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C4SLs, LLTCs and Risk

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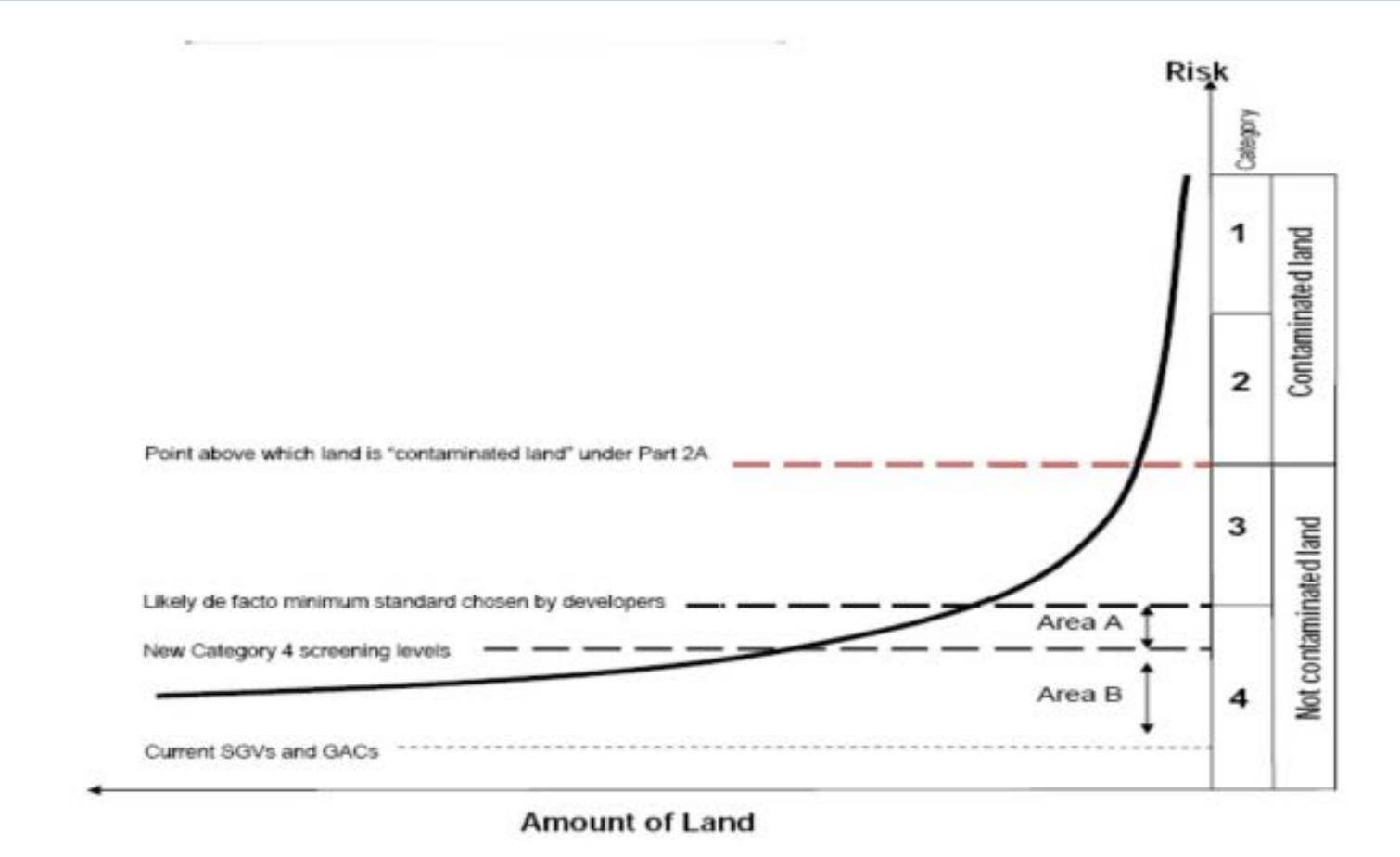
Category 4 Screening Levels (C4SLs)



Defra – C4SLs Policy Companion Document

C4SLs (cont)

"4.20 *The local authority should not assume that land poses a significant possibility of significant harm if it considers that there is no risk or that the level of risk posed is low. For the purposes of this Guidance, such land is referred to as a "Category 4: Human Health" case. The authority may decide that the land is a Category 4: Human Health case as soon as it considers it has evidence to this effect, and this may happen at any stage during risk assessment including the early stages."*

Defra – Part 2A Statutory Guidance

"The C4SLs were proposed to be more pragmatic (whilst still strongly precautionary) compared to existing generic screening levels. It is anticipated that, where they exist, C4SLs will be used as generic screening criteria that can be used within a GQRA, albeit describing a higher level of risk than the currently or previously available SGVs."

