HUMAN HEALTH RISK ASSESSMENT AND ITS ROLE IN BROWNFIELD REDEVELOPMENT

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ABSTRACT

Human Health Risk Assessment is a complex science requiring input from a range of disciplines each with its own inherent uncertainty. These uncertainties arise both from the use of scarce and inconclusive toxicological data to predict health effects and the need to represent the behaviour and sensitivity of many individuals with generic assumptions. However, when used effectively and within a specific context, Human Health Risk Assessment is a useful and necessary tool within the management of land contamination. Within the UK, Human Health Risk Assessment is used as a specific tool under the Contaminated Land and Planning Regimes and is supported by a range of technical guidance documents. In Ireland, the concept of risk-based assessment in all areas of environmental management has been broadly adopted; however, human health risk assessment for contaminated land is largely restricted to use of generic assessment criteria, developed by other nations. In the light of the recent withdrawal of the UK Soil Guideline Values, and the resulting uncertainty on how to proceed, there is a need for a clearer understanding of the purpose and limitations of human health risk assessment tools. In particular the role of the conceptual model in reducing costs from inappropriate assessment and remedial action.

INTRODUCTION

With respect to brownfield redevelopment the term "human health risk assessment" generally has a narrow scope and relates specifically to risks to human health caused by exposure to contaminants within soils and groundwater. Human Health Risk Assessment (HHRA) in this sense should not be confused with Human Health Impact Assessment which has a much wider remit, covering any health impacts, both physical and psychological arising from any aspect of a proposed development. National approaches and guidelines with respect to HHRA for contaminated land have generally been developed for a specific purpose, with a defined scope and a number of limiting assumptions. Therefore, it is important to understand the context in which HHRA sits within the wider issue of contaminated land management and its regulatory context.

Currently, Ireland has no established methodology for the assessment of risks to human health from contaminated soils or groundwater and there is a growing consensus that Ireland should adopt the approach currently being used by the UK. However, before this can occur , it is necessary to understand both the scientific and technical assumptions underpinning this favoured methodology, as well as the regulatory context of the UK risk assessment approach and its relationship to the situation in Ireland.

CONTAMINATED LAND AND HUMAN HEALTH RISK ASSESSMENT IN UK LEGISLATION

The UK has a rich industrial heritage, which has resulted in a legacy of "brownfield" or potentially contaminated sites. The issue of land affected by historical contamination is addressed within the Contaminated Land and Planning regimes. Prevention of pollution from ongoing activities is managed under the Pollution Prevention and Control Regime (PPC).

The Contaminated Land Regime as set out in Part IIA of the Environmental Protection Act, 1990, came into effect in England in April 2000, and provides a regulatory framework for the identification and remediation of land affected by historical contamination. PartIIA provides a statutory definition of "Contaminated Land" and is based on a "suitable for use" approach, which is focused on identifying unacceptable risks, i.e. those which give rise to "significant possibility of significant harm" to human and environmental receptors. These risks are assessed on the basis of the current land use, or any use for which planning permission has already been obtained but not implemented. PartIIA also sets out liabilities incurred by those found to have caused or be in possession of contaminated land. The regime is implemented by specific regulations[1] and statutory guidance[2] published by Department of Environment Food and Rural Affairs (Defra) and is supported by various non-statutory technical guidance[3] and advice published by the Environment Agency (England and Wales)(EA), Defra and other

[1] Contaminated Land (England) Regulations 2006
[2] Defra Circular 01/2006
[3] Includes CLR series of reports published by the Environment Agency

organisations[4]. Similar regimes were introduced in Scotland and Wales in July 2000 and July 2001, respectively. A contaminated land regime has yet to be formally introduced within Northern Ireland, although all the principles have been adopted as best practice. Statutory guidance on *"The Waste and Contaminated Land (Northern Ireland) Order 1997: Part 3"* is available[5] and will be enacted towards the end of 2009.

Part IIA was designed and intended to encourage voluntary remediation through the Planning Regime, whilst also providing a driver for assessment and remediation of brownfield sites not intended for a change in land-use. Under the Planning Regime, land contamination, or the possibility of such, is a "material consideration" for Town and Country Planning with respect to both Area Development Plans and individual planning applications[6]. The Planning Regime considers all land potentially affected by contamination regardless of whether it meets the statutory definition of "Contaminated Land" under PartIIA and applies to both the current and proposed use of the site. However, when it comes to identifying the presence or absence of unacceptable risks, the Planning Regime adopts the principles of risk assessment, which underpin PartIIA.

