Uncertainty in Risk Evaluation and Unacceptable Intake

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Introduction

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- Risk evaluation – "deciding whether a risk is unacceptable" (CLR11)
  - "The acceptability or significance of risk, including socio-economic aspects, is considered in general terms in the *Guidelines for Environmental Risk Assessment and Management*"
- DEFRA CLAN 2/05:
  - "Part 4 of Chapter B of the statutory guidance (which deals with the manner in which the determination of contaminated land is to be carried out) and Table B of Chapter A, in particular, make it clear that to determine land as contaminated land on the grounds of a "significant possibility of significant harm" to human health, the local authority must be satisfied that:
    - *"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.""*

Introduction (cont)

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- Further definitions (MQ):
  - "Significant possibility of significant harm" (SPOSH) is a written expression of the *degree of risk* that land has to pose to a human receptor (by virtue of the chemicals in, on or under it) in order for the land to be determined as "contaminated" under Part 2A.
  - "Unacceptable Intake" (UI) is a written expression of the *undesirability of a dose* of a chemical substance to a human receptor.
  - It surely follows that, in order for there to be SPOSH, there must be a *significant possibility* of UI.
  - The possibility and extent of exposure to a chemical substance can be explored on a site-specific basis using suitable assessment techniques (computer modelling, monitoring, etc).
  - UI must be, to some extent, generic.

Introduction (cont)

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"All individuals have unconditional rights to certain levels of protection... converts into fixing a limit representing the maximum level of risk" (Reducing Risks, Protecting People – Health and Safety Executive, 2001. As quoted in the "Way Forward".)

Current DEFRA Guidance

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- DEFRA, 2008 – "Guidance on the Legal Definition of Contaminated Land":
  - "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)

Current DEFRA Guidance (cont)

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- DEFRA, 2008 (Para 39):
  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)."

Current DEFRA Guidance (cont)

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- DEFRA, 2008 (Footnote 10):
  - "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."

Current HPA Guidance

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- HPA, 2008 "Land Contamination and Public Health":
  - "[HCVs] do not represent an unacceptable intake (DEFRA, 2008a)."
  - UI (from land pollution) is not a toxicological parameter.
  - UI is a policy decision which can only be taken by the local authority.
  - For threshold contaminants, lifetime exposures above the TDI may not inevitably lead to increased health risk.
  - For non-threshold contaminants, Excess Lifetime Cancer Risk (ELCR) estimates are generally not supported (except for asbestos, arsenic and ionising radiation, which have good quality human data).
  - Margin of Exposure (MoE) approach will be used in future for non-threshold substances.

(Section 5.1.3 – "Unacceptable Intake"?)

Current HPA Guidance (cont)

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- HPA, 2008 (cont):
  - "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."

(Section 5.1.3 – "Unacceptable Intake"?)

Current EA Guidance

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- Science Report SC050021/SR3 (2009 - CLEA Report):
  - "HCVs represent a tolerable or minimal risk to health from chronic exposure"
  - "HCV is the collective term used to describe a level of exposure to a chemical derived from toxicity data for the purposes of safeguarding human health."
  - HCVs for threshold substances:
    - Tolerable Daily Intakes (TDIs)
    - corrected for background exposure (via an assumed Mean Daily Intake – MDI) to provide a Tolerable Daily Soil Intake (TDSI)
  - HCVs for non-threshold substances:
    - Index Doses (IDs)
    - "Associated with some, albeit minimal, and often unquantifiable, level of risk."
    - As Low As Reasonably Practicable (ALARP) principle applies (presumably at the risk management stage)
  - Further considerations sign-posted, including:
    - short-term / acute effects;
    - pathway additivity;
    - chemical mixtures; and
    - route-to-route extrapolation.

Current EA Guidance (cont)

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- CLEA Report (cont):
  - "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 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)."

