% for “land transport” related deaths. Workplace exposure limits (WELs) for carcinogens in the UK are typically associated with a lifetime cancer risk of about 1 in 1000 but for threshold substances many WELs are set at the lowest level or even above the lowest level that adverse effects have been observed in workers. The development of WELs does take account of the cost of implementation (and associated impact on employment) which can lead to a reduced level of protectiveness. The application of air
quality or drinking water standards is based on individual substances and does not take account of the effect of mixtures as would be required for contaminated land.

4.7 OPTIONS APPRAISAL

Overview

The overall approach to human health risk assessment for contaminated land is consistent across different countries with the exception that the water environment is not included as a source of soil-related exposure in UK guidance as it is covered by a separate regulatory regime.

The CLEA model has emerged from this review as the leading tool to assist human health risk assessment and it is already widely used by LAs. It is not therefore proposed to consider developing or recommending an alternative approach.

The major difficulty in human health risk assessment that has been identified by the review is in determining the level of intake that is deemed unacceptable. This is primarily a policy issue but it is related to the development and interpretation of the data used to underpin the development of site specific assessment criteria. Four possible approaches have been identified:

- Development of national approach to determining unacceptable intake based on the development of benchmark doses for common contaminants combined with policy guidance on the appropriate “margin of exposure” for different types of health endpoint;
- Setting soil concentration action criteria levels at a national level;
- Broadly adopting the new English Guidance on Part 2A; or
- Retaining the status quo with the possible provision of some supplementary guidance.

The supplementary guidance might address the conservatism in the CLEA model, the assessment of toxicological data and the derivation of appropriate exposure estimates for the purposes of Part IIA. Each of the options is reviewed below and a concluding summary table of the advantages and disadvantages of each approach is provided at the end of this section.

Benchmark Dose/MoE approach

EA guidance (SR2) does not provide guidance on the level of intake of a substance that would be deemed as unacceptable. The approach described for developing toxicological reference values in SR2 is not amenable to the development of a simple definition of unacceptable at a national level. An approach to assessing the toxicological data through the development of a benchmark dose (BMD) for both threshold and non-threshold substances as described in section 2.5 above would enable the Scottish Government to provide advice on the minimum margin of exposure (MoE) required for different types of health end point. The MoE of exposure should be based on the proven extent of interspecies and interindividual differences in susceptibility to different types of chemical agent by different routes of exposure. It should also take account of the severity of effect and the quality/certainty of the dose-response information that is available. The advice would also include how to take account of whether the BMD was based on animal or human data, and whether it was based on findings in a lifetime or short term study. This would effectively enable the Government to provide guidance at a national level on the intake perceived as “unacceptable” for different types of health endpoint. The variables affecting human exposure would be assessed by LAs as at present, leading to locally determined site specific assessment criteria (SSAC) consistent with the spirit of Part IIA but underpinned by a nationally agreed approach to developing the toxicological reference dose used to derive the SSAC.

The BMD approach provides a scientifically defensible method of assessing toxicological data that will lead to a reference dose that is less subject to the vagaries of experimental design than the traditional approach of identifying the NOAEL or LOAEL. The use of a BMD approach means that it is possible to develop a toxicological reference value for any substance for which appropriate toxicological or health data are available. If appropriate data are available, it is also possible to develop different BMDs for different life stages, which is of particular relevance for substances believed to adversely affect children’s development.
If the Government sets the MoEs required for different types of health endpoint at national level, this should help to create consistency between LAs and provide a firm foundation for LAs to develop appropriate toxicological reference values. It will also create a greater level of consistency between substances than if pre-existing reference values are selected from a range of different standard setting organisations, each with a different approach to standards setting. In addition, approaches to extrapolating from animal doses to human equivalent doses and the choice of uncertainty factors have changed through time as well as varying between different standard setting bodies. Even where standards have been set by an individual standard setting organisation, the standards for different substances may be associated with very differing levels of risk to human health.

From the perspective of LA officers, it would be desirable for the Scottish Government to develop or to sponsor the development of a national list of BMDs which would ensure consistency between LAs. This requires central Government spend at a time of cost saving combined with the small on going costs that would be associated with periodically reviewing the BMDs in the light of new data. Although the cost to central Government would be significant (£10sK), it would represent best value at national level, as the alternative of devolving the development of BMDs to LAs would lead to duplication of effort with several different LAs independently developing BMDs for individual substances.

It could be argued, that it would be more in the spirit of Part IIA for LAs to develop their own BMDs and pressure on Government spending might also be a driver to make the development of BMDs part of the LA assessment process. This would seem to offer poor value for money at national level because of the implied repetition of effort. In addition there would be substantial training costs incurred in providing LA officers with sufficient knowledge of toxicology for them to feel comfortable in determining BMDs. Although the US EPA BMDS software is free to download and there is good explanatory material available, it would be unreasonable to expect LA officers to have the relevant technical background to be able to develop BMDs. In addition, at present, few of the consultancies working in contaminated land would have sufficient expertise to be able to support LAs in the development of BMDs. Given the unfamiliarity of most LA officers with BMDs, the requirement for LAs to develop their own BMDs would probably result in a reduced rate of site assessments under Part IIA.

**Soil concentration action criteria levels**

The provision of a list of action levels for concentrations of commonly encountered contaminants in soil similar to the Dutch Intervention values could remove the uncertainties associated with Part IIA and greatly streamline the risk assessment process for individual sites. If a statistically significant exceedance of an action level existed for a given contaminant, then the site would be determined as contaminated and action would have to be taken. Once in place, such a list could remove the uncertainties in relation to Part IIA determinations and would represent a significant cost saving for LAs. Risk assessments would be much less technically demanding, cheaper and come to a clear conclusion. The risk of legal action against LAs would be reduced, provided that they had implemented a robust sampling strategy supported by analytical data meeting appropriate quality standards. This would be expected to greatly increase the rate at which sites are considered under Part IIA. The introduction of action levels would also potentially benefit the planning process and remove the uncertainties for developers although it is likely to be desirable to set more demanding targets for development projects. The costs and other adverse impacts of remediation of land at development sites are likely to be relatively lower than for land that is in use. In developing a national list of action levels, however, there is a risk that the threat of legal challenge in regard to “unacceptable intake” would lead to the levels being set so high as to be inadequately protective. Equally, there is a risk that instinctive caution would lead to action levels being set at levels well below any real risk of adverse health effects bringing a large area of land unnecessarily into the Part IIA regime.

Our consultation with LAs indicated that many would welcome the introduction of action levels whereas others with extensive contaminated land expertise were less enthusiastic. A major disadvantage of developing national soil action levels is that they are not site specific and there could be significant uncertainties as to the appropriateness of national action levels for a specific site. Although different action levels could be set for different broad use categories and for several soil types relevant to the Scottish environment, they are likely to be associated with very different potential health risks at different sites, depending on site specific circumstances. In most cases, this is likely to
lead to the recommendation of action levels that are lower than might have been derived as a site specific value based on an equivalent intake of the contaminant in question. However, although action levels are not tailored to be site specific, this may be outweighed by the substantial uncertainties in determining site specific values. The apparent benefit to the management of the risks to human health associated with site specific risk assessments may be theoretical rather than real.

The development of national soil action levels would require substantial central Government spend at a time of cutbacks. The experience of the EA and Defra in developing SGVs indicates that it can be difficult to gain consensus on appropriate levels, although this could be reduced by having a stronger framework of rules within which guidelines are developed (for example, similar to the Dutch approach where action levels for threshold contaminants are set to equate to a lifetime cancer risk of $10^{-4}$). The difficulty in reaching consensus is likely to lead to a long time scale of implementation. The development of national action levels would be against the spirit of Part IIA which requires site specific decision making by the LA. It would also be significantly out of step with practice elsewhere in the UK.

**Broadly adopting the new English Guidance on Part 2A**

The development of new Scottish statutory guidance that mirrors the new guidance developed by Defra for England would maintain the general consistency of the approach taken to Part IIA with that south of the border. This may be advantageous for consultants and developers that work on both sides of the border. Other areas of regulation or guidance relating to other activities however, have been distinctively Scottish since before devolution without apparently causing major difficulties. The English guidance has not been designed for the Scottish context and our different local government structure.

The cost implications of adopting a version of the new English guidance are small for central Government as relatively little additional work would be required to review the English guidance and implement it in Scotland in comparison with the resource required to implement the two options discussed above. It is unclear, however, whether the new English guidance as it stands will benefit the decision process. It seems likely that LAs are already able to confidently identify Category 1 and Category 4 sites and deal with them accordingly. The proposed development of Category 4 Screening Levels (C4SLs) may be helpful in eliminating sites from further consideration under the Part IIA process but may have little utility in practice as the sites in question are likely to have contaminant levels within the range of typical urban soils. Given the extremely slow rate at which SGVs were developed in the past, it also seems unlikely that C4SLs will be available for a wide range of substances in the near future. The recent Defra tendering exercise for the development of C4SLs only included six candidate substances (Defra Competition P1010).