The broad principles of risk assessment are applied across all areas of environmental policy and decision making within the UK[7] and the concept of risk together with the concept of the "Pollutant Linkage" or the source, pathway, receptor approach is clearly defined within the PartIIA statutory guidance.

The specific approach to the management of land affected by contamination is set out in the Model Procedures for the Management of Land Contamination (CLR11), which is non-statutory technical guidance produced by the EA and Defra and can be applied equally under PartIIA and the Planning Regime. The Model Procedures present a three-phase approach comprising Risk Assessment, Options Appraisal and Remediation Design and Implementation. The Risk Assessment phase is a tiered approach applicable to all receptors, not just human health, central to which is the development of a conceptual model:

1. **Preliminary Risk Assessment**: initial development of the conceptual model to identify sources, pathways and receptors;
2. **Generic Quantitative Risk Assessment**: Comparison of observed soil environmental concentrations with generic assessment criteria and refinement of conceptual model; and
3. **Detailed Quantitative Risk Assessment**: Refinement of conceptual model based on site specific details of subsurface environment and human behaviour and use of mathematical algorithms to determine site specific assessment criteria.

Most countries with a formalised methodology for risk assessment have adopted a similar tiered approach, with the degree of complexity increasing with each tier and conversely the level of uncertainty reducing.

Specific technical guidance on assessment of risks to human health from soils, which includes the Contaminated Land Exposure Assessment (CLEA) Model[8], and guidance on toxicological assessment[9] has been published by the EA along with a software tool[10]. These have been designed to aid the derivation of assessment criteria for the purpose of identifying potentially unacceptable risks to human health in the context of the regulatory regime and to identify the need for remediation. The term remediation is defined within Part IIA and can include, additional risk assessment and investigation, long term monitoring and/or engineering solutions. This is intended to ensure that remedial measures are proportionate and limited to mitigating unacceptable risks by breaking the pollutant linkage.

CONTAMINATED LAND WITHIN IRELAND

In contrast to the UK, historical industrial development within the Republic of Ireland has been restricted primarily to the main port cities. Therefore, land affected by contamination is less widespread and is related primarily to unregulated disposal of waste, agricultural practices and point source releases to ground from discrete sites.

There is no statutory definition of "Contaminated Land" within Ireland, and the term is generally used to refer to all land affected by land contamination. The issue of contamination is covered in a number of existing legislative acts; which are focused primarily on ensuring prevention of pollution from ongoing activities rather than driving clean up from historical use. To date, remedial action with respect to contaminated soils has been driven by the planning and

[4] Includes Chartered Institute of Environmental Health and Health and Safety Executive
[5] Statutory Guidance issued by Department of the Environment, Northern Ireland
[6] Planning Policy Statement 23
[7] Defra, 2000
[8] Formerly CLR10 (EA,2002) superseded by Science report SC050021/SR3 (EA,2008b)
[9] Formerly CLR9 (2002) superseded by Science Report SC050021/SR2 (EA,2008a)
[10] CLEA UK Software tool

development process and more recently by the requirement for local authorities to identify and assess unregulated waste disposal sites.

The principles of risk assessment, including the concept of the source-pathway-receptor linkage, have been adopted by the Environmental Protection Agency (EPA) for the assessment of Environmental Liabilities[11] and Unregulated Waste Disposal Sites[12]. However, there remains no formalised approach to the assessment of risks to human health from contaminated soils or groundwater.

In the absence of a relevant Irish guidance it has become general practice to reference the UK approach of CLR11 and the CLEA model (and other associated technical guidance) when faced with the issue of land contamination. However, in practice detailed quantitative risk assessment, such as that described in the technical guidance, is rarely applied in the Ireland. Instead risk assessment tends to be confined to the generic quantitative stage with dependence on generic assessment criteria derived by other Nations (in particular the Netherlands and the UK) to address the issue of contaminated land[13].

