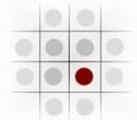


SoBRA



Toxicological Aspects of SPOSH



Society of Brownfield Risk Assessment and
Royal Society of Chemistry - Toxicology Group

Current Issues in Contaminated Land Risk Assessment – 2011

Burlington House, London
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MIKE QUINT

Contents

2

- **Legal Context**
- **Statutory Guidance - Existing**
- **Statutory Guidance – Consultation Draft**
- **Existing Technical Guidance**
- **Detailed Approaches**

Legal Context

3

- Environment Act 1995 inserted Part 2A into the Environmental Protection Act 1990 (“Part 2A”).
- Legal definition of contaminated land within Part 2A as follows:
 - *“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”.*
- The “significant possibility of significant harm” (SPOSH) bit is primary legislation - not going away!

Legal Context (cont)

4

- Part 2A was implemented via a Statutory Instrument in 2000, with associated Statutory Guidance.
- Statutory guidance up for revision – consultation now ended (<http://www.defra.gov.uk/corporate/consult/contaminated-land/index.htm>)

Statutory Guidance - Existing

5

- Definition of “significant harm” to human beings (Table A of current SG):
 - *“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 this Chapter, this description of significant harm is referred to as a “human health effect”.”*

Statutory Guidance – Existing (cont)

6

- **Definition of “significant possibility of significant harm” to human beings (Table B of current SG):**

Human health effects arising from

- the intake of a contaminant, or
- other direct bodily contact with a contaminant

If 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.

Such an assessment 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.

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.

- **Includes considerations of additivity and synergism (Para B.41 of current SG)**

Statutory Guidance - Consultation Draft

7

- **“The objectives of the Part 2A regime are:**
 - a) To identify and remove unacceptable risks to human health and the environment.
 - b) To seek to bring damaged land back into beneficial use.
 - c) To ensure that the burdens faced by individuals, companies and society as a whole are proportionate, manageable and sustainable.”

Statutory Guidance - Consultation Draft (cont)

- **Changes include:**
 - Colour-code system (red/amber/green) or categories 1-4
 - “Background contamination” (natural and anthropogenic) should be Category 4 (excluded from the regime)
 - If site-related exposure is low relative to “background intake” (a “small proportion”), then Category 4
 - Use risk assessment to assess the possibility of significant harm (POSH) first
 - Make uncertainty explicit
 - Decisions to determine on the basis of SPOSH can include considerations of the cost-benefit of remediation etc (Categories 2 and 3)

Statutory Guidance - Consultation Draft (cont)

● Risk Assessment

- “3.1 The 1990 Act takes a risk based approach to defining contaminated land.
- 3.2 For the purposes of this Guidance, "risk" means the combination of: (a) the likelihood that significant harm, or significant pollution of water, will occur as a result of substances in, on or under the land; and (b) the magnitude and seriousness of the harm or pollution if it did occur.”
- “3.26 The uncertainty underlying risk assessments means there is unlikely to be any single “correct” conclusion on precisely what is the level of risk posed at a site, and it is possible that different suitably qualified people could come to different conclusions when presented with the same information. It is for the enforcing 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.”
- General approach (MQ summary):
 - ✦ tiered approach
 - ✦ current use
 - ✦ “reasonably likely” exposure scenarios
 - ✦ appropriate level of detail
 - ✦ conducted in a timely fashion
 - ✦ can use GACs

Statutory Guidance - Consultation Draft (cont)

● Assessing POSH

- “4.13 The term “possibility of significant harm” as it applies to human health, for the purposes of this guidance, means the risk posed by one or more relevant pollutant linkage(s) present at a site. It comprises:
 - a) The estimated likelihood that a potential form of significant harm might occur to an identified receptor, taking account of the current use of the site in question.
 - b) The estimated impact if the significant harm did occur – i.e. the nature of the harm, the seriousness of the harm to any person who might suffer it, and the extent of the harm in terms of how many people might suffer it.
- 4.14 In estimating the likelihood that a potential form of significant harm might occur the local authority should, among other things, consider the estimated probability that the significant harm might occur: (a) if the site continues to be used as it is currently being used; and (b) where relevant, if the site were to be used in a different way (or ways) in the future having regard to the guidance on “current use” in Section 3.
- 4.15 In estimating likelihood, the local authority should consider the strength of evidence underlying the estimation. It should also consider the key assumptions on which the estimate of likelihood is based, and the level of uncertainty underlying the estimate.
- 4.17 The local authority should estimate the timescale over which the significant harm might become manifest.”