The focus of the new regime will be on Category 2 (C2) versus Category 3 (C3) ie the need to remediate or not. At first sight, the idea of C2 and C3 sites is attractive as it enables progress to be made in relation to individual sites where uncertainties exist without having to prove beyond all reasonable doubt whether they are contaminated or not. This would appear to ease the decision making process for LAs as it provides a legal defence for the designation of sites as contaminated on a precautionary basis. Given a starting assumption under the new guidance that land is not contaminated, LAs will, however, still have to demonstrate that land is contaminated or highly likely to be contaminated in order to categorise sites as C1 or C2. The cost implications of categorising as C2 rather than C3 are substantial as are the cost implications of classifying as C3 and then subsequently reclassifying as C2. It is not clear that there is sufficient new in the guidance that will enable LAs to make the distinction with confidence. The cost implications arising from identifying land as C2 are likely to lead to a continuing reluctance to make decisions in relation to sites that are difficult to assess. There is no proposal to develop C2SLs which would potentially have a much greater impact on the speed of the decision process. It is likely that repeated risk assessments will be undertaken before a site is categorised as 2 (effectively equivalent to SPOSH) or 3 (probably not SPOSH). There is unlikely to be any reduction in the costs and timescales associated with making determinations. The creation of the C2 option under the new English guidance could lead to many more sites being declared as contaminated leading to remediation and some associated certainty for local communities affected by the land. The widening of the net to include C2 sites under SPOSH may or may not be beneficial at local level depending on circumstances as it may speed up determinations and the remediation process. There is likely to be a substantial economic disadvantage at national level, if a
substantial proportion of sites brought into the Part IIA regime are C2 sites leading to remediation costs that may be associated with little or no health benefits.

In terms of human health risk assessment and the determination of whether SPOSH exists, the new English guidance is couched entirely in qualitative terms that are open to a wide range of interpretation by different LAs. There has been a retreat from the earlier attempt by Defra to provide a numerical basis for determining SPOSH. Overall, it seems likely that sites that were difficult to assess under the old regime will remain difficult to access despite the change in terminology. The adoption of the English guidance is unlikely to ease the process of determination in relation to human health, reduce LA costs or increase the rate of progress in implementation of Part IIA. There will be continued uncertainty for local communities that may have adverse economic impacts and contribute to negative well being in local residents. The lack of rigid guidance on SPOSH is also likely to have a knock on effect on the planning regime as there will be a continuing requirement on developers to take a highly precautionary approach in relation to contaminated sites. The current uncertainty as to the levels that future C4SLs will be set up means that the SGVs that were formerly developed are likely to continue to be used as target remediation levels, even although it is acknowledged that the future C4SLs will be set at much higher levels. This implies that “over-remediation” leading to excessive costs for developers (and ultimately the wider community) will continue.

The creation of 4 different categories of land under the new English guidance without an accompanying improvement in the clarity of guidance in relation to “unacceptable” will increase the potential extent of variability in the interpretation and determination of SPOSH by different LAs relative to the status quo. Although local decision making is in the spirit of Part IIA, in practice this could cause substantial uncertainty for communities and businesses and could lead to significant disparities in the level of protection enjoyed in different areas. There would be a risk that communities of poorer socio-economic status in areas of industrial decline would be less protected than communities in more affluent parts of the country. Even if the differences had no practical consequence (because of the small risks involved), they could lead to community concern and a perception of inequality.

The new English guidance encourages LAs to weigh up the costs and benefits of declaring individual sites as contaminated as part of the consideration of placement in C2 or C3 but does not indicate how this should be undertaken. Some important costs are extremely difficult to quantify such as the impacts on the psychological and cardiovascular health of residents faced with the cost of remediating their gardens as the original polluter has long since gone. While cost-benefit analysis is helpful in regulatory decision making and may help a LA in framing its contaminated land strategy, it may not be a sensible approach to take at the individual site level. At the extreme, if you had a row of five terraced houses with gardens with some level of contaminant that gave rise to a 1% lifetime cancer risk, the chances of anybody developing cancer are much less than the chances of not becoming ill. There would be little apparent benefit in undertaking remediation. It is highly unlikely, however, that most people would view a 1% increase in lifetime cancer risk as acceptable, even although we all live with a lifetime cancer risk of >30%. Although cost-benefit analysis does not work at individual garden level, it would, however, be reasonable to encourage LAs to examine health issues associated with potentially contaminated sites in a more holistic fashion than simply assessing direct toxicological impacts. In some cases a very small toxicological risk may be weighed against substantial socio-economic consequences that would follow the determination of the site as contaminated. For example, the benefits to well being associated with an area of green space that is extensively used by the local community could vastly outweigh a small hypothetical cancer risk associated with buried contamination, provided that the contamination was not associated with other potential risks such as pollution of the water environment.

Finally simply adopting a version of the new English guidance without some further enhancement of the guidance available to support the underlying scientific process implies a retention of SR2 which may not provide the most robust approach to the interpretation of toxicological information.

Overall, the new English guidance is not tailored to Scottish circumstances and there would appear to be little to commend its adoption in Scotland. There is a much stronger case for doing something different in Scotland. The adoption of the English guidance would lead to continuing and probably increasing opportunities for contaminated land consultants but would not reduce the uncertainties as to whether SPOSH exists at an individual site with an associated negative impact on economic activity and societal well being.
Retaining the status quo with the possible provision of some supplementary guidance

The retention of the status quo in relation to Part IIA represents the cheapest option for central Government and would avoid the uncertainties that would be created by a substantial change in approach. LAs have developed an expertise to work within the current framework. Some supplementary guidance could be provided to assist LAs in the selection of appropriate toxicological reference values where no HCVs are available and in the selection of exposure variables in order to reduce the level of conservatism associated with the generation of SSACs using CLEA. More guidance could also be provided on sampling strategy and the statistical handling of site data. There is, however, a universal desire among LAs for reforms leading to a clearer definition of SPOSH, in particular an unambiguous definition of “unacceptable intake”. The existing approach to toxicological assessment embodied in EA guidance and CLEA that are used by LAs does not lend itself to the definition of “unacceptable intake” at a national level. The retention of the status quo will be associated with a continued high level of uncertainty around the definition of unacceptable. Although the uncertainty around what constitutes SPOSH creates plenty of opportunity for contaminated land consultants, it does not represent best value in terms of LA expenditure. Where individual sites are not grossly contaminated but have above background levels of contaminants present, repeated risk assessments may be undertaken without coming to a conclusion on whether SPOSH exists. The existing difficulties and uncertainties in determining SPOSH will not be reduced by new guidance that simply expands on that already available as the problem lies less in the process of risk assessment than in the decision as to what constitutes unacceptable. This is a value rather than scientific judgement. A new approach to risk assessment is required in order to facilitate the development of effective guidance on the definition of unacceptable such as the adoption of the BMD/MoE approach advocated above.

LAs have developed considerable expertise in the existing process of site assessment, particularly in relation to examination of the factors influencing modelled exposure levels and in adjusting the default assumptions within CLEA to create a site specific model. In many cases, when these exposure-related variables are made site-specific, soil contaminant levels can be demonstrated to be well below a SSAC based on a highly conservative toxicological reference value such as the HCVs in CLEA. Supplementary guidance could be developed to assist LAs in developing appropriate exposure estimates using the CLEA tool but avoiding the level of conservatism that is inherent in the assumptions underlying CLEA. CLEA only includes HCVs for a limited number of contaminants which do not include lead, which is an extremely common contaminant. LAs have little confidence in selecting toxicological reference values from other sources and both HCVs or alternative reference values are likely to be highly protective rather than marking the boundary between “acceptable” and “unacceptable” intake. The toxicological approach taken in SR2 is less robust than the use of a benchmark dose/MoE approach to setting reference levels (above). There is virtually no guidance for LAs on how to determine the lower threshold of “unacceptable” and most LA officers do not have the technical background required to “unpick” reference values in order to set an appropriate upper bound on acceptable intake. Even if excellent technical guidance was available, it is not reasonable to expect the relevant toxicological expertise and experience to be available at LA level or to expect individuals without this experience to make decisions simply on the basis of their interpretation of the guidance. LQM have developed a commercial product that is intended to assist LAs in the determination of “unacceptable”, which has the attraction of providing information in a readily understandable graphical form. There are some technical deficiencies in the way data have been treated within the LQM roadmap tool however, and the maps may be misleading for some contaminants, particularly if interpretation is undertaken by an individual with little or no experience of interpreting toxicological data. While LAs should be free to use the LQM roadmap tool and may find it useful, it would be inappropriate to endorse its use at national level.

