

# THE SOIL AND GROUNDWATER TECHNOLOGY ASSOCIATION

## SAGTA REPORT 20 - HUMAN HEALTH RISK ASSESSMENT

### Introduction

On 5<sup>th</sup> March 2003 SAGTA held a workshop, hosted by Innogy, on the current status of the science and the application of human health risk assessment within the UK contaminated land regulatory framework. The workshop was attended by SAGTA members, representatives from the Department of Health, Environment Agency (EA), Local Authorities (LAs) and environmental consultants engaged on development of guidance.

The objectives of the workshop were wide ranging:

- To review the current thinking on the development of Soil Guideline Values (SGVs) through use of the Contaminated Land Exposure Assessment (CLEA) model, including the toxicological basis for risk assessment
- To gain a better understanding of:
  - effects of using different quantitative risk assessment models and SGVs
  - linkages between measurement and modelling
  - use of SGVs and HHRA in decision support, including communication between stakeholders
  - the effect of background concentrations on the communication and decision making process.

It is clear that a significant amount of guidance ranging from the preparation of toxicology reports, SGVs and procedural guidance is currently being prepared. The workshop was therefore extremely timely and presents an opportunity for the EA and SAGTA to work together.

### *SAGTA's Perspectives*

- SAGTA members have a wealth of experience in applying existing guidance and risk assessment tools in both the UK and elsewhere.
- There are particular concerns associated with the implications of using SGVs or site specific risk assessments for compounds for sensitive end uses, in particular where the risk assessed values are either close to, or below, local background concentrations. This has been shown to be an issue for Benzo(a)Pyrene (B(a)P), for example, with concerns that this situation may be replicated for certain other non-threshold substances.
- Certain commentators have asked whether such concentrations represent a significant health risk and whether application of current guidance could lead to outputs that are not sustainable in terms of driving a requirement to remediate. This is in account of the levels of conservatism introduced at each stage in the SGV generation and assessment process (in part driven by application of the As Low As Reasonably Practicable (ALARP) principle).
- An increasing number of residential property transactions have associated chemical analysis data available. Because LA's have information presented to them from individual dwellings that they may feel obliged to act upon, (despite being aware that the measured concentrations are not significantly different to elsewhere in the community) SAGTA foresee that LA's could be faced with a decision dilemma that may also create localised blight. A decision not to act exposes the LA to what may be undue criticism by apparently choosing to ignore a robust scientific assessment of an area of land. Conversely, application of the same criteria also impacts the development of housing on brownland as it could lead to remediation standards that are inappropriately onerous. It seems to SAGTA that it is neither in the interests of regulators or the regulated to be placed in such a position.

- At present, the links between the type of analytical data typically collected during site investigation and the detailed quantitative risk assessment process are ill understood by the contaminated land community. This can lead to a danger of overly conservative outcomes and hence higher than necessary compliance costs. A better understanding of the input parameters used for HHRA is therefore required. In particular:
  - there is a need to align more explicitly some of the chemical analysis methods with existing and proposed CLEA guideline values (e.g. metals, Total Petroleum Hydrocarbons (TPH), cyanide)
  - further study is required in relation to bioavailability and plant uptake
  - guidance should be developed on how to deal with risk assessments associated with mixtures of compounds.
- A simplified risk assessment framework could act as a valuable aid to the wider understanding and acceptance of the whole risk assessment process and need not be confined to the background concentration issue discussed above. Such a document might also represent an opportunity to resolve some of the issues associated with the link between:
  - the output from a risk assessment
  - the requirement to remediate
  - the risk communication process in general.
 In effect, such an approach could provide a decision support tool to regulators seeking to adopt a pragmatic and robust approach to such issues.
- It is also generally recognised that, where possible, measurement is better than modelling, as long as the measurement process is controlled and its limitations understood. The simplified risk assessment process discussed above could be used to help to strengthen the link between measurement and modelling.
- SAGTA view the ability to move away from default parameters is currently limited due to the closed architecture of the current general release version of CLEA. (It was apparent from discussions that the CLEA model was currently being widely employed as a site-specific risk assessment tool by practitioners). SAGTA feels this could be improved if the EA were to release a formal version of CLEA that was suitable for detailed site specific risk assessment. If the EA see short term constraints in being able to do this as an in-house task, SAGTA suggests alternative ways should be considered in bringing this tool to the market, e.g. release of the existing software under licence to a developer who could then produce and market an open architecture version.