Defra - C4SLs Policy Companion Document

C4SLs (cont)

- Use in planning:
  - Lord de Mauley (Defra Minister) - Letter to all Local Authorities (dated 3/9/14):

    "The Impact Assessment agreed during the revision of the Part 2A Statutory Guidance was developed on the basis that C4Sls could be used under the planning regime, as well as within Part 2A. This intent is reflected within DCLG's Planning Practice Guidance on Land Affected by Contamination, which was revised on 12 June and now includes reference to the use of C4SLs in risk assessment under planning. I would like to highlight that C4Sls provide a simple test for deciding when land is suitable for use and definitely not contaminated (i.e. it is in category 4). Exceeding a C4SL means that further investigation is required, not that the land is necessarily contaminated.

    The introduction of C4Sls has an important part to play in the assessment of potentially contaminated land, and I would encourage. the relevant officials in your Authority to read Defra's Policy Companion Document and .the research itself."
  - DCLG Planning Practice Guidance (online):

    "Defra has published a policy companion document considering the use of 'Category 4 Screening Levels' in providing a simple test for deciding when land is suitable for use and definitely not contaminated land."

C4SLs (cont)

- Exposure modelling with CLEA, as per SGVs, except for (adapted from Table 3.5 of the C4SLs Report):

Final modifications to CLEA exposure parameter values for the derivation of C4SLs

Proposed change	Change invoked?		
	Residential	Allotments	Commercial
Reduce soil adherence factors in children (AC1 to AC12) for residential land-use from 1 to 0.1 mg cm^{-2}	✓		
Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year (AC1 to AC18)	✓		
Update vapour inhalation rates to the mean values recommended in USEPA, 2011 (AC1 to AC18 – see Table 3.2)	✓		✓
Use of 90th percentile estimates of consumption rates for "top two" produce types and mean consumption rates for remainder (see Tables 3.3 & 3.4) *	✓	✓	

Notes

* - Initial proposal was to use mean consumption rates for all produce types by this was modified in light of steering committee/stakeholder comments and results of the probabilistic modelling.

Low Levels of Toxicological Concern (LLTCs)

- Toxicity assessment as per SR2, except for the following (adapted from Table 2.4 of the C4SLs Report):

Key aspects of the derivation of LLTCs and HCVs.

Aspect	HCV	LLTC
Critical effect	Most sensitive effect	Most sensitive effect. Care must be taken to ensure that an LLTC derived using this data does not overlap the next most sensitive effect.
POD	NO(A)EL/LO(A)EL/BMDL*	BMD*/NO(A)EL/LO(A)EL
BMR	Not used in any HCVs to date 10% (animal carcinogenicity studies); <10% could be used if data sensitivity allows.	10% (animal carcinogenicity studies); <10% BMR could be used if data sensitivity allows. Maximally a BMR of 10%.
Uncertainty evaluation - threshold chemicals	Default generic UF/CSAF	CSAF/default generic UF
Uncertainty evaluation - non-threshold chemicals (animal data)	Default 10,000	CSM or generic 5,000
Uncertainty evaluation - non-threshold chemicals (human data)	Not used in any HCVs to date	CSM or generic margin to complement choice of BMR to achieve a notional ELCR between 1 in 10,000 – 1 in 50,000
ELCR	1 in 100,000	1 in 10,000 - 1 in 50,000

* SR2 states that a BMD approach could be taken to deriving an HCV but in practice it has never been adopted. In principle, a BMDL of the lowest response seen in the study would be the minimal risk POD. For an LLTC derivation, BMD modelling is suggested as the preferred approach, if data allow.