Given the uncertainties associated with the interpretation of toxicological information and exposure modelling, the delays and inconsistencies in site determination are likely to continue unless a radical new approach is taken that would enable the SG to provide a clear definition of “unacceptable intake”. If the status quo continues, Part IIA is likely to continue to consume a disproportionate level of LA resource relative to progress made (eg as a result of the commissioning of multiple studies for single sites). There is also an associated indirect cost for developers as the site investigation and remediation work required by LAs under the planning regime is affected by the uncertainties in the implementation of Part II A.
Overall, the retention of the status quo with the possible addition of some extra guidance is the lowest cost option for the Scottish Government, does not incur the substantial disadvantages that would be associated with adopting the new English guidance and builds on existing LA expertise. There would, however, be little or no reduction in the current climate of uncertainty in relation to the determination of SPOSH. At a time of little economic growth, there is likely to be a knock on effect on the willingness of developers to commit to expensive remediation under the planning regime in the absence of an unambiguous definition of SPOSH.

Summary

The advantages and disadvantages of each of the four options is summarised in the Table below. Of the four options, the development of soil action levels or the adoption of the English guidance would appear to be the least attractive. The soil action levels approach is unattractive because of the probable long timescale of implementation, cost and uncertainties of relevance at individual sites. Adoption of the English guidance does not offer any obvious advantages over the status quo and may have some disadvantages in relation to considering costs and benefits at individual site level. The development of a benchmark dose/MoE approach to developing toxicological criteria and providing the basis for defining “unacceptable intake” would offer a real improvement over the status quo and could greatly ease the process of site determination. This is, however, provided that a centrally held resource of BMDs was available to LAs rather than requiring this level of toxicological expertise at local level. The Scottish Government would have to invest in the development of a bank of BMD values for a range of contaminants. The fourth option of retaining the status quo but with the provision of some additional guidance would be much less costly for central Government but would lead to continued uncertainty of the definition of “unacceptable intake” and is unlikely to lead to progress in the Part IIA regime. It is also likely to be a more costly option at LA level.
Summary Table

<table>
<thead>
<tr>
<th>Approach</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benchmark Dose/MoE approach – National list of BMDs</td>
<td>Provides a mechanism by which unacceptable intake can be clearly defined by central Government; Scientifically robust (more robust than existing use of toxicological reference values from multiple sources); Allows for a consistent approach to be taken to evaluating sites across Scotland but retains flexibility for LA to develop SSACs taking account of site specific factors that govern exposure; Significant cost savings for LAs</td>
<td>Increased central Government spend at a time of cost saving, small on going costs of review in light of new data; LA officers unfamiliar with approach</td>
</tr>
<tr>
<td>Benchmark Dose/MoE approach – LAs develop BMDs</td>
<td>More scientifically defensible than current approach; central Government can provide policy guidance on suitable MoEs for different health endpoints giving rise to a degree of consistency between LAs while retaining LA focus of Part IIA;</td>
<td>Unreasonable to expect LA officers to have the relevant technical background to develop BMDs; substantial training costs; LA officers may avoid using a BMD approach leading to reduced progress in implementing the Part IIA regime; much duplication of effort between different LAs leading to greater costs at national level (but not necessarily visible in central government spend) and probably a reduced rate of site assessments; relatively few consultancies are likely to have required level of toxicological expertise</td>
</tr>
<tr>
<td>Soil concentration action criteria levels</td>
<td>Significant cost savings for LAs, removal of uncertainties in relation to Part IIA; significant cost savings for developers; vast increase in rate of site assessments (once action levels available); greatly reduced risks of legal challenge</td>
<td>Very significant central Government spend, difficulty in gaining consensus on appropriate levels, long time scale of implementation; against the spirit of Part IIA which is based on local decision making; significantly out of step with practice elsewhere in the UK; uncertainties on appropriateness of national action levels for a specific site;</td>
</tr>
<tr>
<td>Broadly adopting the new English Guidance on Part 2A</td>
<td>Maintains general consistency with approach taken south of the border (advantage? Other areas of regulation were distinctively Scottish prior to devolution); small central Government cost; provision of plenty of ongoing opportunity for consultants</td>
<td></td>
</tr>
<tr>
<td>Retaining the status quo with the possible provision of some supplementary guidance.</td>
<td>Small central government cost; provision of ongoing opportunity for consultants; avoid uncertainties associated with change, LAs have developed considerable expertise in implementation of the existing regime</td>
<td>Existing difficulties and uncertainties will not be reduced by new guidance without the implementation of a different approach to risk assessment; existing approach does not lend itself to the definition of unacceptable at a national level and a high level of uncertainty around definition of unacceptable will remain; CLEA only includes HCVs for a limited number of contaminants excluding lead which is a common contaminant. LAs have little confidence in selecting toxicological reference values from other sources and the delays and inconsistencies in site determination likely to continue, Part IIA is likely to continue to consume a disproportionate level of LA resource relative to progress made (eg as a result of the commissioning of multiple studies for single sites). There is an associated indirect cost for developers as the site investigation and remediation work required under by LAs under the planning regime will be influenced by uncertainties in the implementation of Part IIA. The toxicological approach taken in EA guidance is less robust than the use of a benchmark dose/MoE approach to setting reference levels.</td>
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4.8 CONCLUSIONS

This study has not identified an underlying deficiency in the guidance available to LAs for the purposes of human health risk assessment. There is possibly a requirement for some supplementary guidance on extra steps that should be taken at sites where potentially significant concentrations of contaminants are present and SPOSH may exist in relation to human health. These extra steps include a closer investigation of the toxicological information underlying the reference intake and factors that could be taken into account in the determination of an unacceptable intake. Similarly, LAs
should be encouraged to consider the plausibility of modelled exposures in the context of specific sites where generic assumptions about receptors and their behaviours may not apply. Some issues that could be included in supplemental technical guidance for LAs are outlined in chapter 5.

The study has identified an overwhelming desire that “unacceptable intake” is defined at national level. While desirable, this is likely to be technically difficult as the current outputs of the risk assessment process do not lend themselves to ready quantification in comparable terms. Although primarily a policy issue, it is related to the development and interpretation of the toxicological data used to underpin the development of site specific assessment criteria. Four possible approaches have been identified:

- Development of benchmark doses for common contaminants with policy guidance on the appropriate “margin of exposure” for different types of health endpoint;
- Setting soil concentration action criteria levels at a national level;
- Broadly adopting the new English Guidance on Part 2A; or
- Retaining the status quo with the possible provision of some supplementary guidance.

The benchmark dose approach would provide a more robust toxicological framework for decision making but requires some development work and the development of BMDLs is resource intensive. The level of toxicological expertise required is unlikely to be available at LA level. It also would be possible for the SG to develop a Scottish list of “unacceptable intakes” by contaminant for different types of receptor at national level, possibly through the services of the HPS. This would require a level of investment that is out of line with current policies to reduce government spend, although the introduction of some certainty in the determination of SPOSH would lead to a substantial long term cost saving at LA level. It is worth noting that the risk levels associated with other environmental exposures are highly variable and environmental quality limits set to protect human health generally incorporate an element of affordability disguised in the term “reasonably practicable”. The development of soil concentration action levels is attractive in terms of creating a unified national approach but given the huge variability in site conditions and circumstances, a one size fits all approach is unlikely to be appropriate. There is a significant risk that action levels would be either set too high, in order to prevent legal challenge in relation to “unacceptable”, or set too low as a result of society’s risk aversion. If set too high, the action levels will not be sufficiently protective and if set too low, then large areas of land will be brought unnecessarily into the Part IIA regime. The only advantage of adopting the new English guidance would be that the costs to central government would be small as Scotland could broadly adopt what has been developed south of the border. The new English guidance does not provide any new clarity on the definition of “unacceptable intake” and it is unclear that the creation of 4 different categories of land is likely to ease site assessment, reduce LA costs or increase the rate of assessments. The results of Defra funded research commissioned to support the new guidance in England and Wales may, however, be informative in a Scottish context (for example, the C4SLs). Retaining the status quo in Scotland with the possible development of some supplementary guidance is the cheapest option for central government but is likely to lead to continued uncertainty at LA level and continued slow implementation of Part IIA. A clear and readily applicable definition of “unacceptable intake” and methods for determining that intake are required in order to improve progress under Part IIA and reduce the costs of its implementation.
5  Suggested contents of draft guidance

Notes: The text in this chapter is intended to be indicative of the topics that could be included in new guidance for LAs undertaking human health risk assessment for long term exposure to contaminants present in land for the purposes of Part IIA. This chapter is focussed on health risk assessment and not the wider aspects of investigation of contaminated sites. It is intended to be a guide to existing published guidance rather than a stand-alone complete handbook for human health risk assessment for contaminated land. Sections that are directly relevant to the determination of SPOSH may need to be revised if the SG decides to update its policies in relation to the assessment of SPOSH in the light of the options appraisal presented in chapter 4.

5.1  OVERALL APPROACH TO RISK ASSESSMENT

The approach to site investigation for potentially contaminated sites is outlined in BS10175:2011. The guidance here is focussed on human health risk assessment.

Human health risk assessment for hazardous substances involves characterisation of the hazard in terms of the quantities of the substances present, their toxicological properties and characterisation of potential exposure to the hazard. Risk is assessed on the basis of predicted exposure levels and the anticipated toxicological effects of those exposures based on any available information that links exposure to effect (exposure-response relationship). Under Part IIA, local authorities are required to determine whether the risks to health associated with the levels of contamination present are associated with a significant possibility of giving rise to significant harm (SPOSH) such that the risk to health is unacceptable, taking account of contaminant concentrations, their toxicological properties and potential levels of exposure.

