

## CAN TOXICOLOGISTS FURTHER DEFINE “UNACCEPTABLE INTAKE” FOR CONTAMINATED LAND?

Findings of a Discussion Meeting Convened by the Royal Society of Chemistry's Toxicology Group held at 15<sup>th</sup> May 2009, Burlington House, London.

### Introduction

A discussion meeting was held at the Royal Society of Chemistry to review and discuss the concept of "unacceptable intake" (UI), within the context of identifying "significant possibility of significant harm" (SPOSH) to human health, as specified within the contaminated land legal regime.

The meeting was aimed at exploring if a view could be formed on whether toxicologists could provide further help on defining what UI means, notwithstanding the policy statements and guidance which have been issued by the UK Department for Environment, Food and Rural Affairs (DEFRA), the Health Protection Agency (HPA) and the Environment Agency (EA).

The meeting commenced with brief introductory talks covering current legislation and guidance on the topic, including the Contaminated Land Exposure Assessment (CLEA) model, Soil Guidance Values (SGVs) and a history of the legislation and guidance. These were followed by presentations from representatives of local authorities, the Homes and Communities Agency (HCA) and industrial 'problem holders'. The presentations provided background information and set the scene for the plenary discussions. The meeting was attended by contaminated land practitioners, local authorities, learned and professional societies, toxicologists and non-governmental organisations (NGOs).

### Legislative Background to the Issue

The primary legislation which underpins the UK contaminated land regime is contained within Part 2A of the Environmental Protection Act 1990<sup>1</sup> (Part 2A), which was inserted via Section 57 of the Environment Act 1995<sup>2</sup>. The regime was brought into force in England via a Statutory Instrument in April 2000 (September 2001 in Wales), with detailed Statutory Guidance<sup>3</sup> (SG), being implemented simultaneously. The SG provided further details of how the regime must be enforced and, although certain aspects of it have been updated since the original version, the requirements relating to how land should be determined as "contaminated" based on risks to human health have remained unchanged since 2000. Section 78A of Part 2A defines contaminated land as:

<sup>1</sup> [http://www.opsi.gov.uk/acts/acts1990/ukpga\\_19900043\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/ukpga_19900043_en_1.htm)

<sup>2</sup> [http://www.opsi.gov.uk/acts/acts1995/ukpga\\_19950025\\_en\\_6#pt2-11g57](http://www.opsi.gov.uk/acts/acts1995/ukpga_19950025_en_6#pt2-11g57)

<sup>3</sup> <http://www.defra.gov.uk/environment/land/contaminated/pdf/circular01-2006.pdf>

*“Any land which appears to the local authority in whose area the land is situated to be in such a condition, by reason of substances in, on or under the land, that (a) significant harm is being caused or there is a significant possibility of such harm being caused; or (b) pollution of controlled waters is being, or is likely to be, caused”.*

Harm is defined within Section 78A as:

*“Harm to the health of living organisms or other interference with the ecological systems of which they form part, and in the case of man, includes harm to his property.”*

In terms of the overall assessment process for land suspected of being contaminated, the SG associated with the contaminated land regime states the following (at Paragraph A9):

*“The definition of contaminated land is based upon the principles of risk assessment. For the purposes of this guidance, “risk” is defined as the combination of:*

- (a) the probability, or frequency, of occurrence of a defined hazard (for example, exposure to a property of a substance with the potential to cause harm); and*
- (b) the magnitude (including the seriousness) of the consequences.”*

Within Table A the SG states that the following should be regarded as “significant harm” to humans:

*“Death, disease, serious injury, genetic mutation, birth defects or the impairment of reproductive functions. For these purposes, disease is to be taken to mean an unhealthy condition of the body or a part of it and can include, for example, cancer, liver dysfunction or extensive skin ailments. Mental dysfunction is included only insofar as it is attributable to the effects of a pollutant on the body of the person concerned.”*

In order for land to be determined as contaminated land on the grounds of SPOSH to human health, the SG asserts in Table B that the local authority (LA) must be satisfied that (bold added):

