ENVIRONMENTAL HEALTH SCIENCES
LIMITED

Joint SAGTA / SoBRA Workshop

Category 4 Screening Levels: Industry Application

What is the View of the Outside World?

BAE Systems, Farnborough
8 April 2014

MIKE QUINT

Contents

Introduction

- Ambitious project
- Consortium's overall approach was clear from the outset
- Finer details subject to input from wider community
- Process was important

Defra

- Recently accepted and published the Consortium's final report(s)
- General endorsement of approach
- Clarifications in the Policy Companion Document:
  - Endorsement of a Benchmark Dose (BMD) approach to toxicological assessment and the use of a Benchmark Response (BMR) of 10% (for animal data), or lower (for human data)
  - Derivation of a Low Level of Toxicological Concern (LLTC) for non-threshold chemicals using a Chemical Specific Margin (where data allow) or a generic margin of 5,000 (when BMD_{10} used). Alternatively, if human data allow it, use an Excess Lifetime Cancer Risk (ELCR) of 1 in 50,000
  - Where necessary, policy-based LLTCs should be used to avoid disproportionately targeting soil
  - Lead LLTC = 3.5 µg/dl (blood)
  - Endorsement of use of US EPA's IEUBK model, and CLEA, for lead
  - Changes to both exposure modelling and toxicological assessment should be used
  - DCLG responsible for planning policy
  - Fate of the SGVs lies with the Environment Agency (but CLEA, SR2 and SR3 should be retained)

Steering Group (in addition to Defra)

- Environment Agency
- Department of Communities and Local Government
- Food Standards Agency
- Public Health England (formerly Health Protection Agency)
- Homes and Communities Agency
- Natural Resources Wales
- Welsh Government

"The final report, and Policy Companion Document, do not necessarily represent a collective view of the Group."

Stakeholders

- Stakeholder engagement built into the project, with three stakeholder workshops being incorporated into the research
- Feedback and comments from stakeholders were incorporated and/or taken into account

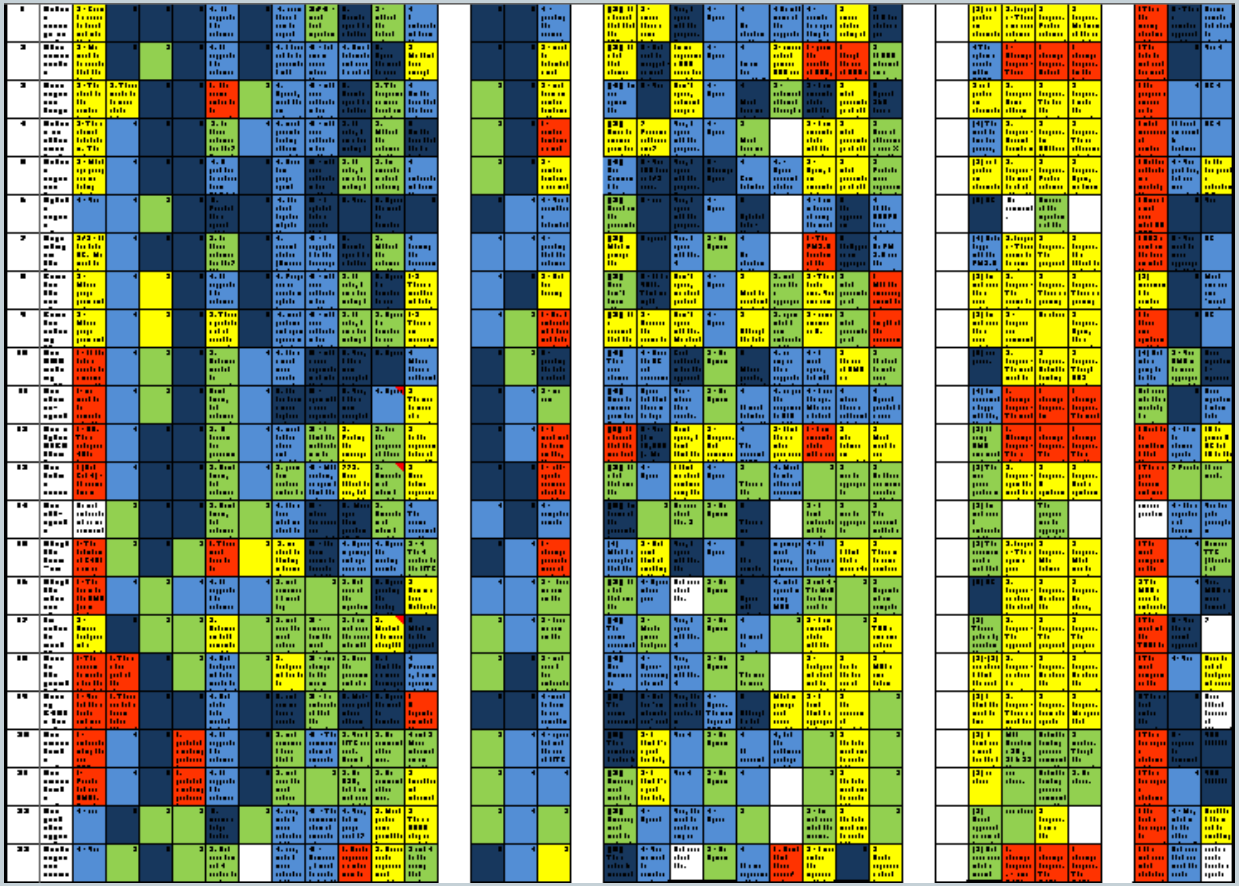
Stakeholders (cont)