Statutory Guidance - Consultation Draft (cont)

- **“Deciding whether a possibility of significant harm is significant (human health) (Para 4.19-4.21 of consultation draft of revised SG):**
 - 4.19 In deciding whether the possibility of significant harm being caused is significant, the authority is deciding whether the possibility of significant harm posed by contamination at the site is sufficiently high that regulatory action should be taken to reduce it, with all that would entail. In taking such decisions, the local authority should take account of the broad aims of the regime set out in Section 1 of this Guidance.
 - 4.20 The decision on whether the possibility of significant harm being caused is significant is a regulatory decision to be taken by the relevant local authority. As far as possible it should be based on the authority’s assessment of possibility of significant harm, including the estimated likelihood that significant harm might occur, the magnitude and seriousness of such harm if it did occur, the timescale in which it might occur, and the level of certainty/uncertainty attached to these estimates. In less straightforward cases other (e.g. socio-economic or environmental) factors may also be taken into account.
 - 4.21 Under Part 2A the decision on whether a “significant” possibility of significant harm exists is a positive legal test. In other words, for a site to meet the test, the local authority needs reasonably to believe that there is a “significant” possibility of significant harm, rather than to demonstrate that there is not.”

Statutory Guidance - Consultation Draft (cont)

12

- **“Sites that should be assumed to pose a significant possibility of significant harm (Category 1)**
 - 4.22 The local authority should assume that a significant possibility of significant harm exists in any case where it considers there is an unacceptably high probability, supported by robust science-based evidence, that significant harm would occur if no action is taken to stop it. For the purposes of this Guidance, such sites are referred to as “Category 1: Human Health” sites. A site should be assumed to be a Category 1: Human Health site where:
 - a) the authority is aware that similar sites or situations are known, or strongly suspected on the basis of robust evidence, to have caused such harm before in the UK or elsewhere; or
 - b) the authority is aware that similar degrees of exposure (via any medium) to the substance(s) in question are known, or strongly suspected on the basis of robust evidence, to have caused such harm before in the UK or elsewhere;
 - c) the authority considers that significant harm may already have been caused at the site, and that there is an unacceptable risk that it might occur again if no action is taken. (The authority may decide to determine a site on these grounds if it considers that it is likely that significant harm is being caused at the site, but it considers either: (i) that there is insufficient evidence to be sure of meeting the “balance of probability” test for demonstrating that significant harm is being caused; or (ii) that the time needed to demonstrate such a level of probability would cause unreasonable delay, cost, or disruption and stress to affected people particularly in cases involving residential properties).”

Statutory Guidance - Consultation Draft (cont)

- “Sites that should be assumed not to pose a significant possibility of significant harm (Category 4)
 - 4.23 The local authority should assume that a site cannot pose 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 sites are referred to as “Category 4: Human Health” sites. The authority may decide that a site is a Category 4: Human Health site as soon as it considers it has sufficient information, and this may happen at any stage during risk assessment (including the early stages).
 - 4.24 The local authority should consider that the following types of site cannot pose a significant possibility of significant harm (and therefore be placed into Category 4: Human Health), unless there is a particular reason to consider otherwise:
 - (a) Sites where no relevant pollutant linkage has been established.
 - (b) Sites where there are only background levels of contaminants in soil, as explained in Section 3 of this Guidance.
 - (c) Sites that have been excluded from the need for further investigation on grounds of comparison with generic assessment criteria in accordance with Section 3 of this Guidance.
 - (d) Sites where estimated levels of exposure to substances in soil are likely to form only a small proportion of what a receptor might be exposed to anyway through other sources of environmental exposure (e.g. in relation to average estimated national levels of exposure to substances commonly found in the environment, to which receptors are likely to be exposed in the normal course of their lives).
 - 4.25 Local authorities may decide that specific sites matching the descriptions of paragraph 4.24 (b) or (d) immediately above pose sufficient risk to qualify as contaminated land. However, such cases are likely to be exceptional and the authority should take particular care to explain why the decision has been taken, and to ensure that it is supported by robust scientifically-based evidence.”