*“The amount of the pollutant in the pollutant linkage in question which a human receptor in that linkage might take in, or to which such a human might otherwise be exposed, as a result of the pathway in that linkage, would represent an **unacceptable intake** or direct bodily contact, assessed on the basis of relevant information on the toxicological properties of that pollutant.”*

No further details are provided in the SG on what should be regarded as an “unacceptable intake” (UI), although Table B also notes that any assessment of its likelihood should take into account:

- *“the likely total intake of, or exposure to, the substance or substances which form the pollutant, from all sources including that from the pollutant linkage in question;*
- *the relative contribution of the pollutant linkage in question to the likely aggregate intake of, or exposure to, the relevant substance or substances; and*
- *the duration of intake or exposure resulting from the pollutant linkage in question.”*

It is also noted that:

*“The question of whether an intake or exposure is unacceptable is independent of the number of people who might experience or be affected by that intake or exposure. Toxicological properties should be taken to include carcinogenic, mutagenic, teratogenic, pathogenic, endocrine-disrupting and other similar properties.”*

Taken together, Part 2A and the SG provide a clear legal need for regulators to establish, and act in accordance with, what constitutes an UI of a given substance, in order to determine land under Part 2A on the basis of SPOSH to humans. There is therefore a need among contaminated land practitioners, “problem holders” (landowners, etc) and others to have clear guidance on this issue.

### **Technical Background to the Issue**

Although Part 2A and the SG go some way towards describing how land should be determined as “contaminated” from a human health risk point of view, DEFRA and its predecessors (DETR and the DoE) have left it to non-statutory technical guidance to provide further detail on the complex processes involved in contaminated land risk assessment under Part 2A. While a great deal of relevant and useful guidance has been produced in this regard (primarily from the Environment Agency<sup>4</sup>), the essential question of what constitutes UI (and therefore SPOSH) has never been answered with the clarity needed by local authority regulators and other affected parties.

Central to the government’s non-statutory technical advice on the human health risk assessment of contaminated land is the CLEA model<sup>5</sup> and its associated inputs and outputs. The CLEA model is a multi-pathway quantitative risk assessment computer model which can be used to generate chemical-specific assessment criteria for comparison with site-related concentrations of contaminants in soil. CLEA has been used by the EA to establish SGVs for several substances to date<sup>6</sup> (with more being planned) and it is also available to researchers and others for the production of Generic Assessment Criteria (GACs) and Site-Specific Assessment Criteria (SSACs). As well as being chemical-specific, SGVs also tend to be land-use specific and, in some instances, specific to other site-related variables (eg, soil pH).

As with all human health risk assessment modelling approaches, a key aspect of the CLEA model is the toxicological input criteria. These are referred to within the overall CLEA approach as “Health Criteria Values” (HCVs) and they are defined by the EA as “benchmarks for protecting human health”<sup>7</sup> and by DEFRA as “dose levels at which substances might pose either *no appreciable risk* (threshold substances) or a *minimal risk* (non-threshold substances)

<sup>4</sup> See, for example, <http://www.environment-agency.gov.uk/research/planning/33710.aspx>

<sup>5</sup> [http://www.environment-agency.gov.uk/static/documents/Research/CLEA\\_Report\\_-\\_final.pdf](http://www.environment-agency.gov.uk/static/documents/Research/CLEA_Report_-_final.pdf)

<sup>6</sup> <http://www.environment-agency.gov.uk/research/planning/64015.aspx>

<sup>7</sup> [http://www.environment-agency.gov.uk/static/documents/Research/TOX\\_guidance\\_report\\_-\\_final.pdf](http://www.environment-agency.gov.uk/static/documents/Research/TOX_guidance_report_-_final.pdf)

to human health”<sup>8</sup>. HCVs are derived and published by the EA (in consultation with others), with a SGV being the chemical concentration in soil at which the Average Daily Exposure (ADE) to a specified human receptor (typically a child) is modelled by CLEA to be equivalent to the HCV<sup>6</sup> under standard assumptions. Given their provenance, both HCVs and SGVs can be viewed as being “authoritative”, as is required by the SG.