It is not uncommon for practitioners in Ireland to use criteria derived for assessment of contaminated land, alongside regulatory standards derived for other purposes. An example of this would be the use of the Waste Acceptance Criteria, as pollution of soil and groundwater in Ireland commonly occurs from the unregulated disposal of waste. This has led to considerable confusion among environmental practitioners, planners and regulators about the fundamental differences between waste and contaminated land which in some cases has led to the word "hazardous" being considered synonymous with "contaminated". In actuality, the principles of risk assessment and in particular the source-pathway-receptor approach allows that a "hazard", which could include material designated as "hazardous" under Council Decision 2003/33/EC[14] does not necessarily present a risk to environmental or human health receptors.

Confusion in the proper application of generic assessment criteria and the risk assessment methodologies used to derive them will inevitably introduce additional uncertainty into the decision making process and will result in unnecessary or inappropriate proposals for remediation. Given that "remediation" within Ireland is generally taken to mean physical removal or treatment of soil, the uncertain or inappropriate assessment of potential risks can result in disproportionate action with unnecessary expenditure on behalf of both public and private bodies.

In order to be able to use human health risk assessment for effective decision making with respect to the need for, and nature of remediation, it is necessary to appreciate the basic principles and assumptions behind generic assessment criteria and risk assessment tools. It is also critical to be mindful of the limitations and uncertainties associated with these. This can be illustrated by the example of the CLEA model within the UK.

LIMITATIONS OF HUMAN HEALTH RISK ASSESSMENT AND THE CLEA MODEL

Risk is defined as *"the combination of the probability, or frequency of occurrence of a defined hazard and the magnitude of the consequences of the occurrence"* (Defra, 2000). In relation to risks to human health from soils, the estimation of risk is achieved by comparing two factors. The first, termed the exposure concentration, is the amount of a contaminant that a person can take into their body, based on their behaviour and the fate and transport of the particular contaminant. The second, termed the health criteria value, is the concentration of a contaminant that would result in health effects based on its toxicology. If the exposure concentration of a contaminant exceeds its health criteria value, it can be concluded that there is a potential risk to human health from exposure to a contaminant at a particular concentration.

This does not in and of itself determine the degree of significance of the risk, instead it is the final step, the risk evaluation, which presents the greatest challenge to risk assessors and regulators. Both Part IIA and the Planning Regime in the UK are based on the concept of identifying and mitigating the occurrence of "unacceptable risks" or "significant possibility of significant harm"(SPOSH). The difficulty is that there is no quantifiable benchmark to define either of these terms.

Part IIA requires that any risk assessment guidance or tool used in the determination of "Contaminated Land" should be scientifically based, authoritative and relevant. The non-statutory technical guidance, which includes the CLEA model, was designed by the EA to meet these specific requirements. The technical guidance sets out the assumptions and methods used by the EA to derive Soil Guideline Values (SGVs) for selected contaminants. The SGVs are

[11] EPA, 2006
[12] EPA 2007
[13] Cleary & O'Shea, 2007
[14] Council Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills

generic assessment criteria for use in assessing risks to human health from soils and are based on a defined conceptual model developed to represent a particular land use scenario. The purpose of generic assessment criteria, such as the SGVs, is to reduce the need for detailed quantitative risk assessment. However, if the conceptual model of the site being assessed is not comparable with that used to derive the SGVs, site specific criteria, rather than the SGVs, is required in order to assess risks to human health. This would be the case for land-use scenarios not defined within the CLEA model such as public open space or a school.

The SGVs were intended as indicators of unacceptable risk to human health with respect to soil concentrations, such that an exceedence of the SGVs indicated unacceptable risk. This would result in the site being classified as contaminated land under Part IIA, thus requiring remedial action. However, due to the inherent uncertainty and the conservative nature of some of the assumptions within the technical guidance a consensus of opinion emerged that an exceedence of an SGV did not necessarily constitute unacceptable risk, but rather a non-exceedence indicated the absence of unacceptable risk.

A taskforce was set up in 2004 to investigate a number of issues associated with the practical use of the SGVs, including the emerging belief that they represented too stringent a benchmark. Defra took leadership of the taskforce in 2005 and in 2006 published its findings in a document known as the Way Forward[15]. This document was intended to encourage wider stakeholder engagement on the use of SGVs as well as the technical guidance used to identify unacceptable risk.

The document identified the level of complexity involved in establishing a risk assessment framework which could be used both for the derivation of generic assessment criteria and site-specific assessment. It also acknowledged the scientific and practical limitations to determining an exact level of risk for different intakes across a range and combination of substances.