Statutory Guidance - Consultation Draft (cont)

- **“Other Sites**
 - 4.26 On sites that cannot be decided in accordance with the two sub-sections immediately above, the local authority should decide whether or not a significant possibility of significant harm exists in accordance with this subsection. If the authority decides such a possibility does exist it will become a “Category 2: Human Health” site. If not it will be a “Category 3: Human Health” site.
 - 4.27 Before making its decision on whether or not a significant possibility of significant harm exists, the local authority should consider the following factors:
 - ✦ (a) The authority’s estimate of the possibility of significant harm (as described above), including the estimated likelihood of such harm; the estimated impact if it did occur; the timescale over which it might occur; and the levels of certainty attached to these estimates.
 - ✦ (b) The likely direct and indirect health impacts of regulatory intervention. This would include any direct impacts to workers or local residents from contaminants being mobilised during remediation (which would in any case have to be considered under the environmental permitting regime); and any indirect impacts such as stress related health effects that may be experienced by affected people, particularly local residents. This consideration should not necessarily involve quantification of the impacts, particularly if the authority considers it is not possible or reasonable to do so.
 - ✦ (c) Whether or not the likely health benefits of intervention would outweigh the likely health impacts caused by the presence of significant pollutants.
 - ✦ (d) The authority’s initial estimate of what remediation would involve; how long it would take; what benefit it would be likely to bring; whether the benefits would outweigh the financial and economic costs; and any impacts on local society or the environment from taking action that the authority considers to be relevant.”

Statutory Guidance - Consultation Draft (cont)

- “Other Sites (cont)

- 4.28 The local authority should consider these factors in the context of the broad objectives of the regime as set out in Section 1. It should also be mindful of the fact that the decision is a positive legal test, meaning that the starting assumption should be that a site does not pose a significant possibility of significant harm unless there is reason to consider otherwise. The authority should then decide which of the following two categories the site falls into:
 - ✦ (a) Category 2: Human Health. These are sites where the authority concludes there is a strong case for considering that risks at the site are of sufficient concern that the land should be considered to pose a significant possibility of significant harm, with all that this might involve (e.g. the possible determination of the land as “contaminated land”, likely remediation requirements, and the benefits, costs and other impacts of regulatory intervention). This may include some sites where there is little or no direct evidence that similar sites, situations or levels of exposure have caused harm before, but nonetheless the authority considers on the basis of the best available scientific evidence and expert opinion that there is a strong case for taking action on a precautionary basis.
 - ✦ (b) Category 3: Human Health. These are sites where the authority concludes that the strong case described in (a) does not exist, and therefore the legal test for significant possibility of significant harm is not met. This may include some sites where the risks are such that the authority and others would prefer they did not exist, but nonetheless the authority considers that regulatory intervention under Part 2A is not warranted. In practice, this would not stop others from taking action to manage risks (outside of the Part 2A regime) and the authority should consider making available the results of its investigation to the owners/occupiers of Category 3 sites so they can consider whether they wish to take action themselves.
- 4.29 In making its decision on whether the strong case described in paragraph 4.28(a) exists, the local authority should give particular consideration to its assessment of the possibility of significant harm. If a site poses a high degree of risk, the authority should normally decide to place the land in Category 2 regardless of other factors (such as the cost or inconvenience of remediation). Conversely, if a site poses a low degree of risk (particularly if it is not clear that the health benefits of intervention would outweigh the health impacts) it should be placed in Category 3 regardless of other factors. In other cases other factors may be given more weight to arrive at a decision.”

Statutory Guidance - Consultation Draft (cont)

16

● Toxicology and SPOSH?

○ “The objectives of the Part 2A regime are:

- ✦ To identify and remove **unacceptable risks** to human health and the environment.”

○ Category 1:

- ✦ “The local authority should assume that a significant possibility of significant harm exists in any case where it considers there is an **unacceptably high probability**, supported by robust science-based evidence, that significant harm would occur if no action is taken to stop it.”

○ Category 4:

- ✦ “The local authority should assume that a site cannot pose a significant possibility of significant harm if it considers that there is **no risk or that the level of risk posed is low**.”

○ Other sites:

- ✦ “..the local authority should give particular consideration to its assessment of the possibility of significant harm. If a site poses **a high degree of risk**, the authority should normally decide to place the land in Category 2 regardless of other factors (such as the cost or inconvenience of remediation). Conversely, if a site poses a **low degree of risk** (particularly if it is not clear that the health benefits of intervention would outweigh the health impacts) it should be placed in Category 3 regardless of other factors.”