While the HCVs and associated SGVs are helpful in assessing contaminated land risks to human health, the fact that the former are aimed at health protectiveness rather than UI makes it difficult to use the latter directly in establishing whether or not there is SPOSH at a particular site. Indeed, this potential mismatch between the technical guidance and the legal requirements of the regime led DEFRA, in 2005<sup>9</sup>, to state that:

*“Given the definition of HCVs set out in CLR 9 (and above), and the nature of the CLEA methodology, it should be a matter for careful consideration by local authorities whether concentrations of substances in soil equal to, or not significantly greater than, an SGV would meet the legal test set out in Table B. From discussions within the Soil Guideline Value Task Force (see below) it is apparent that there is a wide body of opinion that such concentrations would not necessarily satisfy that legal test. This remains the case where the site corresponds to the generic model used to produce an SGV. This view would also apply to any assessment criteria or site-specific criteria generated (in the absence of an SGV) using a published HCV and the CLEA software (or other exposure model).”*

Resolving this issue in a straightforward manner has proved to be difficult, if not impossible, to date, although attempts have been made to do so<sup>10,11</sup>.

The current positions of the relevant central government bodies on how regulators and other interested parties should judge whether there is UI and/or SPOSH to human health at a given site are provided by their respective policy statements on the issue. In a document entitled “Guidance on the Legal Definition of Contaminated Land”, DEFRA states<sup>7</sup>:

- *“The second challenge raised by the risk-based approach is how to distinguish SPOSH from non-SPOSH. Scientific risk assessment allows assessors to get the best practical understanding of the possibility of significant harm on a site. But science alone cannot answer the question of whether or not a given possibility of significant harm is significant. The question of what is significant is a matter of policy based firmly on scientific risk assessment taking account of all relevant and available evidence.” (Para 21)*
- *“Thus, if an SGV is exceeded, the assessor will usually need to conduct a detailed quantitative risk assessment to discover whether there is a possibility of significant harm and, if so, the nature of that risk. Whether or not SPOSH exists will depend on*

<sup>8</sup> <http://www.defra.gov.uk/ENVIRONMENT/land/contaminated/pdf/legal-definition.pdf>

<sup>9</sup> <http://www.spelthorne.gov.uk/clan2-05-sgvs.pdf>

<sup>10</sup> [http://www.doeni.gov.uk/sgvs\\_-\\_the\\_way\\_forward.pdf](http://www.doeni.gov.uk/sgvs_-_the_way_forward.pdf)

<sup>11</sup> [http://www.cieh.org/library/Knowledge/Environmental\\_protection/Contaminated\\_land/Contaminated\\_Land\\_Determinations.pdf](http://www.cieh.org/library/Knowledge/Environmental_protection/Contaminated_land/Contaminated_Land_Determinations.pdf)

*the results of risk assessment, the existence and nature of any pollutant linkages, and (ultimately) the judgement of the local authority. As a general guide:*

- i. For substances where there is an SGV, the more the SGV is exceeded, the more likely it is that an authority should consider the risks to be SPOSH.*
  - ii. Generally, the cautious nature of SGVs means that local authorities may conclude that SPOSH is unlikely to exist at concentrations close to SGVs.*
  - iii. 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.*
  - iv. 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).” (Para 39)*
- *“The statutory guidance requires that local authorities’ decisions on what is an “unacceptable intake” (i.e. SPOSH) must be assessed on the basis of toxicological risk assessments. Decisions cannot be based solely on such risk assessments because, whilst they can inform an authority about the possibility of significant harm at a site, risk assessments cannot answer the policy question about what is acceptable or unacceptable. Thus, in Defra’s view, decisions should be firmly based on scientific risk assessment, but they should also take account of the purpose of Part 2A and the local context in which the decision is being made.” (Footnote 10)*