LLTCs (cont)

- SR2 states that:

  "Where there is evidence for chemical interaction, this should be taken into account; when such evidence is not available, each chemical should be assumed to be acting independently."

  and

  "...interactions, whether synergistic or antagonistic, often occur only once a metabolic or cellular threshold is breached. Such effects are therefore unlikely at exposures below the HCV."

- C4SLs Report states:

  "If synergism is suspected, an aspect of precaution can be applied by using higher uncertainty factors or captured in a qualitative uncertainty analysis. Care should be taken not to account for such effects more than once in the evaluation or attempt to apply quantitative judgements where there is no evidence to draw upon."

- Recent multi-authored paper on carcinogenic potential of low dose mixtures in the environment (*Carcinogenesis*, 2015, Vol. 36, Supplement 1, S254–S296)

Risk Assessment

- Part 2A Statutory Guidance – underlines added:

  "Part 2A takes a risk-based approach to defining contaminated land. For the purposes of this Guidance, "risk" means the combination of: (a) the likelihood that harm, or pollution of water, will occur as a result of contaminants in, on or under the land; and (b) the scale and seriousness of such harm or pollution if it did occur."

  "The process of risk assessment involves understanding the risks presented by land, and the associated uncertainties. In practice, this understanding is usually developed and communicated in the form of a "conceptual model". The understanding of the risks is developed through a staged approach to risk assessment, often involving a preliminary risk assessment informed by desk-based study; a site visit and walkover; a generic quantitative risk assessment; and various stages of more detailed quantitative risk assessment. The process should normally continue until it is possible for the local authority to decide: (a) that there is insufficient evidence that the land might be contaminated land to justify further inspection and assessment; and/or (b) whether or not the land is contaminated land."

Risk Assessment (cont)

- DQRA:
  - site-specific changes to the conceptual model
  - application of statistical techniques to chemical test data
  - changes to exposure assumptions and/or modelling approaches
  - obtaining and using bioaccessibility measurements
  - sampling and analysis of environmental exposure media
  - derivation and use of site-specific media uptake factors
  - human bio-monitoring (HBM) studies (eg, hair, urine, blood)
  - medical and/or epidemiology studies
  - adjustment of toxicological criteria and benchmarks
  - consideration of potential toxicological mixture effects
  - use of “margin of exposure” (MOE) approaches
  - consideration of acute risks
  - sensitivity analysis, to help identify key areas of uncertainty
  - uncertainty analysis (eg, Monte Carlo simulation)

Uncertainty in Risk Assessment

- Part 2A Statutory Guidance:

  "The uncertainty underlying risk assessments means there is unlikely to be any single "correct" conclusion on precisely what is the level of risk posed by land, and it is possible that different suitably qualified people could come to different conclusions when presented with the same information. It is for the local authority to use its judgement to form a reasonable view of what it considers the risks to be on the basis of a robust assessment of available evidence in line with this Guidance."

Uncertainty in Risk Assessment (cont)

Source of uncertainty	Magnitude and direction of influence on perceived risk[1]
The concentration of a chemical across a site is unknown. Often, it is assumed that the concentration across the site is the maximum that was found. The measurements are subject to error, and there is spatial variability in the concentrations.	– –/+
The level of exposure is usually a conservative estimate based on the most susceptible receptor spending an unrealistic amount of time at a site; this will vary with the tier in the assessment and extent to which site-specific characteristics are incorporated.	– – –/+
Any mathematical model that is used as part of a risk assessment is an approximation of reality. The differences between the model and reality are unknown due to the complex nature of exposure from contaminated land.	– –/++
There is great uncertainty in both hazard classification and dose-effect responses when extrapolating from animal data to humans and with human evidence itself. The database on all toxic effects for the chemical contaminant is rarely complete, and this will lead to further uncertainties.	– – –/+++
Chemicals are generally considered individually. Any interactions between impacts on health of exposure to different contaminants are generally ignored.	+/++
There are a number of other uncertainties that stem from assumptions that underpin the methods of risk assessment and characterisation, but these are thought to be minor in comparison with the uncertainties detailed above.	–/+
Overall assessment of uncertainty affecting the perceived risk from contaminated land. There is sizeable uncertainty in an assessment of risk for a contaminated land site. A fair portion of this uncertainty comes from an incomplete understanding of how chemicals pass to susceptible people and how much of the chemical is present across a site. The greatest contributor is the uncertainty about the toxicological effect of the contaminants, which stems from a lack of adequate data on causal effects of the chemical.	– – –/+++

[1] The +/- symbols indicate whether each source of uncertainty has the potential to increase (+) or decrease (-) the assessment outcome (i.e. the risk). The number of symbols provides a subjective relative evaluation of the magnitude of the effect (e.g. +++ indicates an uncertainty that could make the true risk much higher). If the effect is uncertain, or could vary over a range, lower and upper evaluations are given (e.g. - / ++ or + / ++).