The normal practice in risk assessment for contaminated land is to establish risk-based “assessment criteria” for individual contaminants at an early stage in the investigation. Measured contaminant concentrations are compared against these assessment criteria in order to determine whether a significant risk to health exists. The assessment criteria may be generic or site-specific but are based on the potential for exposure to a given soil contaminant as a function of its concentration in soil and (for Part IIA) the predicted level of exposure above which the risk to health would be unacceptably high as determined from the contaminant’s toxicological properties. Under other circumstances, such as the consideration of sites under the planning regime, the assessment criteria might be based on the predicted exposure associated to give rise to no or minimal risk to health.

A staged approach to risk assessment for potentially contaminated sites is recommended by the Environment Agency for England and Wales (EA) in its Model Procedures (CLR11) and also described by the Health Protection Agency (HPA) involving:

- Preliminary risk assessment;
- Generic quantitative risk assessment; and
- Detailed quantitative risk assessment (DQRA).

The preliminary risk assessment involves the identification of potential sources of contamination, contaminants of concern, development of a conceptual site model (CSM) and a preliminary assessment of whether human exposure to the contaminants is likely.

If exposure is possible, a sampling strategy should be devised to provide information for quantitative risk assessment. This should be based on the CSM and inform the selection or development of “assessment criteria”. The sampling strategy should take account of the type of assessment required such as:

- Direct comparison with assessment criteria or comparison of the criteria with a site average;
- Whether sampling should be targeted towards suspected sources of a pollutant linkage;
• Whether it is appropriate to consider the site as a single entity or to subdivide it into zones with differing potentials to give rise to exposure, ensuring sufficient information is collected for each zone;
• What additional information about the site and soil is needed to carry out generic and detailed quantitative risk assessments; and
• Whether contaminants of concern need to be speciated (e.g., trivalent versus hexavalent chromium).

Once the sampling and analysis is completed, quantitative risk assessment can be undertaken. The first "screening" phase can be based on generic assessment criteria (GAC) derived on the basis of generic assumptions about exposure and based on Health Criteria Values (HCVs) or equivalent toxicological reference values for substances for which HCVs are not available. Screening against assessment criteria can only be undertaken with confidence, however, if the available data set is supported by a robust investigation strategy.

Should the screening criteria be exceeded or there is other evidence that suggests significant contamination may be present, a detailed quantitative risk assessment (DQRA) should be undertaken. This may involve the collection of plant material for analysis, dust and vapour monitoring or other measurements relevant to determining human exposure to contaminants. Site specific assessment criteria (SSAC) are derived in a DQRA on the basis of a site specific understanding of factors affecting exposure.

The outcome of the DQRA may lead to a further re-evaluation of toxicological and exposure information during the assessment of whether contaminant levels are likely to give rise to unacceptable intakes.

It is important to develop “assessment criteria” early in the risk assessment process in order that the appropriate data are collected to enable the decision to be made. The US EPA has described the process in their guidance on Data Quality Objectives for Superfund sites. In practice most risk assessments are iterative, but the guidance is relevant to framing each round of investigation.

5.2 DEVELOPMENT OF CONCEPTUAL SITE MODEL (CSM) AND PRELIMINARY RISK ASSESSMENT

The CSM describes how people (or other environmental receptors) may be exposed to contaminants originating from the site. It represents an understanding of the site in terms of the contaminants of concern, potential receptors and the pathways by which receptors may be exposed to these contaminants (pollutant linkage). The exposure pathways include all relevant exposures (direct and indirect) resulting from dermal contact with, ingestion or inhalation of soil contaminants, excluding exposure via drinking water or bathing (these are separately regulated). EA guidance (SR3) describes how the CSM is developed and the various routes by which people may be exposed to soil contamination. The description of the receptors includes taking account of factors such as age, behaviour and time spent at the location that may affect exposure and vulnerability to contaminants. In considering these factors, account must be taken of foreseeable changes within the permitted current land use. For example, it is foreseeable that where gardens are not currently used for growing produce, future residents could develop an interest in growing their own food.

Preliminary risk assessment considers the likelihood of the existence of a pollutant linkage. If the CSM indicates a pollutant linkage may be present then it would normally be appropriate to undertake further investigation and quantitative risk assessment. Where it is uncertain whether a specific potential pollution source or exposure route exists, it may be appropriate to undertake targeted soil sampling or intrusive ground investigation in order to refine the CSM.

5.3 CHARACTERISATION OF CONTAMINANT LEVELS

It is essential that prior to undertaking site investigation a sampling strategy is developed based on the objective of the investigation and the CSM. BS 10175 provides authoritative advice on designing a sampling strategy and the Chartered Institute for Environmental Health (CIEH) have also produced guidance on sampling strategy including sample numbers. Sufficient samples should be collected and analysed to be representative of the body of soil including sampling over a relevant depth range,
bearing in mind contaminant concentrations may be highly variable within the space of a few centimetres to decimetres. The sampling strategy should take particular account of locations where elevated contaminant concentrations would be predicted on the basis of past use or visible features such as discoloration or plant death. Samples should be collected at depths at which direct human interaction with soil is likely, although additional samples may be required in order to assess risks to the water environment or where vapour emission may be an issue. No sampling strategy can eliminate the possibility that a contaminant hot spot is missed, although most contaminants, other than asbestos and extremely insoluble compounds, will disperse in soil to create a halo around the source of contamination. In many cases, contaminants are unevenly distributed across a site and it is often appropriate to divide a site into areas of differing levels of contamination, provided sufficient data are available to characterise each area. While small patches of elevated contaminant levels may not have a substantial impact on risk, it is important that sufficient samples are collected and analysed in order to be able to confidently establish the 5th, 50th and 95th percentile concentrations of the contaminants of interest across the area being accessed.

There are substantial uncertainties in the results of laboratory analysis of soil samples and an uncertainty of about 10% in reported results may be typical for most analytes. Considerably greater uncertainties may be associated with results reported for some difficult to analyse substances. Where possible, analyses should be undertaken by laboratories with ISO 17025 accreditation for relevant analytes (check UKAS website: www.ukas.org) and who participate in interlaboratory proficiency testing schemes such as CONTEST. Where it is not possible to use a laboratory with appropriate ISO 17025 accreditation, it would be appropriate to establish the quality control procedures that are in place and the anticipated uncertainty in the analytical results.

5.4 GENERIC RISK ASSESSMENT

Soil concentration data can be compared with GACs in order to determine whether a more detailed, site specific assessment is required. These GACs include Soil Guideline Values (SGV) derived by the EA and Defra, if applicable, and GACs developed by the EIC/AGS/CL:AIRE and LQM-CIEH for other substances. Independently developed GACs are also available from the ATRISK database but these values may not have been subject to the same level of peer review as the other sources. If GACs developed by individual consultancies are used, care should be taken to ensure their derivation has followed a transparent and defensible process. Neither the LQM-CIEH nor ATRISK GACs are free to access.

If measured soil concentrations are clearly well below GACs/SGV, then no further investigation is likely to be required. If concentrations are close to or exceed GACs/SGVs, it is likely to be appropriate to undertake a DQRA in order to generate site specific assessment criteria (SSACs). The CIEH provide a useful guide to the statistical analysis of data and comparison with a GAC or SSAC to meet either the requirements of the planning regime or Part IIA. The CIEH guidance suggests that when considering soil concentrations in relation to planning, it should be demonstrated that the upper confidence limit on the calculated mean of measured concentrations is below the SSAC/GAC – you need to be 95% certain that the mean is below the SSAC/GAC. For Part IIA, the lower confidence limit on the calculated mean of the measured concentrations should be above the assessment criterion. Clearly, however, it is important to consider the overall distribution of measured concentrations as there will be circumstances where the unevenness of contaminant concentrations could lead to an overall mean of concentrations that is not significantly greater than the SSAC/GAC but it would be possible to identify an area or areas within the site where the mean concentration is substantially greater than the overall mean and is significantly greater than the SSAC/GAC.

Selection of an appropriate GAC is critical in that it must be consistent with the linkages described in the CSM, appropriate for use within the Scottish regime and derived in a transparent and defensible manner. LAs should not base investigations on withdrawn SGVs or screening levels developed elsewhere unless they can demonstrate that they are appropriate to the site being assessed. A review of Soil Screening Values (SSVs) in different EU countries published in 2007 found that the SSVs in place for individual contaminants in different EU countries varied by over an order of magnitude.
5.5 **TOXICOLOGICAL INFORMATION: UNACCEPTABLE INTAKE**

Part IIA requires an assessment of whether risks to health are unacceptable based on the available toxicological and human health information. This requires the derivation of health-based assessment values on which SSACs can be based that represent intakes above which the risks to health are believed to be unacceptable. The human health criteria values (HCVs) provided in CLEA represent levels of intake believed to give rise to no risk to human health (tolerable daily intake) for substances that have an apparent threshold of effect and minimal risk (index dose) for non-threshold substances such as genotoxic carcinogens. Intakes that exceed HCVs do not necessarily represent unacceptable risk. HCVs and other published reference values are normally set with large uncertainty factors (UFs) in order to ensure that intakes are controlled well below the levels at which harm could arise. In contrast under Part IIA, LAs are required to determine the level of intake above which significant harm is likely to occur. A more precautionary approach is taken under the planning regime and the threshold levels for acceptable exposures to chemicals are likely to be lower in a planning application scenario than in a Part IIA situation.