The Health Protection Agency (HPA) 2008 document entitled “Land Contamination and Public Health”<sup>12</sup> also describes (at Section 5.1.3) how HCVs do not represent UI and that UI (from land pollution) is not a toxicological parameter. It further asserts that “UI is a policy decision which can only be taken by the local authority.” Pointers provided to LAs in this regard are provided by the following:

*“The HCVs, and GACs based upon them represent trigger values above which there might be a possibility of significant harm. Whether there is a significant possibility will be linked to factors such as the margin of exceedence, the duration and frequency of exposure, and other site-specific factors.”*

The EA has echoed DEFRA’s positions in their recent publications connected with the HCVs and CLEA, as follows:

- *“[HCVs] represent a baseline and health-protective position to minimise the risks of significant harm; they do not themselves necessarily represent thresholds above which an intake would be unacceptable, representing a significant possibility of significant harm in the context of Part 2A, but they can be a useful starting point for such an assessment (DEFRA, 2008b). Science alone cannot answer the question of whether or not a given possibility of significant harm is significant, since what is either significant or unacceptable is a matter of socio-political judgement, and the law entrusts decisions on this to the enforcing authorities (DEFRA, 2008b).”<sup>6</sup>*
- *“SGVs do not of themselves represent the threshold at which there is a significant possibility of significant harm nor do they automatically represent an unacceptable intake in the context of Part 2A of the Environmental Protection Act 1990 (Part 2A), but they can be a useful starting point for such an assessment (DEFRA, 2008b). Science alone cannot answer the question of whether or not a given possibility of*

<sup>12</sup> [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1242198452810](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1242198452810)

*significant harm is significant, since what is either significant or unacceptable is a matter of socio-political judgement, and the law entrusts decisions on this to the enforcing authorities (DEFRA, 2008b).*<sup>18</sup>

While these policy statements go some way towards constituting central government guidance on what does not constitute UI and SPOSH, many LAs and other practitioners feel that they offer little in terms of specifying in a practical sense how this important aspect of human health risk assessment under Part 2A should be judged on a site-specific basis and, in particular, consistently. The general and qualitative nature of the guidance seems to be at odds with the highly detailed, quantitative guidance developed for other aspects of the risk assessment process under the CLEA project<sup>13</sup> and, importantly:

- most LAs and other practitioners / affected parties are not toxicologists and therefore their ability to make informed expert judgements on a case-by-case basis is limited;
- leaving aside the issue of chemical mixtures, the question of what constitutes UI from a substance should logically be generic, in the sense that it applies to all humans of a particular receptor group, rather than being of a site-specific nature (the site-specificity of decisions regarding SPOSH arises via the chemical testing and exposure modelling carried out as part of the overall site-specific risk assessment);
- decisions regarding contaminated land, and whether or not remediation is required at specific sites, have to be made many times, by local authorities and others, under both Part 2A and due to the link between Part 2A and the planning process for brownfield sites<sup>14</sup>;
- in order to avoid a “post-code lottery” in health protection, there is a need for consistency across the country in terms of what level of contamination does or does not merit intervention / remediation;
- decision-makers need to balance the health risks of under-determination / remediation (i.e. by not intervening in situations which warrant it) with the costs, upheaval and potential health impacts (e.g. due to anxiety) of over-determination / remediation;
- overly-cautious approaches can result in unnecessarily large amounts of site remediation, potentially resulting in avoidable losses of landfill space and other environmental impacts and a reduction in the economic viability and practicability of brownfield redevelopment;
- the buyers and sellers of property (both residential and commercial) need clarity in defining the size of potential contamination liabilities;
- counter-parties to corporate transactions similarly require clarity on environmental liabilities (e.g. during mergers and acquisitions); and

---

<sup>13</sup> <http://www.environment-agency.gov.uk/research/planning/33714.aspx>

<sup>14</sup> <http://www.communities.gov.uk/documents/planningandbuilding/pdf/pps2annex2.pdf>

- reasonably accurate contaminated land liabilities are required to be disclosed by many large corporations under relevant accounting standards and regulations (e.g. FRS12 and Sarbanes-Oxley).