Current EA Guidance (cont)

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- Science Report SC050021/SR2 (2009 - Tox Report)
  - "HCVs...are considered to be protective of human health."
  - "[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).
  - In the context of Part 2A, an assessor using HCVs derived in accordance with the principles and framework in this report can conclude that (DEFRA, 2008b):
    - human exposure below the HCV is unlikely to represent a *significant possibility of significant harm;*
    - human exposure above the HCV might represent a *significant possibility of significant harm*, with the significance linked to the margin of exceedence, the duration and frequency of exposure, and other factors that the enforcing authority may wish to take into account."

Current EA Guidance (cont)

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- Tox Report (cont):
  - reiterates UK resistance to the use of low-dose extrapolation methods for modelling cancer risk from animal data.
  - describes the possible use of the benchmark dose concept for threshold and non-threshold substances.
  - suggests that, where appropriate, IDs should be based on a $BMDL_{10}$ and a 10,000 uncertainty factor (MoE approach), or an ELCR estimate of 1 in 100,000 (where circumstances permit). Also mentions "minimal risk levels" and existing national/international guidance.
  - states that threshold effects of non-threshold substances should not be overlooked, nor should the possible effects of chemical mixtures.
  - states that ALARP applies to non-threshold substances.

Current EA Guidance (cont)

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- Tox Report (cont):
  - In terms of UI, the document states that exposures greater than HCVs should be assessed on a case-by-case basis, considerations to include:
    - magnitude and duration of the exceedence;
    - whether TDI is based on chronic or acute effects;
    - steepness of the dose-response curve;
    - reversibility of sub-chronic / acute effects;
    - body burden / half-life / bioaccumulation considerations; and
    - possibility / nature of adverse effects other than the "critical effect".

Current EA Guidance (cont)

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- Arsenic SGV Report (2009):
  - Oral ID of 0.3 ug/kg-day, based on the UK drinking water standard - equates to an ELCR of 40-400 in 100,000.
  - "minimal risk" approach would result in a much lower ID, but in order to be proportionate, the above value is adopted.
  - Inhalation ID based on WHO air quality guideline (equivalent to 1 in 100,000 ELCR).
  - SGVs based on oral/dermal intake only.
  - "Although the likelihood of an exceedance of the oral ID representing a *significant possibility of significant harm* is much greater than would be the case if the oral ID was based on minimal risk, the SGVs are unlikely to represent a *significant possibility of significant harm*."

Other Recent Publications

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- CIEH, 2006 - Professional Practice Note (The determination of contaminated land: deciding what is an "unacceptable intake"):
  - Presents various options for local authorities to help define UI, including the use of LOAEL data and ELCR estimates.
- DEFRA, 2006 - CLAN 6/06 (Assessing Risks from Land Contamination – a Proportionate Approach. Soil Guideline Values: the Way Forward):
  - Amongst other things, proposed defining UI based on changes to the TDSI for threshold substances (including reference to LOAEL values) and the use of ELCR estimates for non-threshold substances.

Other Recent Publications (cont)

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- RSC, 2009 – Note on a Toxicology Group Meeting of 15 May 2009 (Can Toxicologists Further Define "Unacceptable Intake" for Contaminated Land?)
  - "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."
  - "Decisions on 'unacceptable' should be taken at a national level rather than potentially inconsistent decisions being taken at a local level."

Further Considerations

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- Precedent from historic Part 2A determinations (Defra grants?)
- Precedent from other UK regulators (eg, HSE, UK radon and radioactively contaminated land policy / guidance)?
- Legal precedent (eg, personal injury cases)?
- Epidemiological case studies (occupational or public health)?
- Other published toxicological criteria – eg, US "Immediately Dangerous to Life or Health" (IDLH) levels?
- ELCR approaches (USA, Netherlands, etc)?
- MoE approaches?
- Wider use of the toxicological literature (eg, human ED_{Lo} values)?

Further Considerations (cont)

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"A good decision is based on knowledge and not on numbers"

Plato

Thanks!

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