The UFs used in setting HCVs and other reference values are based on expert judgement and usually take account of the seriousness of the health endpoint and the uncertainty in the underlying data. There are few or no human toxicological data available for many substances. If, a "no observed effects level" or “lowest observed effects level” for a defined effect has been determined in an animal experiment that exposed small numbers of animals to a limited number (typically three) dose levels over a limited time period, there are considerable uncertainties in predicting the level of long term exposure that may be harmful to humans. A larger group of animals would probably have included some more susceptible individuals who would have responded at a lower dose level. Similarly, a longer period of exposure would also be likely to give rise to adverse effects at lower levels of exposure. The animal species used in the experiment could be more or less susceptible to the toxin than humans. It is not even necessarily certain that the animals were monitored for the full range of biological changes that would be predictive of harm in humans. In determining the dose that could be considered unacceptable under Part IIA, LAs should allow for the potentially substantial differences in response to a substance between species and strains of the same species and between individuals. Allowance should also be made for groups in the exposed population that may be particularly vulnerable to adverse effects such as the unborn child, young children, older people or people with particular health conditions such as asthma. In some cases it may be appropriate to assess toxicity separately for adults and children to take account of land use scenarios where children are or are not likely to be present. A brief description of how health-based reference values are derived and sources of toxicological information is provided in the Appendices to this draft guidance (section 5.12.1). When considering HCVs and other toxicological reference values, it is extremely important to read the small print in order to understand the uncertainty in the source data and the extent of conservatism in the UFs applied. The more uncertain the source data and more severe the health effect, then the greater the size of the UF that is appropriate. Consequently any SPOSH threshold value derived for a chemical for which there is limited toxicological data is likely to be more conservative (lower) than for a chemical for which there is good human data, in order to allow for these uncertainties.

5.6 **DEVELOPMENT OF SITE SPECIFIC ASSESSMENT CRITERIA (SSAC)**

**Overview**

The development of an SSAC for Part IIA involves estimating potential human exposure to a soil contaminant as a function of its concentration in soil and using this relationship together with a health-based assessment value in order to derive a calculated soil concentration believed to represent an intake that if exceeded, the risk of adverse effects would be unacceptable. SSACs are developed using a similar methodology as GACs but the model input parameters are based on site specific information and therefore better reflect site specific exposures. SSACs developed for the purposes of Part IIA should be based on the use that is currently being made, or is likely to be made, of the land, and which is consistent with any existing planning permission or otherwise lawful use under town and country planning legislation. This may require consideration of potential exposure routes that do not currently exist. Where sites are being assessed in relation to planning applications rather than Part IIA, land must be suitable for the intended use and developers must demonstrate that the associated risks to human health are acceptably low.
When undertaking DQRA the CSM should be reviewed to ensure that all relevant exposure pathways are included and pathways that are unlikely to exist at a specific site are excluded. In some circumstances, it might be desirable to generate separate SSACs for surface and more deeply buried soil to take account of differences in the potential for exposure, particularly if soil characteristics also change with depth. The potential for dermal contact, inhalation or accidental ingestion should be assessed together with the likely extent of any exposure.

Software to assist DQRA

There are a number of free and commercially available software tools available that are designed to assist in the development of health-based SSACs. In selecting a model it is essential that its operating mode enables assessment of the pollutant linkages detailed in the CSM for your site including potential exposure to soil vapours and vapours from groundwater. The model of choice should be appropriate to Scottish conditions in general and site and contaminant being assessed in particular. The CLEA[^49] or SNIFFER[^51] models are likely to be the most appropriate to use for most contaminants other than asbestos. The commercially available RBCA[^68] and RISC[^69] models are primarily designed for the US market, but have UK or European operating modes. These US packages include more sophisticated approaches to modelling contaminant behaviour in water and air than employed by CLEA and the relative contribution of these pathways to overall exposure will vary by contaminant. There are, however, UK-specific modelling tools such as ConSim for the water environment that are likely to be more appropriate. In considering models developed outside of the UK, it is important to take account of differences in the regulatory regime in Scotland versus that in place elsewhere and to ensure that relevant exposure pathways are included in the assessment. Whatever software is used to assist in the development of SSACs, it is important to be aware of the underlying assumptions about receptor, contaminant behaviour, soil properties and factors affecting exposure that are contained in the model. The appropriateness of these underlying assumptions to the site CSM must be considered and adjustments made to fit site specific conditions. More detail about the use of CLEA and the importance of reviewing the input parameters and assumptions underlying the model in a site specific context are given the Appendices to this draft guidance (Section 5.12.2).

The CLEA model is not appropriate for assessment of the risks associated with asbestos contaminated soils and at present there is no UK guidance for undertaking risk assessment for asbestos in soil. Information about fibre concentrations associated with different soil asbestos concentrations is available from IOM[^124] and RIVM[^125,126,127] reports. It is possible to estimate fibre concentrations associated with specific activities by using the IOM information in combination with modelled dust (not fibre) exposures developed using the Advanced REACH Tool (ART) for exposure modelling[^128]. Three different exposure response functions based on the findings of workplace studies[^129,130,131] are available for the purposes of risk quantification based on estimated fibre concentrations[^128,130,131].

[^128]: http://www.advancedreachtool.com/
Bioaccessibility

Bioaccessibility is the term used to describe the proportion of a contaminant in soil that is actually absorbed by a human receptor. Bioaccessibility has a substantial influence on received dose and associated risk and is being increasingly taken into account during DQRA in the UK. Both the CLEA and SNIFTER models have a facility to include bioaccessibility in the derivation of SSACs. The bioaccessibility of many substances is reduced by the presence of other substances in soil and is also related to particle size and surface area. Various experimental test systems have been developed in order to assess the bioaccessibility of contaminants in soils in order to inform the development of SSACs. These include the Physiologically Based Extraction Test (PBET) that replicates the chemical but not microbiological conditions in the stomach and small intestine. This test has been widely used in the UK. The BARGE Unified Method (UBM) has been derived from the Dutch RIVM physiologically based in vitro extraction test and has been calibrated against in vivo data. Neither system has been fully validated and there is a requirement for the future development of validated and harmonised internationally accepted methods that are recognised by the OECD and/or as an ISO-CEN standard by the European Committee for Standardisation.

Care is required in the interpretation of experimental data as experimental conditions will not completely replicate conditions in the human digestive system and the bioaccessibility of inhaled contaminants or contaminants in contact with the skin is very different from that following ingestion. In addition, the absorption of ingested substances is influenced by age and diet. It is also important to consider the chemical speciation of the contaminant of interest in the exposure on which the HCV is based. For example, many metals are more readily absorbed from soluble rather than insoluble compounds and may exert an apparently greater toxicity when administered to animals in a soluble rather than insoluble form. Particle size can have a substantial influence on bioaccessibility, partly because smaller particles have larger surface to volume ratios and are likely to dissolve more quickly but also because particle size governs the fate of inhaled particles. Particles less than about 5 µm in diameter are able to penetrate to the gas exchange region of the lung where high rates of blood flow to the alveoli may help to give rise to substantially greater levels of absorption than for ingested particles. The science of assessing bioaccessibility is still at a developing stage and there are substantial uncertainties in the data provided by current laboratory tests. The CIEH (2009) have produced a professional practice note on the interpretation of bioaccessibility information.

5.7 ANALYSIS OF UNCERTAINTIES

It is important to understand the uncertainties in the underlying data used in any decision making process. There are uncertainties both in the measured soil concentration data and in the exposure and toxicological information used to derive GACs or SSACs. Models such as CLEA provide a single figure estimate of a GAC or SSAC and it is tempting to attribute more certainty to the assessment criterion than is justified by the uncertainties in the data upon which it is based. Sources of uncertainty in model inputs should be described and the sensitivity of model outputs to uncertainties in the input data assessed. This requires the model to be tested with different input variables in order to determine which variables have the greatest influence on model outcomes. The linkage of soil concentrations of a contaminant to potential human exposure in models such as CLEA involves a multiplicative combination of a series of variables in order to estimate overall exposure. If a reasonable worst case estimate is made for each individual variable, the overall exposure estimate is likely to be an extreme worst case estimate (the multiplicative combination of three estimates of the 95th percentile value of individual exposure parameters will give rise a 99.99th percentile estimate of overall exposure). Although CLEA has been reworked to reduce this tendency towards over-estimation of “reasonable worst case”, it is still important to be aware of how estimates of the individual parameters influencing exposure combine and the potential to vastly the over-estimate reasonable worst case. In the future probabilistic modelling tools that take account of known or expected variability in input variables may enable a better assessment of the “reasonable worst case”. The US EPA have provided a description of the use of probabilistic modelling in contaminated land risk assessment but there is little information about the variability of many of the input values and no supporting software.