Government guidance on UI and SPOSH, or the lack thereof, has a direct bearing on all of the above.

## **Plenary Discussion**

Having reviewed the above, the plenary discussion took the form of an open debate around several questions posed by the Chair, aimed at elucidating some of the issues highlighted as being of concern. The Chair's questions are provided below, along with a summary of the findings of the resulting discussions.

### **1. Can SPOSH And Unacceptable Intake Be Defined?**

As described above, a site can be determined as "contaminated" under Part 2A on the basis of, amongst other things, SPOSH to human health posed by the chemicals in, on or under the land. From the wording of the legislation and its associated statutory guidance, it would appear that for there to be SPOSH, there must be a significant possibility of an UI. The SPOSH requirement can be translated to mean "a more likely than not chance that an exposed individual would receive a dose corresponding to an UI".

UI is loosely defined in the Statutory Guidance and it is clear that it is related to some form of dose or intake estimate (rather than a chemical concentration in soil). Technical guidance connected with the legal regime has not defined UI in any further detail, however. Policy statements from DEFRA, the HPA and EA appear to leave this up to individual local authorities.

Trying to identify UI levels for specific chemicals using only human data is problematic from several points of view. Firstly, most studies of harm to health tend to be toxicological (i.e. via the use of *in vivo* and/or *in vitro* tests) rather than epidemiological (i.e. via studies of exposed human populations). Secondly, where epidemiological data does exist, its extrapolation may be limited due to a lack of information about chemical speciation, the bioavailability of the substance being studied and the fact that potential exposure to a substance is not directly related to a quantifiable dose in a receptor species.

'Significant harm' appears to be defined in the legislation as the human dose that will cause those effects, that are substance and exposure dependant, in the receptor (human) in specific target organs (see above, and Table A of the SG, for a definition of the kind of

“harm” that should be regarded as “significant”). This is a surrogate measure, however. As with all such legislation there is an issue as to how the language of risk is used by policy makers. Risk is a product of dose and exposure and all parts of the equation can be derived and assessed for significance. It should be noted that the concepts of SPOSH and UI are not used by the Health and Safety Executive (HSE) or the Food Standards Agency (FSA).

The concept of ‘possible’ is alien to toxicology, which uses the concept of ‘probability’. Possibility appears to have more to do with exposure, with dose potentially missing from the scenario. The statutory guidance at Table B refers to ‘might take in’ but it does not specifically equate possibility to probability. Toxicology is about quantification. Probability is about ratios and whether something is more likely than not.

In toxicological terms, “significant” may either be used as a statistical term, as in ‘statistical significance’, or used to convey a level of (empirical) toxicity. For example in toxicological studies, loss of bodyweight might be considered a minor event, and related to some other metabolic disturbance. Likewise, liver hypertrophy (increase in the organ volume due to the enlargement of its component cells) might be a response to substance-induced enzymic metabolic activity. However, if the liver changes were more serious (e.g. severe fatty changes), then one could ascribe a higher toxicological significance to those findings, as opposed to reversible hypertrophy. In this context ‘significant harm’ can have a toxicological meaning - although of course the ‘significance’ would have to be defined and justified.

Some similarity exists between the wording of Part 2A and that of EU chemical hazard classification, where the risk phrase R48 – “danger of serious damage to health by prolonged exposure” - can be used where there is clear functional disturbance or morphological change which has toxicological significance. The documentation for chemical classification defines the conditions under which R48 is appropriate. Changes in bodyweight, food or water intake, small changes in clinical biochemistry/haematology, minor changes in organ weights, adaptive responses (e.g. the hypertrophy referred to above), species-specific toxicity, would not lead to R48 classification. It could therefore be possible to derive a generic definition of significant toxicity based on current legislation and toxicological expertise in another setting.