The document identified a number of areas of uncertainty within the technical guidance including:

- The toxicological assessment and the process of deriving health criteria values from limited data sets;
- Assumptions about human behaviour and selection of certain algorithms to represent particular exposure pathways; and,
- The role of generic assumptions in site-specific decision making.

Proposals were made to revise the technical basis of the CLEA model and the methodologies used to derive health criteria values, the most radical proposal being to set a benchmark value for non-threshold contaminants. This benchmark would define unacceptable intake based on modelled estimates of excess lifetime cancer risk, i.e. toxicological data would be used to define the point at which significant possibility of significant harm occurred.

The result of this consultation process[16] was the withdrawal of the SGVs in August 2008 and a revision of the non-statutory technical guidance, including the CLEA model, and the approach to derivation of health criteria values from toxicological data. However, the more radical benchmarking idea was not adopted on the basis that to do so would be to change the technical guidance such that it would define the legal trigger point of unacceptable risk and significant possibility of significant harm. Given the uncertainties associated with estimates of excess lifetime cancer risk this approach would not have met the requirements of Part IIA as representing good science. Moreover there was considered to be a legal complication in using non-statutory guidance to indicate a legal trigger point.

Revised technical guidance[17] and an improved software tool have been issued and new SGVs are currently being developed. In the meantime risk practitioners are being encouraged to develop site-specific criteria which, while frustrating and potentially costly, has highlighted the need to understand the assumptions behind a risk assessment tool. This has placed greater importance upon developing a detailed and relevant conceptual model at the preliminary risk assessment stage, which will:

- Drive the need for further investigation;
- Provide a focus for quantitative risk assessment; and,
- Ultimately determine the nature of remediation required.

The changes to the UK technical guidance appear to have been generally ignored within Ireland with continued use of the former SGVs and Dutch Guidelines as “trigger values”.

[15] Defra, 2006b
[16] Bulletin Issued by Defra, 2008
[17] EA, 2008a&b

CONCLUSIONS

In the UK there is a clear regulatory regime, based on the principles of risk assessment for the management of land affected by contamination. Human health risk assessment plays a well-established and specific role within this regulatory context. In contrast Ireland does not necessarily have a need for a regulatory regime to manage contaminated land given the lack of industrial heritage. However, Ireland is yet to fully embrace human health risk assessment as a decision-making tool in relation to land contamination issues, either historic or contemporary, despite promoting risk based assessment in all areas of environmental management.

The recent revision of the technical guidance and withdrawal of generic assessment criteria within the UK, due to uncertainty over their context within a defined regulatory regime, has highlighted the importance of a thorough understanding of the technical basis behind a risk assessment tool and the manner in which it should be applied. Despite the availability of robust technical guidance, decisions made with respect to contaminated land in the UK are still essentially a judgement call, making it essential that all assumptions made within the risk assessment process are relevant and justifiable and presented within a comprehensive conceptual model.

In the Republic of Ireland there is no requirement to use a particular risk assessment tool (including generic assessment criteria). The former SGVs along with other generic assessment criteria continue to be used as a "screening value" purportedly to place data in context although in reality they are being used in the decision making process. While this is not necessarily wrong within the Irish legislative context, the legal and technical context in which decisions on contaminated land are being made is perhaps not as well understood as it should be.

Risk based assessment is inevitably going to play a key role within all areas of environmental policy and decision making within the Ireland in the future. In the current economic climate there is a need for spending to be as cost efficient as possible. This requires remedial solutions to be pragmatic as well as sustainable. This can only be achieved through robust and appropriate assessment, the basis of which is a thorough understanding of the conceptual model and how that relates to the tools being applied. The earlier that this understanding is developed within the lifecycle of the project, the more cost effective the assessment and remediation process will be.

The warning that Ireland should heed from the UK is that even with a clear regulatory context for the use of a particular risk assessment tool, there is still scope for considerable uncertainty and confusion. The key to managing that uncertainty is to have an appreciation of the scientific basis and regulatory objective behind any approach. Practitioners in Ireland have a greater freedom than their UK counterparts in the selection and application of risk assessment tools; although, this places greater responsibility on the individual to ensure that the selected approach is appropriate and defensible.

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