5.8 EXPOSURE TO MIXTURES

The development of SSACs considers individual contaminants in isolation and it is typical UK practice to assess most contaminants individually and make a qualitative assessment of the importance of
multiple contaminants in determining overall risk levels. Exceptions are for groups of closely related substances such as dioxin and dioxin-like substances and TPH where the group is treated as a single entity. The IGHRC have indicated that in assessing the potential risks of chemical mixtures, the effects of individual substances should be regarded as additive where they act by a common mechanism, or, if the mechanism of action is unknown, they act on the same target organ. For example, if two or more contaminants can give rise to related effects such as kidney damage (various metals) and are present at concentrations just below their SSACs, it would be prudent to allow for potential additive effects, unless there is good evidence that interactions do not occur. The most common approach to assessing the risk associated with chemical mixtures, particularly for chemicals that are likely to have related effects is to calculate a hazard index (HI). In this approach a hazard quotient (HQ) is calculated as the ratio of the intake or concentration of a substance relative to its reference value. The HI is the sum of the HQs for the individual substances and generally risks are considered to be adequately controlled if the HI is less than unity. This approach is endorsed by the Health Protection Agency for environmental exposures. It is also used in managing the risk associated with exposure to multiple substances in workplace air: concentrations of individual substances are compared with the relevant workplace exposure limit and the resultant ratios are summed as outlined by the UK Health and Safety Executive (HSE) in in EH40. The approach is described in detail by the US EPA who also provide guidance on how the HI can be modified to take account of anticipated interactions between chemicals.

5.9 CONSULTANTS REPORTS

Consultants who provide human health risk assessments for contaminated land must include in their report a description of the assumptions used to model human exposure in order to derive reported GACs, SSACs or risk estimates in their reports. This includes explicit description of the parameters entered into CLEA or other modelling tools that have been employed. Each assumption must be justified in relation to the specific site in question. In addition, the toxicological reference value used to derive the GAC or SSAC and its origin should be stated and justified. For example, a US EPA derived value may have been chosen because no UK value was available or because it is based on more recent information (e.g., a recently published well-conducted study in humans), and there is good reason to believe that it is more reliable than the UK value.

5.10 RISK COMMUNICATION AND COMMUNITY ENGAGEMENT

Under most circumstances where sites are being investigated in relation to Part IIA, it will be essential to engage with stakeholders including the local community as early possible in the process. In the first instance it is likely to be desirable to communicate with the NHS Public Health team and those within the LA likely to have an interest including the legal team, those responsible for liability and insurance and the communications team. The HPS have developed succinct guidance on risk communication that is likely to be helpful and the SNIFTER (2010) report on risk communication for contaminated land and the associated summary leaflet provide advice on good risk communication that is specific to contaminated land sites. Stakeholders, the message to be communicated and the method of communication should be decided at an early stage taking account of local community issues. The guidance describes a range of methods of community engagement and provides advice on key issues including building and maintaining trust.

5.11 SIGNIFICANT POSSIBILITY OF SIGNIFICANT HARM (SPOSH)

It is not the intention of this guidance to define SPOSH in a Scottish context beyond the definition provided in the Statutory Guidance. There are, however, several documents that may be helpful to those charged with determining SPOSH. The Royal Commission on Environmental Pollution has made some useful comments on setting environmental standards that are relevant including the need for a transparent and open decision process, adequate data and appropriate consideration of

The Department of Health (1997) guidance on communicating about risks to public health provides useful information on types of risk are most likely to be seen as unacceptable and about the risk of death from various causes which can be useful in providing context to numerical risk estimates. A Health and Safety Executive report describing risk in the workplace environment also provides useful information about the risk of death from a variety of causes during the course of normal day to day life. The CIEH statistical guidance is helpful to the determination of SPOSH and the other CIEH guidance on the suitability of land for housing and Part IIA determination may also assist in the decision making process.

In general terms, the assessment value for the determination of SPOSH for the purposes of Part IIA is likely to be higher than the assessment value that might be applied for the purposes of the planning regime (Fig. 5.1). The consideration of SPOSH is substance and site specific. In some circumstances, there are excellent human data and the threshold dose at which effects have been observed is known with a high level of confidence (i.e., the highest dose at which no effects are known to occur or the lowest dose at which minimal or otherwise specified effects have been reported). The toxicological assessment value corresponding to SPOSH can be set to be equivalent to this threshold dose, if the observed effects are deemed to be "significant". Otherwise this dose may be used to derive a SPOSH threshold by incorporating uncertainty factors to allow for the prevalence and severity of effect at the observed threshold.

**Figure 5.1:** Illustration of the relationships between the dose intake representing SPOSH or a reference dose and the primary data

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Lowest dose at which adverse effects observed in animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMD&lt;sub&gt;10&lt;/sub&gt;</td>
<td>Dose estimated to give a 10% incidence</td>
</tr>
<tr>
<td>BMDL&lt;sub&gt;10&lt;/sub&gt;</td>
<td>Lower bound estimate of BMD&lt;sub&gt;10&lt;/sub&gt;</td>
</tr>
<tr>
<td>NOAEL (rodent)</td>
<td>Dose at which no adverse effects observed in animals</td>
</tr>
<tr>
<td>NOAEL (HED)</td>
<td>Human equivalent dose - allows for size related metabolic differences or NOAEL established in human population</td>
</tr>
<tr>
<td>SPOSH</td>
<td>Upper bound of acceptable intake/lower bound of significant risk of significant adverse effects</td>
</tr>
<tr>
<td>HCV/SGV</td>
<td>Lower bound of dose that may be considered SPOSH</td>
</tr>
<tr>
<td></td>
<td>Extremely small risk of adverse effects</td>
</tr>
</tbody>
</table>

In other circumstances where there are only sparse data in animals and the adverse effect is life-threatening, it would be appropriate to apply a relatively large uncertainty factor and the toxicological assessment value might equate to a published reference value. Similarly, although some published toxicological reference values are highly conservative, others are much less protective and may be appropriate to use as the threshold for SPOSH. For most substances, the threshold in humans is not known, hence the published reference value is relatively conservative and the consequently the threshold for SPOSH should be set somewhere between the HCV (or equivalent) as a lower limit and the NOEAL (Human Equivalent Dose) as the upper permissible limit (Fig. 5.1). The benchmark dose (BMD<sub>10</sub>) or the lower bound estimate of BMD<sub>10</sub> may be helpful in the determination of a suitable
threshold level for the purposes of SPOSH. The BMD methodology allows comparison of a modelled exposure with the dose estimated to give an estimated incidence of effect of 10% based on experimental or epidemiological data. The size of the actual or modelled exposure relative to the BMD provides an indication of the potential risk to health: the larger the “margin of exposure” (ratio of BMDL to exposure), the smaller the risk of significant adverse effects. This is discussed further in the appendix to this draft guidance.

In addition, to uncertainties in setting an appropriate toxicological assessment value, there are also considerable uncertainties in the exposure assessment and the assumed behaviours that will lead to exposure. LAs should carefully review the parameters used in CLEA or similar model used in the determination of a SSAC for the purposes of Part IIA in order to eliminate unnecessary conservatism and take account of local circumstances.

Once a SSAC has been derived for the purposes of Part IIA, there is a requirement to demonstrate that that the exceedance of the assessment criteria for a given contaminant is statistically significant: the lower bound confidence limit on the calculated mean soil concentration should exceed the assessment criteria.

The LQM roadmap tool\(^{52}\) is specifically designed to assist in the determination of SPOSH. This tool maps dose-response information for individual contaminants from human and animal studies as a function of dose versus severity of adverse effect. The tool generates a plot of dose versus effect and the user can interrogate the data underlying each point to establish the source of the information and the nature of the study. The plot is intended to assist the user in the identification of a threshold dose, above which effects are likely to be unacceptable on the basis of previously published data in humans and/or animals. The utilisation of all the available dose-response information, visual nature of the tool and intuitive approach to determining the unacceptable dose are very attractive features. The tool should, however, be used with caution for the following reasons:

- Doses have not been scaled to human equivalent intakes;
- Effects on the respiratory system have been treated as if they were systemic effects rather than considered in terms of dose at the target organ (concentration in air);
- Groups of experimental animals, human volunteers or workers do not include the full range of susceptibility likely to be present in the general population and an uncertainty factor should be allowed for the potential presence of more vulnerable groups such as young children;
- Marked differences in susceptibility to individual contaminants has been reported in experiments in different species and in different strains of the same species, and an uncertainty factor should be allowed for the possibility that humans may be considerably more sensitive to effects that the experimental species; and
- Duration of exposure has a substantial impact on the apparent threshold for toxicity and LOAELs and NOAELs reported in lifetime studies in animals are usually much lower than those reported in 13 week subchronic experiments.