## **2. How Do The Principles Of Toxicology Relate To Unacceptable Intake?**

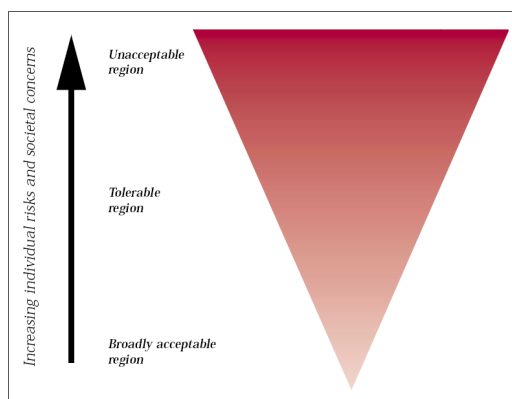
Toxicologists often use animal studies to extrapolate to humans. They look at dose-response curves and the impact of overdosing on health. In particular toxicologists look at a range of pathological changes ranging from the No Observed Adverse Effect Level

(NOAEL) to death. Human data can also be used, if available, from epidemiological studies.

Many HCVs are based on tolerable daily intakes (TDIs), which are themselves estimates of the amount of a substance in air, food or drinking water that can be taken in daily over a lifetime without appreciable health risk. TDIs are typically derived by dividing the NOAEL or the Lowest Observed Adverse Effect (LOAEL) by an “uncertainty factor” (UF). Setting a NOAEL or LOAEL and adding a UF results in a conservative value, which is generally set high enough to cover the level of uncertainty.

Toxicologists are generally not employed to find dose levels at which harm is likely to occur, focusing instead on “tolerable”, “minimal risk” or even “safe” levels. Although the word ‘unacceptable’ is difficult if not impossible to define toxicologically, ‘tolerable’, ‘acceptable’ and ‘minimal’ have been so defined for many years. As an example of some of the thinking that has taken place around this issue, the following figure is reproduced from the Health and Safety Executive’s 2001 document entitled “Reducing Risks, Protecting People”<sup>15</sup>.

Figure 1: HSE framework for the tolerability of risk



As described above, the concept of tolerable risk has been translated into quantified measures based on observations of an absence of effects, with an added UF. UFs are internationally accepted and based on multiples of ten. One possibility for approaching a measure of UI might be to revise the UF downwards. This would entail defining the endpoint such as a pathological change and then determining the NOAEL prior to revising the UFs. This could be done in conjunction with epidemiological evidence to see if there is congruence.

But it must be stressed that this is a policy and not a toxicological issue. The central paradigm of toxicology is to provide protection from harm. Toxicology cannot decide on

<sup>15</sup> <http://www.hse.gov.uk/risk/theory/r2p2.pdf>

what level of harm is acceptable as this is a policy issue based on societal judgement. Toxicology cannot therefore define SPOSH or UI without input from other fields of expertise.

### 3. What Are The Boundaries With Regard To Unacceptable Intake?

Some substances of very high concern (SVHC) have hazardous properties that could have serious consequences. For example, they may cause cancer (carcinogenic), they could remain in the environment for a long time (persistent) or they could gradually build up in the food chain (bioaccumulative). SVHCs also include substances demonstrated to be of equivalent concern, such as 'endocrine disruptors'.

The criteria in REACH, Article 57 for SVHCs are substances:

- meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2 in accordance with Directive 67/548/EEC;
- which are persistent, bio-accumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- which are very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation; and
- giving rise to an equivalent level of concern to substances meeting the above criteria.

In some SVHCs there is no known safe dose (e.g. genotoxic carcinogens) while in others there is a threshold below which no adverse effects have been observed. The test for significance should ideally be based on the additional morbidity or mortality over that which would occur naturally in society. In such cases the 'threshold of toxicological concern' is often set at a lifetime increased risk of (e.g. cancer) of 1 in 1,000,000 ( $1 \times 10^{-6}$ ).