FERA 2009 – Defra SP1002

Uncertainty in Risk Assessment (cont)

- Quantitative uncertainty analysis – BaP (residential with homegrown produce pC4SLs)

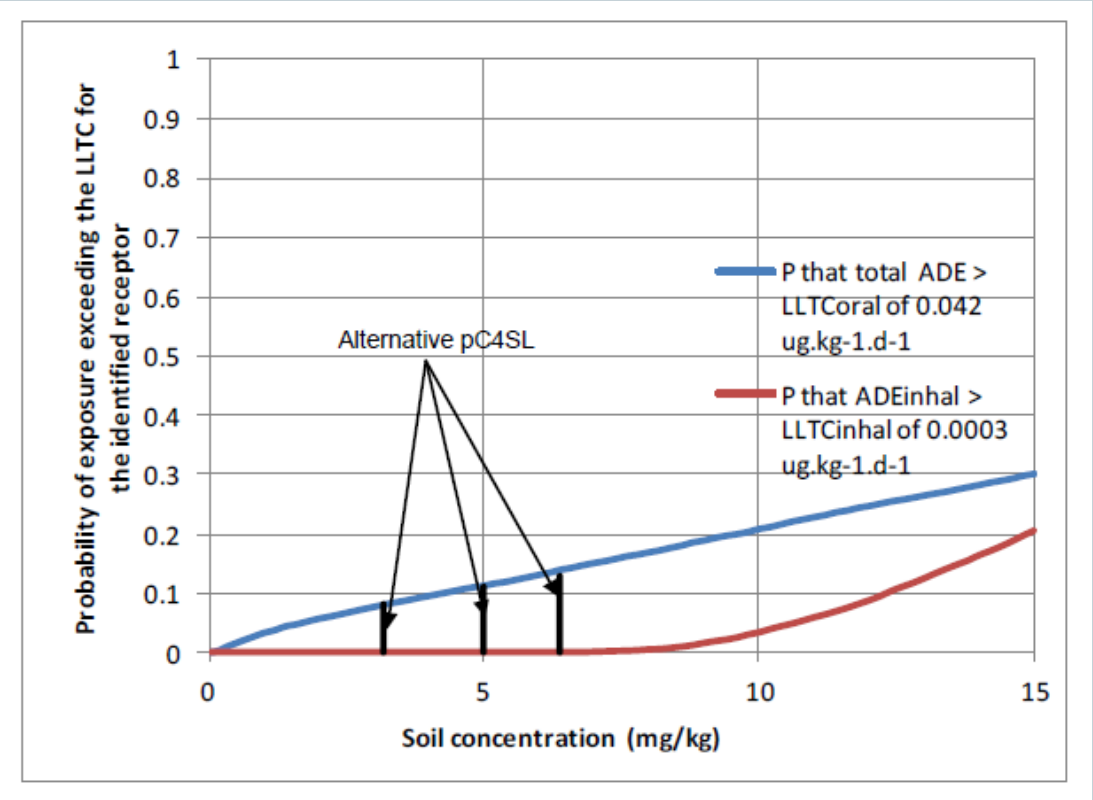


Figure 4.2 of Appendix E of the C4SLs Report

Uncertainty in Risk Assessment (cont)

- Qualitative uncertainty analysis – BaP (residential with homegrown produce pC4SLs)

Overall evaluation of uncertainty for $LLTC_{oral}$: Although the $LLTC_{oral}$ of 0.042 µg kg^{-1} bw d^{-1} is less conservative than other values examined (see Table 5.1), it still contains a number of conservative elements (tending to underestimate the LLTC). The largest uncertainty relates to intraspecies variability, for which the factor of 10 is widely accepted in regulatory risk assessment. Overall it is judged that the toxicological assessment is more likely to be conservative (underestimated LLTC, hence overestimating risk) than unconservative for the purposes of setting the LLTC. In essence, the LLTC represents a dose which is 5000 times less than that which was shown to give rise to tumours in 10% of experimental animals.