The choice of an appropriate point to use as a “SPOSH” threshold form the data cloud developed by the roadmap tool therefore requires a considerable understanding of the toxicological limitations of the underlying data to avoid adopting a misleadingly high potential value.

Although HCVs are not intended to be used as criteria in the context of Part IIA, they may provide a useful starting point for determining a site specific toxicological reference value. Examination of the underlying toxicological evidence base and the uncertainty factors employed in deriving the HCV may assist in determining a local reference value based on the same toxicological evidence but incorporating smaller uncertainty factors while taking account of the factors noted above in relation to the LQM roadmap tool\(^{52}\).
5.12 APPENDICES TO DRAFT GUIDANCE

5.12.1 Derivation of Toxicological Reference Values

**Derivation of health-based limits for contaminant intakes**

Part IIA requires an assessment of whether risks to health are unacceptable (where unacceptable is defined in terms of the definition of SPOSH as significant risk of significant harm). The toxicological database for many substances is incomplete and the results of different studies may be inconsistent. The human health criteria values (HCVs) provided in CLEA represent levels of intake believed to give rise to no risk to human health (tolerable daily intake) for substances that have a threshold of effect and minimal risk (index dose) for non-threshold substances such as genotoxic carcinogens. Intakes that exceed HCVs do not necessarily represent exposure to unacceptable risk. Reference values available from other sources are similarly (usually) set at levels of minimal risk. EA guidance (SR2) describes how HCVs are derived and the available HCVs are supported by toxicological reference documents.

**No effects and lowest effects levels and the benchmark dose**

The methodology outlined in SR2 is based on the identification of no and lowest observed adverse effects levels (NOAEL/LOAEL) for threshold substances and the use of uncertainty factors to derive an HCV. The apparent NOAEL or LOAEL in an experiment is heavily influenced by the choice of dose interval and the number of animals in each exposed group (as group size increases, the range of susceptibility increases and effects may be observed at lower doses). For non-threshold substances, a benchmark dose (BMD; usually BMDL10; the lower bound estimate of the dose believed to give rise to a 10% incidence of effect based on lifetime exposure) is derived and an estimate made of the intake associated with an increase in cancer risk of 1 in 100,000. The development of a BMD makes use of the full experimental data set and is less influenced by experimental design than the NOAEL/LOAEL. The use of BMDs is now recommended for the assessment of both threshold and non-threshold substances by the UK Government’s Interdepartmental Committee on Chemical Risk Assessment. It is possible to calculate the BMD from a published set of experimental findings using the free to download software developed by the US EPA and the associated guidance.

**Scaling for size-related species differences in metabolism**

Most authorities incorporate a scaling factor to convert doses in animal experiments to a human equivalent intake as mg/kg/day for systemic exposure. This is because size and metabolic rate are linked and the effective systemic dose associated with a given intake as mg/kg is bigger for small animals such as mice and rats than for humans. There are differences in the scaling factors used by different organisations, but the allometric (size-related) scaling factors given in guidance for REACH are well supported (Table 5.1). For direct effects on the respiratory system, inhalation concentrations are usually assumed to be equivalent for different species (after scaling for duration of exposure) but some authorities do derive “human equivalent concentrations”.

**Table 5.1:** Allometric scaling factors outlined in the guidance for REACH that are intended to allow for size-related difference in metabolism

<table>
<thead>
<tr>
<th></th>
<th>Dose (mg/kg) equivalent to 1 mg/kg in humans</th>
<th>Human dose (mg/kg) equivalent to 1 mg/kg in other species</th>
<th>Dose (mg) equivalent to 1 mg/kg in other species in 70 kg adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>1</td>
<td>1</td>
<td>70</td>
</tr>
<tr>
<td>Rat</td>
<td>4</td>
<td>0.24</td>
<td>16.8</td>
</tr>
<tr>
<td>Mouse</td>
<td>7</td>
<td>0.14</td>
<td>9.8</td>
</tr>
<tr>
<td>Hamster</td>
<td>5</td>
<td>0.20</td>
<td>14</td>
</tr>
<tr>
<td>Guinea pig</td>
<td>3</td>
<td>0.33</td>
<td>23.1</td>
</tr>
<tr>
<td>Rabbit</td>
<td>2.4</td>
<td>0.42</td>
<td>29.4</td>
</tr>
<tr>
<td>Monkey</td>
<td>2</td>
<td>0.50</td>
<td>35</td>
</tr>
<tr>
<td>Dog</td>
<td>1.4</td>
<td>0.71</td>
<td>49.7</td>
</tr>
</tbody>
</table>
**Uncertainty factors**

HCVs and other published reference values are determined using large uncertainty factors (UFs) in order to ensure that intakes are controlled well below the levels at which harm could arise whereas under Part IIA, LAs are required to determine the level of intake above which harm is likely to occur. UFs used in setting HCVs and other reference values are based on expert judgement and usually take account of the seriousness of the health endpoint. Typically factors of x10, x5 and x5 are allowed for interspecies differences, interindividual (intraspecies) variability, conversion from LOAEL to NOAEL and extrapolation from subchronic (13 weeks) to lifetime (2 years in rats and mice), respectively. Further factors may be added to allow for route to route extrapolation (calculating an inhalation concentration on the basis of oral intake) and/or the quality of the information base.

In determining the dose that could be considered unacceptable for the purposes of Part IIA, the size of the UFs are likely be smaller than for the HCV but should allow for potentially substantial differences in response between species and strains of the same species and between individuals. Where significant shortening of life and/or severely disabling chronic disease are possible, it would be prudent to allow an overall factor of at least 100 (for the NOAEL in lifetime studies) in order to be confident that human exposures would not cause harm. For less serious effects, a smaller factor may be acceptable. For studies of less than lifetime duration, experience suggests that the convention of using a factor of 5 to extrapolate from a 3 month study to 2 year lifetime study in rodents is reasonable.

**Margin of exposure based on the BMDL**

The ratio of the BMDL to the expected human exposure is termed the Margin of Exposure (MoE). A large MoE implies a small risk. When the BMDL is used in setting reference values, the size of the MoE can be selected to reflect uncertainties in the data and the severity of effect. A MoE of 10,000 based on BMDL_{10}, implies a dose level that is 0.01% of that associated with a 10% risk of the effect. Although not strictly equivalent to a risk of one in 100,000 because the shape of the exposure-response function at low doses may be poorly understood, this method has historically been used to estimate the risk of cancer or other adverse effects at low levels of exposure.

**Sources of toxicological information**

In addition to the toxicological reference documents developed by the EA and Defra, there are a number of sources of toxicological information listed at the back of SR2. The most useful are the:

- International Programme for Chemical Safety (IPCS) website: [www.inchem.org](http://www.inchem.org) particularly the Environmental Health Criteria Monographs, the Concise International Chemical Assessment Documents and the summaries of the International Agency for Research into Cancer (IARC evaluations);
- US EPA Integrated Risk Information System: [www.epa.gov/iris](http://www.epa.gov/iris)
- US Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles: [wwwatds.gov/atsdr](http://wwwatds.gov/atsdr)
- Health Protection Agency (HPA)
- Defra Expert Panel on Air Quality Standards (EPAQS) – air only, relatively few substances
- World Health Organisation (WHO): Air quality guidelines for Europe (2nd Edition); Drinking water guidelines (some of these are quite old and may not reflect current thinking)

Some of these organisations have published toxicological reference values that it is believed that an individual can be repeatedly exposed to without harm. Different organisations have developed different recommendations for individual substances as a result of having reviewed different experimental data or used different UFs or different approaches to deriving a reference dose. It is important to read the documentation supporting any recommendation and the strength of the underlying evidence. Care should be taken in determining whether published values are relevant to Scotland. Both the US EPA and the WHO/IPCS present reference values for carcinogens based on numerical risk estimates derived using an approach not endorsed by the UK Committee on Toxicity.

Generally documents produced by the UK organisations and the WHO/IPCS should be given greater weighting than documents produced elsewhere but the date and purpose of the review, the date of
the reviewed data (which may be much older), review methods and scope must be taken into account. Some reviews are based on a partial review of the available literature either because they were not intended to be comprehensive or because they were undertaken a long time ago. An internet search with a tool such as Google may identify a recent review of health effects by another competent organisation such as national authorities in other European countries, Canada, Australia or New Zealand. Existing reviews may predate important new epidemiological or toxicological studies that ought to be included in a substance review. Such studies can usually be identified using PubMed (http://www.ncbi.nlm.nih.gov/pubmed)—a free to access, searchable database of peer reviewed studies relevant to health maintained by the US National Institutes of health.

Reliability of toxicological data

Not all published toxicological findings are equally reliable. Toxicological information described in existing reviews has normally undergone a quality assessment and any information that is considered less reliable is highlighted. Organisations such as US EPA, WHO, EA may exclude studies because of poor design, poor health of unexposed control animals, inappropriate dosing regime or health endpoints considered or because the findings in animals are unlikely to be relevant to humans (eg tumours in an organ that we don’t possess). There is much greater certainty where a reference dose is based on one study representative of the results of several studies than where there are substantial between study variations in apparent risk.