By setting the threshold of concern in the lower part of the dose-response curve it is possible to find a dose that does not cause a defined pathological change. Defining such endpoints for SVHCs is often complicated when extrapolating from *in vitro* studies. However, for example, if policy were to define 'significant harm' as, say,  $1 \times 10^{-4}$  excess lifetime cancer risk then toxicology could be used to derive the dose required to produce such 'harm' and this could then be converted to UI levels or SGVs via the standard CLEA model. (It should be noted that this approach was suggested in the earlier attempts<sup>11, 12</sup> to define UI for non-threshold substances, but it was rejected by the EA and / or HPA<sup>16</sup>,

---

<sup>16</sup> "Contaminated Land Clarification Note No. 1" HPA, Cardiff, 2008

partly on the grounds that the Committee on Carcinogenicity doesn't endorse the low-dose extrapolation of cancer risk when there is only animal data, as is commonly the case for contaminants in soil.)

In considering what order of excess risk may or may not be deemed to be acceptable or unacceptable, it would seem sensible to look further at other possible avenues to explore in terms of experience from other associated areas include:

- analogous situations within other UK or European regulatory regimes (radon protection, radioactively contaminated land, HSE safety risks, REACH, etc);
- epidemiological studies and case studies which have identified "effects levels" in humans (e.g. ED<sub>L0</sub> values);
- international criteria (e.g. US "Immediately Dangerous to Life or Health" (IDLH) levels)<sup>17</sup>; and
- legal precedent (e.g. personal injury / toxic tort cases).

## **Conclusions**

Standard toxicological paradigms are not directly useful in defining UI since they are based on minimal risk. Toxicological tools are, however, available to derive substance-specific doses equivalent to different orders of risk. In the event that a policy decision can be made on what is unacceptable (possibly via a joint effort between toxicologists and policy-makers), toxicologists could deliver the information required to assist the process of identifying UI.

## **Recommendations**

Decisions on 'unacceptable' should be taken at a national level rather than potentially inconsistent decisions being taken at a local level. One way forward is for DEFRA to set the levels nationally with input from the HPA and EA. If DEFRA and the EA are not prepared to take the lead, then this could be taken forward by means of a national concordat between local authorities (the lead regulators) to collaborate on the development of national guidelines. This would lead to the development of better-informed and more consistent decision-making, with greater confidence.

Toxicologists should be approached to contribute by examining the toxicological literature for the 60 identified priority substances found in soil. Toxicologists could help to define a set of

---

<sup>17</sup> <http://www.cdc.gov/niosh/idlh/idlh-1.html>

principles by conducting a meta-study (a comprehensive literature review) in order to produce a set of peer-reviewed values for priority substances. While a generic set of chemical-specific UI levels is unlikely to be forthcoming from such research, data on effects levels drawn from the animal testing / epidemiological literature could be collated in a useful form for decision-makers to use. By relating these to background levels it may be possible to provide local authorities and other affected parties with a better-informed basis for decision-making.

This could be progressed in several ways. It is recommended that the British Toxicology Society (BTS) or the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) be contacted with a view to establishing a working group to discuss this with local authorities and, possibly, other affected parties. Funding could be obtained from various sources.

This Note was produced by a Joint Working Party of the Toxicology Group and the Environment, Health and Safety Committee of the Royal Society of Chemistry.

The Society is a registered Charity. Its Royal Charter obliges it to serve the public interest by acting in an independent advisory capacity. In order to meet this obligation the members of the EHSC and the Toxicology Group are drawn from a wide range of backgrounds and serve as individual experts and not as representatives of their employer.

For further information please contact:

The Secretary  
Health, Safety and Environment Committee  
Royal Society of Chemistry  
Burlington House  
Piccadilly  
London  
W1J 0BA  
Tel: +44 (0) 207 440 3337  
Fax: +44 (0) 207 437 8883  
Email: ehsc@rsc.org

EHSC Notes are available on the Society's web site at:

<http://www.rsc.org/ScienceAndTechnology/Policy/EHSC/EHSCGuidance.asp>

See also

<http://www.rsc.org/Membership/Networking/InterestGroups/Toxicology/index.asp>