Overall evaluation of uncertainty for $LLTC_{inhal}$: the proposed $LLTC_{inhal}$ is based on the Air Quality Standard of 1 ng m^{-3}, which, based on WHO (2006 a&b), represents approximate ELCR of 1 in 10,000. This is higher than the ELCR that would normally be associated with minimal risk (1 in 100,000) but given that the LLTC represents low risk and is based on an air quality standard it is considered a suitable basis for setting the C4SL.

Exposure Modelling Uncertainty	Evaluation of uncertainty
RESIDENTIAL LAND-USE	
Soil and dust ingestion rate.	● / +
Relative bioavailability (RBA).	● / ++
Surrogate marker approach.	- / +
OVERALL EVALUATION OF UNCERTAINTY FOR RESIDENTIAL LAND-USE: Based on the above it is considered that the estimates of total exposure predicted by the probabilistic modelling are likely to be moderately conservative, particularly at specific locations.	

Adapted from Tables 4.3 and 4.4 of Appendix E of the C4SLs Report

Uncertainty in Risk Assessment (cont)

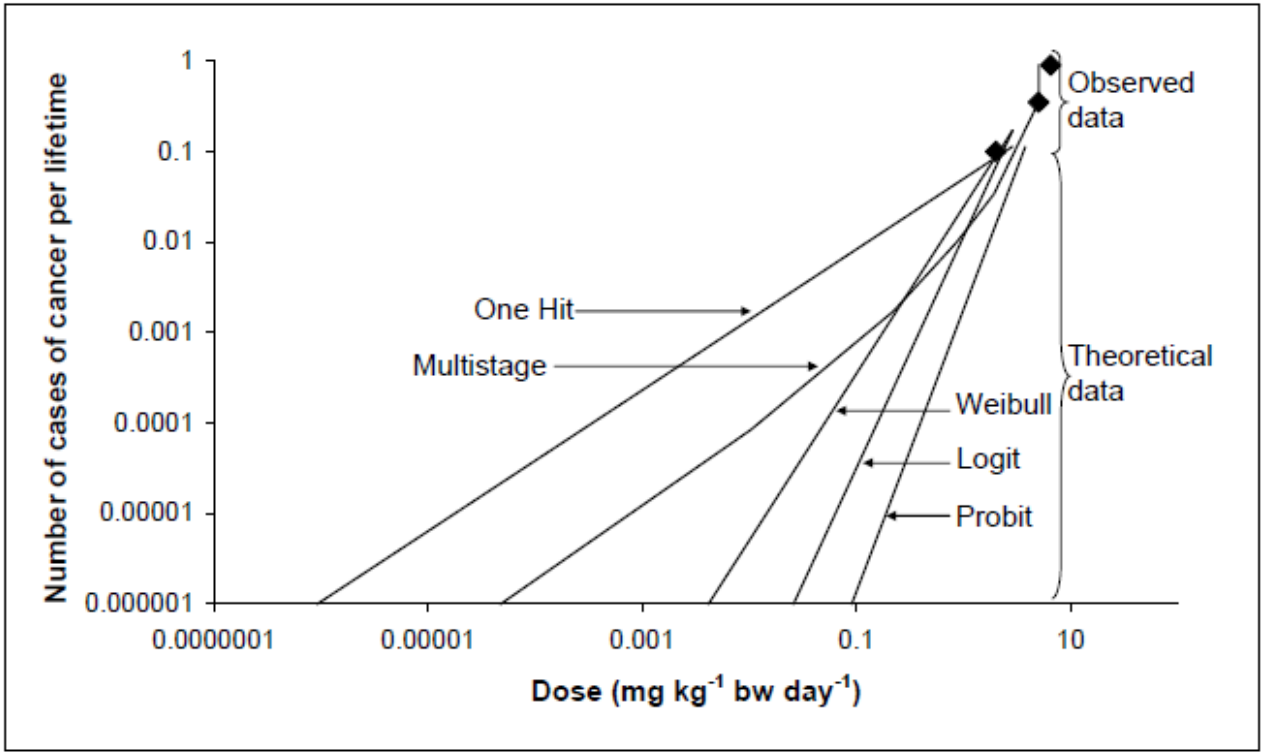


Figure 2.6 Example of variance of quantitative cancer risk models when modelling the same data set (modified from COC, 2004)