Existing Technical Guidance

17

- 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)

Existing Technical Guidance (cont)

18

- **DEFRA, 2008 (Annex B):**
 - “Minimal risk” for non-threshold genotoxic carcinogens:
 - Animal data - $BMDL_{10} / 10,000$ (ie, a margin of exposure (MOE) of 10,000)
 - Human data – 1×10^{-5} excess lifetime cancer risk (ELCR)

Existing Technical Guidance (cont)

- **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).”

Existing Technical Guidance (cont)

20

- **HPA, 2008 - “An Introduction to Land Contamination for Public Health Professionals”:**
 - “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.”
- **Presentation from Dr Sarah Bull (formerly of the HPA) at the 2011 SoBRA lead workshop (in relation to the EFSA BMDL₀₁ of 0.5 µg/kg-day):**
 - MOE of >10 - should not give rise to appreciable risk of clinically significant effects; and
 - MOE >1 (and presumably <10) - risk likely to be low but could not be dismissed as of no potential concern.

Existing Technical Guidance (cont)

21

- **Science Report SC050021/SR3 (2009 - CLEA Report):**
 - “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).”

Existing Technical Guidance (cont)

22

- **Environment Agency's arsenic SGV Report (2009):**
 - Oral ID of 0.3 $\mu\text{g}/\text{kg}\text{-day}$, based on the UK drinking water standard - equates to an ELCR of 40-400 in 100,000 ($4\text{-}40 \times 10^{-4}$).
 - “minimal risk” approach would result in a much lower ID, but in order to be proportionate, the above value is adopted.
 - “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*.”

Existing Technical Guidance (cont)

23

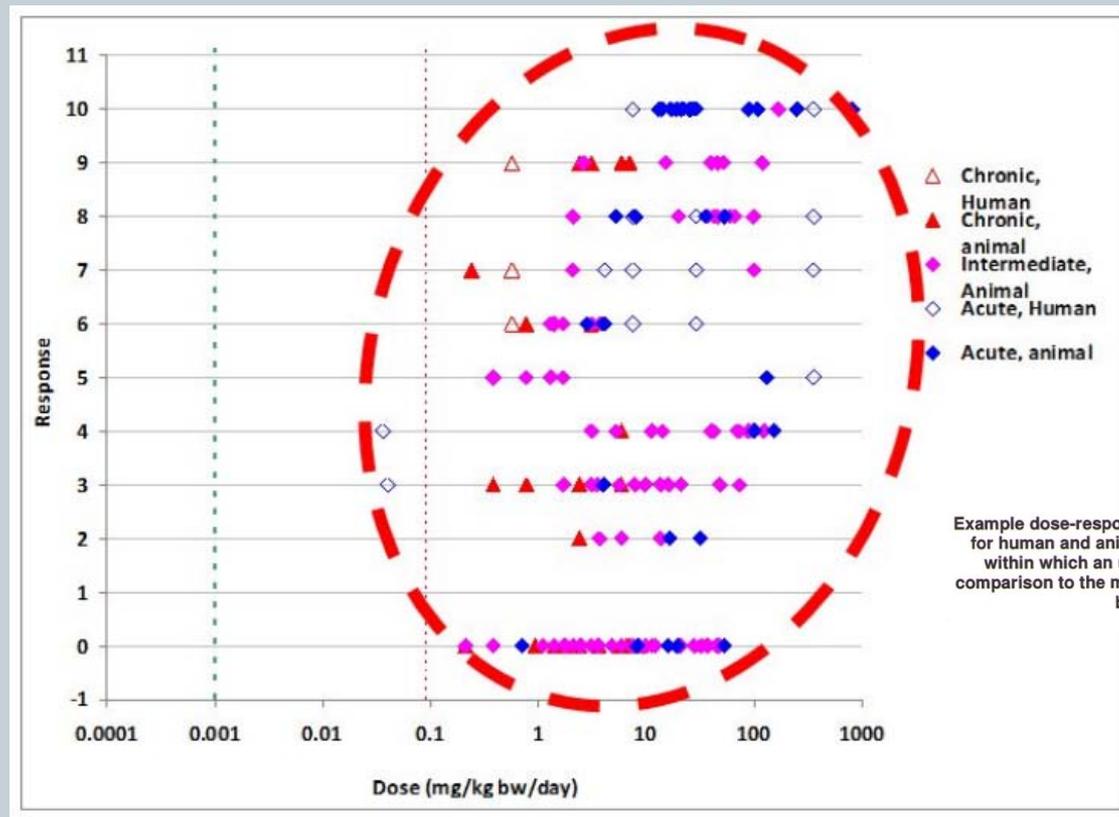
- **Also:**

- CIEH, 2006 - Professional Practice Note (The determination of contaminated land: deciding what is an “unacceptable intake”)
- DEFRA, 2006 - CLAN 6/06 (Assessing Risks from Land Contamination – a Proportionate Approach. Soil Guideline Values: the Way Forward)
- RSC, 2009 – Note on a Toxicology Group Meeting of 15 May 2009 (Can Toxicologists Further Define “Unacceptable Intake” for Contaminated Land?)