Issues to consider when reviewing primary studies from the peer reviewed literature include whether a standard OECD protocol has been followed, the number of animals and doses, the inclusion of unexposed controls, the relevance of the dosing regime, duration of exposure and observed effects to human exposure and the uncertainties in reported findings, particularly in relation to whether observed effects were statistically significant.

If reviewing human data, it is also appropriate to consider whether appropriate unexposed controls (matched for age, gender and socio-economic status and smoking) have been included in the study, the confidence limits on any reported findings, the size of study and its power to detect an effect (reflected in the size of the confidence limits), the reliability of the exposure assessment used to derive exposure-response relationships, the health endpoints considered and those not included, and whether the follow up time was sufficient to detect an adverse effect (for example, there may be a latency of up to 40 years before the carcinogenic effects of some substances such as asbestos become apparent). In most circumstances, human data should be given greater weight than data from animal experiments, but consideration should also be given to the quantity and quality of data available. Information from a large, well conducted animal experiment may provide a better basis for determining a reference value than a poorly reported, anecdotal account of human experience.

Vulnerable individuals

If possible, the toxicological review should identify groups that are potentially particularly vulnerable to adverse effects such as the unborn child, young children, older people or people with particular health conditions such as asthma. It is important to take account of these “vulnerable individuals”, if they are in the population at risk. In some cases it may be appropriate to assess toxicity separately for adults and children to take account of land use scenarios where children are or are not likely to be present.

Summary

The level of intake that is likely to be considered unacceptable in the context of Part IIA is likely to exceed that associated with HCVs and other reference doses but in general terms is likely to be less than a recognised LOAEL or indeed NOAEL due to the need to account for methodological uncertainties in deriving such values based on animal experiments. Account must be taken of both interspecies and inter-individual differences in susceptibility. The following criteria should be met when considering toxicological data for use in deriving a SPOSH value:

- the study/studies was/were well conducted,
- the findings were relevant to humans
- and the overall uncertainty factor is reduced to the lowest level that is defensible.
5.12.2 Use of the CLEA software

The CLEA model incorporates a number of assumptions about human behaviours and other factors influencing exposure that are described in the supporting guidance (SR3)\textsuperscript{6}. The US EPA Exposure Factors Handbook\textsuperscript{66} provides a considerably more comprehensive (but US-based) information source about the factors that influence human exposure that is useful in relation to reviewing the plausibility of assumptions within CLEA and is also helpful, together with SR3, where it is desirable to develop a site specific exposure model from first principles. Updated information on exposure parameters (for example, newer studies of the concentration of soil contaminants in indoor air or house dust) may also be available in more recently published studies that can be identified using PubMed or visiting the US EPA Exposure Research webpages. The CLEA model draws on UK HCVs, but these are only available for a relatively select number of contaminants and do not represent the lower bound of unacceptable intake as required for decision making in relation to Part IIA.

Land use

The standard land uses for which generic settings are available in CLEA are residential with and without homegrown produce, allotment and commercial. Other land uses such as education, healthcare, recreational land or animal husbandry are not included as generic land uses. It is easy to add extra land uses and to create specific scenarios using the model in “advanced” mode. The required input includes information about duration and intensity of exposure by different pathways by age class (AC), building and soil type and dispersion factors. SLR3 provides guidance on generic factors that can be used where site specific data are not available.

Receptors

Identification of receptors: the generic scenarios in CLEA include assumptions about receptors and the most sensitive receptor that may not be appropriate to the local context, for example, in housing specifically designed for older people or where the commercial use of land involves children. Where additional land uses that cannot be adequately described by the generic scenarios in CLEA are considered, then the receptor characteristics should be added. The assumptions about receptors must be defensible and clearly documented.

User habits: the assumptions made about receptor behaviour in the CLEA model for generic land uses were based on an extensive body of research but may be inappropriate in a local context and/or may be likely to substantially over predict exposures and be uninformative in the context of determining unacceptable intakes for Part IIA. The plausibility of generic assumptions should be carefully assessed while bearing in mind that Part IIA is based on consented use. Any changes to default assumptions for generic scenarios within CLEA must be clearly justified. For example, the results of observation or a local survey may indicate that the use that people make of their gardens or allotments is very different from that assumed in SR3 and it may be possible to demonstrate that the pattern of use is unlikely to change in the future. People living in properties with extremely small gardens, for example, can only grow small quantities of fruit and vegetable. The occupancy of commercial buildings is likely to be variable. For example, workers at a bonded warehouse, food processing plant, manufacturing plant or retail park would have different shift patterns. It may be necessary to develop site specific estimates of occupancy – for example, the number of days in a year and hours in a day that a child is inside a school building or in the playground.

Exposure pathways

When undertaking DQRA the CSM should be reviewed to ensure that all relevant exposure pathways are included and pathways that are unlikely to exist at a specific site are excluded. The CLEA model does not take account of the depth of buried contamination (other than in relation to vapour behaviour) and calculates SSACs as if contaminants are present in shallowly buried soils. In terms of direct impacts on human health, contaminants buried at depths below 0.6 m are unlikely to be frequently disturbed by human behaviour and are not available to most plants. Abnormal activities such as digging ponds, foundations or service trenches should be taken into account but with allowance for the infrequency of exposure compared to potential contact with more shallowly buried soil. Similarly account should be taken of deeply rooted fruit trees and bushes and, in some circumstances, the potential for burrowing animals to bring soil to the surface (few domestic gardens
are likely host badger sets, foxes’ earths or rabbit warrens). It might be desirable to generate separate SSACs for surface and more deeply buried soil, particularly if soil characteristics also change with depth. The potential for dermal contact, inhalation or accidental ingestion should be assessed together with the likely extent of any exposure.

Building characteristics

The characteristics of a range of default buildings are included in the CLEA database. There is a facility to add additional buildings and building characteristics. These characteristics include a number of parameters that are likely to be difficult to measure in specific circumstances such as indoor air exchange rates, dust loading factor and soil gas ingress rate. It is important to test the sensitivity of the model output to the assumptions made in deriving these parameters for both standard building types included in the model and for additional building types added by the user.

Site specific Input parameters

When considering the use of site specific parameters it should always be borne in mind that in terms of Part IIA Local Authorities are required to consider “current use”; use that is currently being made, or is likely to be made, of the land, and which is consistent with any existing planning permission or is otherwise lawful under town and country planning legislation.

Soil type: soil has a substantial influence on the mobility of contaminants and their availability to receptors and will impact on the modelled SSAC. The risk assessment should take account of the variability of soil types present on the site and the influence of choice of soil type on modelled SSACs for different types of contaminant (if relevant). Site specific data should be gathered during the investigation to enable assessment.

Soil properties: the CLEA model provides default values for each soil type of porosity (total, air-filled, water-filled), residual soil water content, saturated hydraulic conductivity, van Genuchten shape parameter, bulk density, threshold value of wind speed at 10 m, empirical function for dust model and ambient soil temperature. There is the facility, however, for the user to modify these values on the basis of measured or estimated site specific values. Such modifications should be recorded to ensure transparency and defensibility.

Air quality measurements: the CLEA model will estimate indoor and outdoor concentrations of a contaminant in air but allows site specific data to be entered. It would be necessarily to undertake monitoring for at least three months and preferably longer in order (three months in the winter months and three months in the summer months) to derive representative measurements for indoor or outdoor air quality. Measurements made over shorter periods are unlikely to be representative of long term mean concentrations. It may, however, be appropriate to review measured concentrations of airborne particles in the local area. There is also a substantial body of published information about indoor air quality that may be relevant. Where air quality data are not available, the CLEA model can generate site specific estimates of indoor and outdoor concentrations in air on the basis of site specific parameters including mean annual windspeed, air dispersion factor, fraction of site with hard or vegetative cover, soil gas ingress rate and depth to top of source.

Plant uptake: the CLEA model will estimate contaminant levels in produce, but also allows site specific measurements to be entered. As indicated in SR3, there are large uncertainties in the assumptions used within CLEA to model exposure to contaminants in produce and, it may be desirable to undertake site specific measurements for a representative selection of plant types at sites where exposure in produce is potentially significant. Even where site specific data are available, there are still substantial uncertainties about plant uptake arising from interspecies differences (eg between lettuce and kale) in growth behaviour and contaminant uptake as well as the influence of conditions during different growing seasons and different cultivation practices (eg adding composted manure prior to planting or mulching between rows). If an investigation of plant uptake is undertaken, it is


important that sufficient samples of relevant types of material are collected and analysed in order to adequately characterise the uptake of relevant different plant groups (leaf, root, tuber, tree, shrub or herb fruit) from a well characterised soil that is representative of the site.

The CLEA model incorporates generic assumptions for all these parameters with supporting documentation in SLR3. Where site specific information is not available, some investigation of the potential variability of these parameters and their influence on the modelled SSAC is appropriate.
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