***Areas where SAGTA can contribute***

- SAGTA members would be keen to explore means in which they could help to reinforce the importance of guidance on contaminated land to the property market. Whilst there are many priorities within the EA's remit, SAGTA Members, as major landholders, are acutely aware of the potential technical and commercial vacuum that absence of guidance is creating. SAGTA is anxious to help accelerate production of such information
- Expert support and involvement in the development of draft SGVs for such substances through peer review. This would also add to the EA's resources to assess the cost of compliance and develop policies for managing the impact of such outcomes in advance of publication which would add confidence to the brownfield market
- Support and help develop a simplified risk assessment framework (or route map) through existing guidance and legislation. SAGTA members are happy to assist the EA in developing such guidance to ensure that it remains scientifically robust whilst at the same time being transparent and pragmatic.
- SAGTA members would welcome the opportunity to review the EA project on Detailed Quantitative Risk Assessment (DQRA)

## **Summary of Presentations**

### **Toxicology behind the CLEA Guideline Values.**

It was recognised that toxicology data is virtually always derived from ‘non-ideal’ sources such as animal studies or human epidemiology studies where exposure conditions and other influencing factors were ill understood. Extrapolation to long term, low exposure, scenarios is problematic and the uncertainties coupled with the need to protect the most sensitive elements of the human population generally lead to safety factors of up to 1000 being used.

There are fundamental differences between the way in which threshold and non-threshold (e.g. carcinogens) substances are considered. For non-threshold substances, the DoH do not use slope factors. This has led to the concept of using Index Doses (ID) which are equal to an already accepted level of exposure which represents a minimal health risk. This leads to the need to set limits to ALARP. A direct consequence of this is that for threshold substances exceedances are undesirable and judgement can be applied, whereas for non-threshold substances, exceedances are considered to be unacceptable.

### **SAGTA Industry Viewpoint –A Simplified Risk Assessment Framework**

The need for consistency and communication and the role of risk assessment in the wider context of sustainable land regeneration was emphasised. It was noted that there is still a large variability of approach and that this leads to uncertainty in wider stakeholder groups. Areas of uncertainty include how to deal with background concentrations, the relationship between ALARP and cost/benefit considerations, and the interface between sampling, analysis and the risk assessment process. Simple and transparent guidance was required and a simplified risk assessment framework was proposed. This would help to link the various stakeholders together and hence increase confidence in brownland regeneration.

### **Developments and policy in relation to the CLEA model.**

It was emphasised that CLEA had not been developed to be a site-specific risk assessment tool. Guidance on SGVs is not yet available for many of the key contaminated land risk drivers (although many are in preparation). DQRA guidance was currently in preparation.

### **Comparison of Risk Assessment Models**

Although CLEA is the stated method of choice by UK regulators, many other human health risk assessment models are available. A NICOLE-funded project to compare a range of such models was now underway. This work is still in progress although it would appear that whilst many of the models use the same or similar algorithms, variability arises as a result of variable emphasis on different pathways and the use of different default input parameters.

### **Communication with the Local Authority as Regulator**

Endorsing the messages of communication from SAGTA’s industry viewpoint, the importance of communication with the Regulator was emphasised. It was noted that the LA should be included at each stage in the process and that the information provided should be sufficient to justify the conclusions reached. For example, a black-box derivation of a remediation standard would not be sufficient. In effect, there needs to be a shift from a ‘*trust me*’ culture to a ‘*show me*’ culture.

## Measurement v's Modelling

Three presentations covered the theme of measurement versus modelling:

- *Vapour pathway modelling and the use of GasSim.* It was noted that in one particular project, the output appeared to be counter intuitive but was actually borne out by field observations of odour
- *Vapour monitoring surveying.* One of the conclusions was that it was necessary to understand the limitations of the survey technique. In this particular instance, the results had to be interpreted with care due to the presence of other compounds that also gave a positive signal.
- *Review of background concentrations of B(a)P.* Initial reviews had indicated that generations of anthropogenic poly aromatic hydrocarbon (PAH) dispersal has resulted in urban background concentrations that are higher than the likely CLEA SGV in many instances. This adds to the complexity of remedial decision-making where individual residential properties might be the focus of detailed attention whilst not being significantly more contaminated than the surrounding environment.

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