Detailed Approaches

24

- LQM/CIEH Dose-Response Roadmaps:

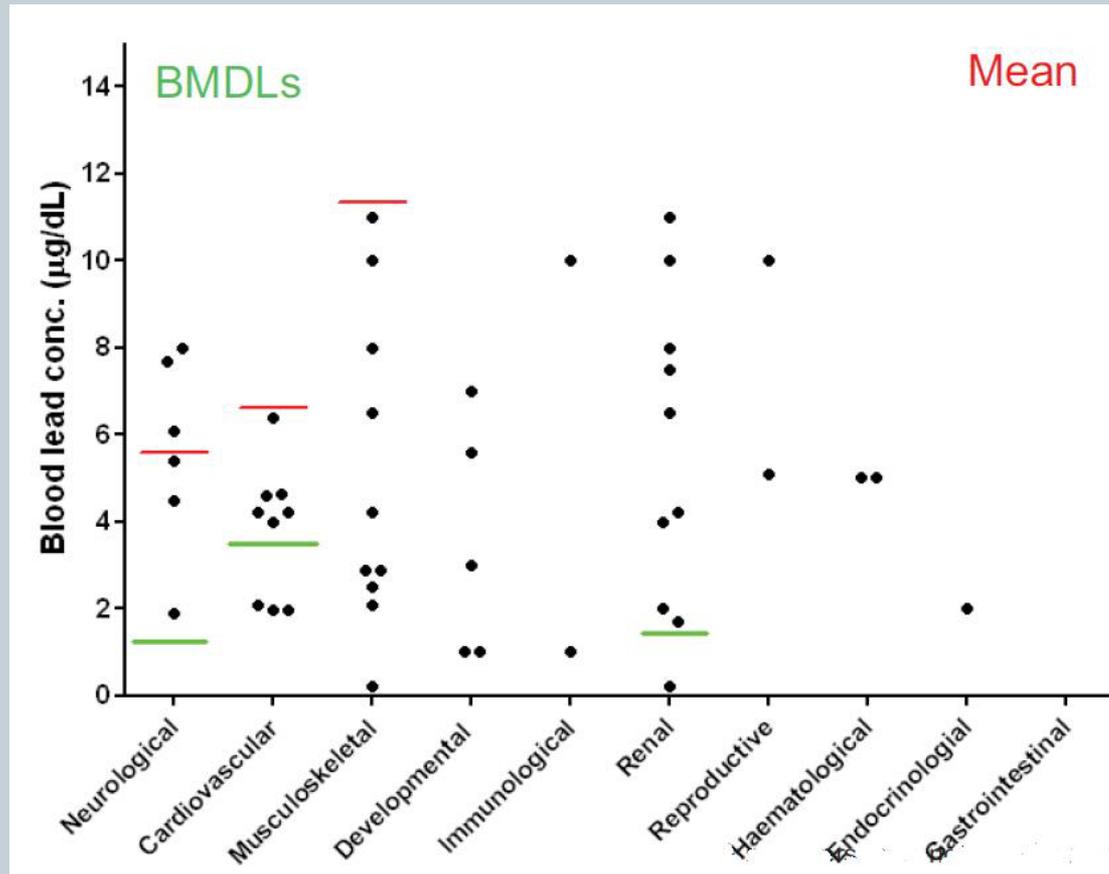


Example dose-response chart showing the toxicological "cloud" for human and animal data (bounded by the red dashed line) within which an unacceptable intake is expected to lie, in comparison to the much lower health criteria value (represented by the green dashed line)

Detailed Approaches (cont)