Source: SR2

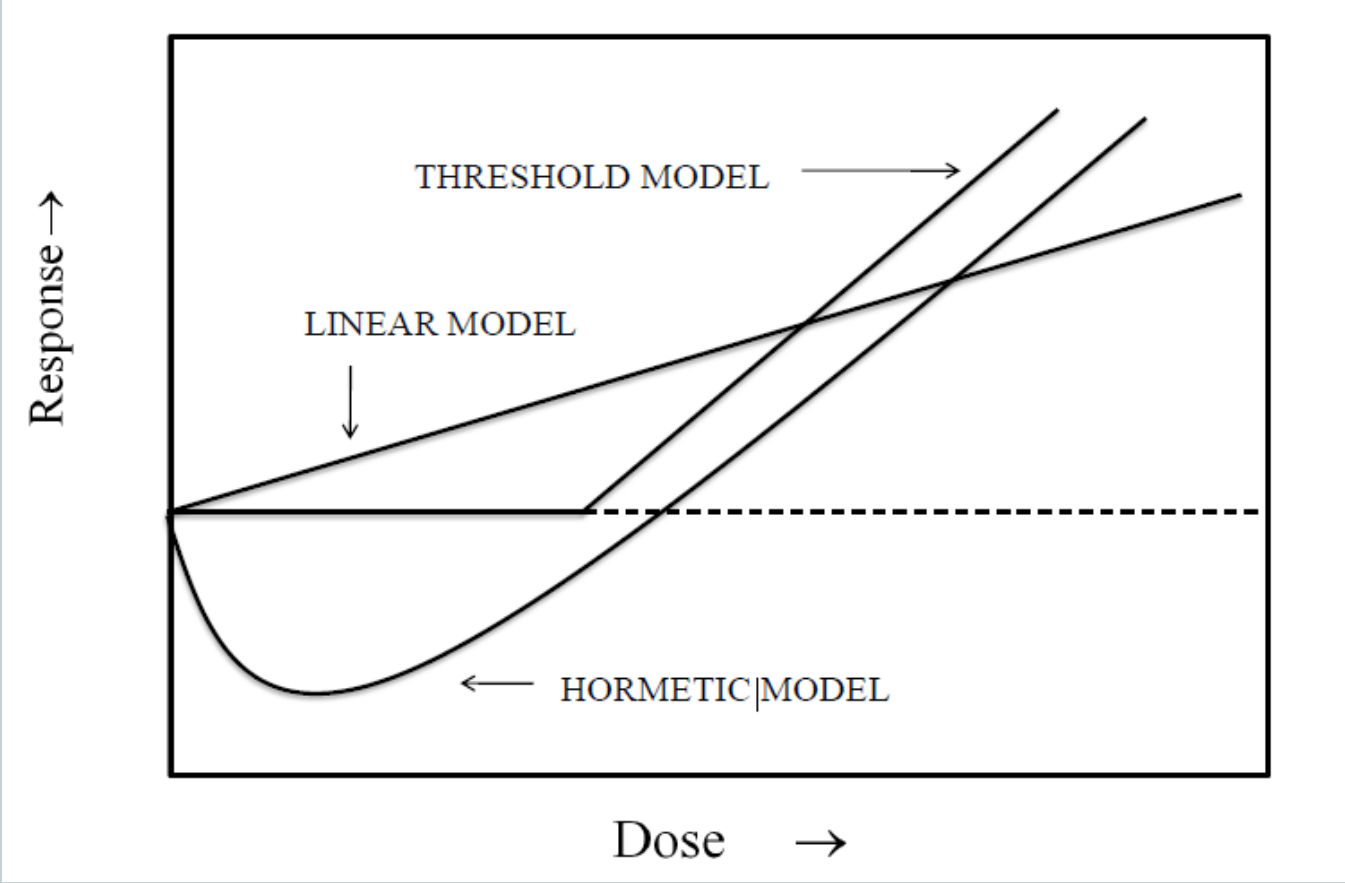
Uncertainty in Risk Assessment (cont)

Oral LLTC Derivation for Benzo(a)pyrene

Model Name	BMD	BMDL
Gamma	0.33	0.16
Logistic	0.13	0.11
LogLogistic	0.33	0.18
LogProbit	0.32	0.20
Multistage	0.22	0.08
Multistage-Cancer	0.21	0.08
Probit	0.13	0.11
Weibull	0.33	0.14
Quantal-Linear	0.07	0.05

Based on Table IV of Appendix E1 from the C4SLs Report

Uncertainty in Risk Assessment (cont)



E J Calabrese, 2012. Presentation to EFSA. Available at http://www.efsa.europa.eu/en/events/event/120614.htm

Decision-Making

Decision-Making (cont)

- Where to draw the line on what level of actual or modelled exposure is acceptable (or unacceptable) is a "risk management" decision
- Zero risk may only be possible with zero exposure
- Conversely, the true risk from a given substance or site, even if C4SLs are exceeded, could be zero
- Dourson and Parker, 2007:

  "Estimates of "safe" doses are accurate but imprecise. They are believed to be without risk, but cannot be used to estimate risk."

ML Dourson and AL Parker. Past and Future Use of Default Assumptions and Uncertainty Factors: Default Assumptions, Misunderstandings, and New Concepts. Human and Ecological Risk Assessment, 13: 82–87, 2007.

Decision-Making (cont)

- Part 2A decisions must ultimately be taken by the regulator, within the context of relevant guidance and science (including an understanding of uncertainty):

  "External experts may advise the local authority on regulatory decisions under the Part 2A regime, but the decisions themselves remain the sole responsibility of the local authority".

  (Part 2A Statutory Guidance)

Decision-Making (cont)

- Part 2A Statutory Guidance:

  "The following health effects should always be considered to constitute significant harm to human health: 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."

  "Other health effects may be considered by the local authority to constitute significant harm. For example, a wide range of conditions may or may not constitute significant harm (alone or in combination) including: physical injury; gastrointestinal disturbances; respiratory tract effects; cardio-vascular effects; central nervous system effects; skin ailments; effects on organs such as the liver or kidneys; or a wide range of other health impacts."

Decision-Making (cont)

- In considering whether SPOSH exists, the SG requires consideration of:
  - the number of people who might be exposed to the risk and/or likely to suffer harm
  - the likelihood of such harm
  - estimated impact if it did occur
  - timescale over which it might occur
  - levels of certainty attached to the risk estimates.
- Part 2A decisions must be made in the context of the broad objectives of the regime
- Part 2A decisions should be based on what is reasonably likely, not what is hypothetically possible
- SPOSH is a positive legal test – it is not necessary under Part 2A for the local authority to "prove clean"

Decision-Making (cont)

- DCLG Planning Practice Guidance (online):
  - *"Local planning authorities will want to have regard to (the SG) alongside...other matters that could affect the amenity of a site and its future occupants. (There could, for example, be contaminants present at levels that could cause nausea, headaches, odour/nuisance to people, or harm to non-protected species of plants and animals.) After remediation, as a minimum, land should not be capable of being determined as contaminated land under Part 2A."*

Decision-Making (cont)

"Systems and procedures are important, but they're not enough. For me the acid test of safe enough gets measured on a different scale. Would I let my son or daughter do that? Would I be happy to see someone I cared about putting themselves at risk in that way? If the answer is no, then why should you feel comfortable asking someone in your business to do it?"

Judith Hackitt, CBE, Chair, HSE

Blog Entry, 30/7/12

Thanks for listening!

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** New Training Course**

- EH Sciences is planning a day-long, hands-on training course (for restricted numbers), in central London (date to be decided), covering:
  - BMD modelling
  - CLEA 1.07 (assuming its release)
  - C4SLs
  - DQRA
  - use of statistics in land contamination risk assessment
  - Part 2A decision-making and site categorisation
- Likely cost will be approx £250 + VAT
- Laptop needed!
- Get in touch if interested (see previous slide for details)