25

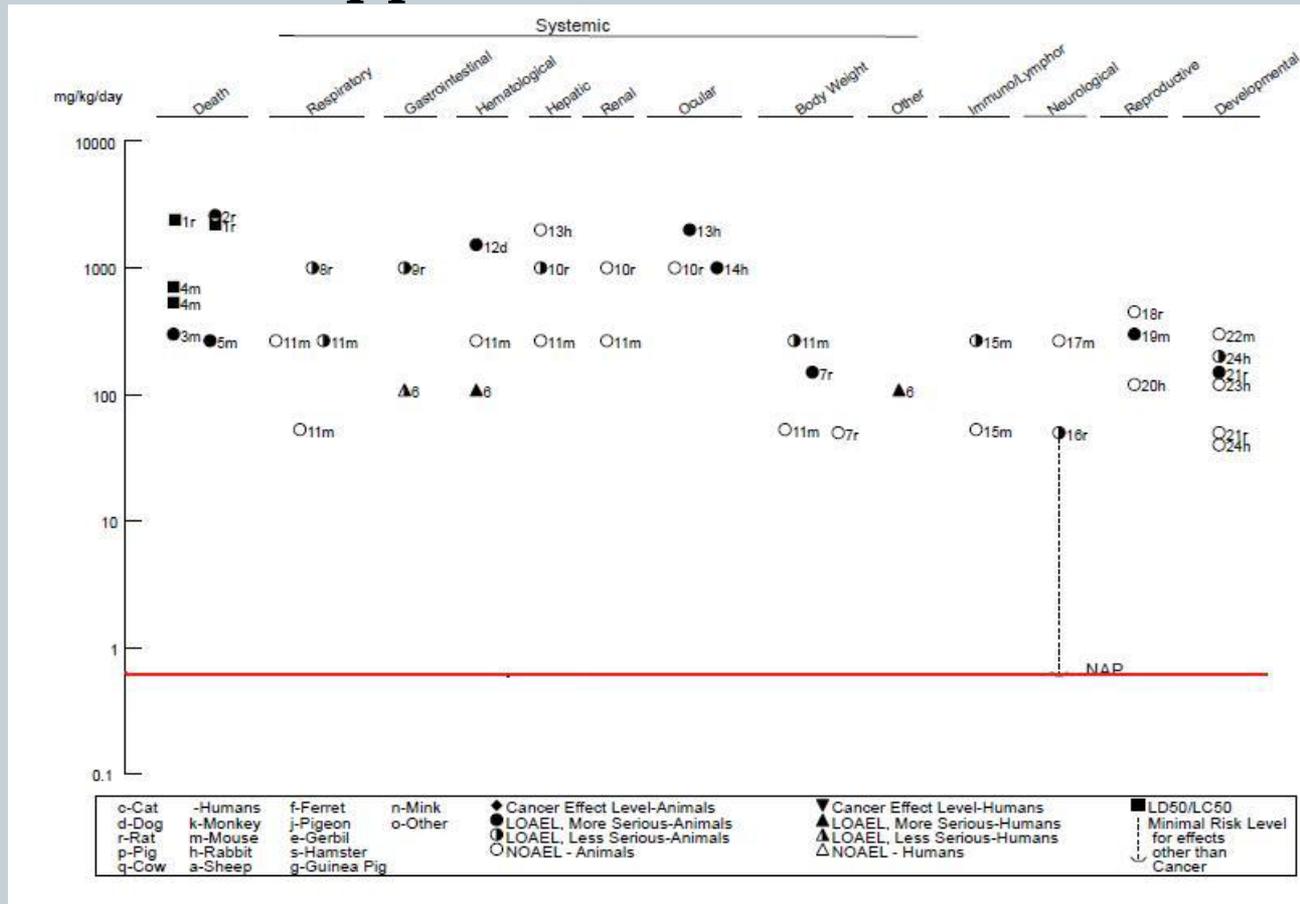
- Dr Sarah Bull – Lead (from 2011 SoBRA Workshop):



Detailed Approaches (cont)

26

- ATSDR-based approach:



Detailed Approaches (cont)

27

- **Important considerations:**
 - All blobs aren't equal!
 - ✦ Species / strain / husbandry, etc
 - ✦ Nature of the study – duration, repro, cancer, etc
 - ✦ Lab, date, sponsor, etc
 - More blobs might be added daily/annually!
 - If used in “forward mode”, should ADEs be estimated for each data point (to give many site-specific lines) or should a statistical measure of the data be used to give a single site-specific line (eg, 95% UCL)?
 - How much white space is acceptable/unacceptable etc?
 - Uncertainty factors (UFs) and margins of exposure (MOEs)
 - Absence of evidence isn't evidence of absence!
 - Mixtures
 - ALARP

Thanks for listening!



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