- Stakeholder Workshop Invitees:

Association of Geotechnical and Geoenvironmental Specialists (AGS)	Local Authorities - South Coast Region
British Geological Survey (BGS)	Local Authorities - South East Region
British Land Reclamation Society (BLRS)	Local Authorities - West Midlands Region
British Property Federation	Local Authorities - West of England Region
British Standards Institution (BSI) - EH/4 Soil Quality Committee	Local Authorities– Yorkshire Region
British Toxicology Society (BTS)	National House Building Council (NHBC)
Chartered Institute of Environmental and Water Management (CIWEM)	North-West Brownfield Remediation Forum (NWBRF)
Chartered Institute of Environmental Health (CIEH)	Planning Officers Society
Chemical Industries Association (CIA)	Professor Chris Collins, University of Reading
City of London Law Society	Professor Len Levy, Cranfield University
Civil Engineering Contractors Association (CECA)	Professor Paul Nathanail, University of Nottingham
Committee on Toxicity (COT)	Professor Simon Pollard, Cranfield University
Energy Institute	Register of Ground Engineering Professionals (RoGEP)
Environmental Industries Commission (EIC) – Contaminated Land Working Party	Royal Institution of Chartered Surveyors (RICS)
Environmental Protection UK (EPUK) – Land Quality Group	Royal Society of Chemistry (RSC) – Toxicology Group
Geological Society of London (GeolSoc)	Royal Town Planning Institute (RTPI)
Greater Manchester Contaminated Land Officers Group	Society for Environmental Geochemistry and Health (SEGH)
Health and Safety Laboratory (HSL)	Society of Brownfield Risk Assessment (SoBRA)
Home Builders Federation (HBF)	Society of Chemical Industry (SCI)
Institution of Civil Engineers (ICE)	Soil and Groundwater Technology Association (SAGTA)
Institution of Environmental Sciences (IES)	Specialist in Land Condition (SiLC)
Local Authorities - East Midlands Region	UK Contractors Group (UKCG)
Local Authorities - East of England Region	UK Environmental Law Association (UKELA)
Local Authorities– London Region	Waste and Resources Action Programme (WRAP)
Local Authorities - North East Region	Welsh Contaminated Land Working Group

Stakeholders (cont)

- Stakeholder Feedback from Workshop 1:



Stakeholders (cont)

- Stakeholder Feedback from Workshop 2:

1	The point of departure from which to derive	5	3	2	1	4	4		2	1	3	3			5	5	4	2	1	2	1	3		1	2	1	1
		5	3	4	4	5	3		4	4	5	3			1	3	2	5	5	2	1	3	5	1	5	5	1
		5	4	4	4	4	3		4	4	3	3			2	1	4	5	5	2	1	3		1	5	2	1
		5	2	4	1	2	3		2	2	3	3			1	5	3	3.5	1	2	1	3		1		4	1
		5	2	1	1	2	2		2	1	3	3			1	5	2	2.5	1	2	1	3		1		4	1
2	A chemical specific margin of 5000 being	4	4	2	4	1	4		4	4	4	3	2		4	5	4	4.5	4	4	1	2	5	1	2	5	1
3	The LLTC$_{int,r}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP	4	4	4	5	4	3	2	4	4	4	3			4	5	5	5	5	4	2	4	5	2	5	5	1
4	Based upon the description of the	4	3	4	4	5	3		4	4	4	3			4	3	4	3.5	2	3	2	2	3	2	1	4	1
5	Based upon the description of the	4		4	4	5	3		4	4	4	3			4	3	3	4	4	4	2	2	3	2	5	4	1
6	The proposed modifications to deterministic	4		3	2	5	4	4	5	2	4	3			4	4	4	5	5	4	2	4	5	1	?	4	1
7	For POS 1, please could you indicate your	4	2	5	4	1	3			4	1	2	1		1	1	4	5	2	4	4	3	5	4	4	3	1
			3	2	2	4	3	3	X	2	1	2	1		1	1	2	5	5		2	3		2	4	1	1
			3	4	3	4	5	5		4	5	4	5		4	5	2	5	2		2	3		2	2	5	4
8	The choice of exposure parameters for POS		4	4	4		4	3	3	4	4	4			4		4	5	5	4	4	3	3	4	3	5	
9	The choice of exposure parameters for POS		4	3	2		4	3	4	4	4	4			4		3	4	5	4	4	3	3	4	3	5	
10	The use of probabilistic modelling as a line of	4	4	4	5	5	5	5	4	4	4	4			4	4	4	4	2	2	4	4	5	4	4	5	1
11	The use of the qualitative evaluation of	3	4	3	5	3	5	5	4	4	5	4				4	3	5	5	4	2	4	5	2	4	4	1
12	The inclusion of 'other considerations' as	4	1	5	2		5	5	3	2	5	5				5	4	5	5	4	2	4	5	2	1	5	1
13	The proposed C4SL meet the policy	5	3	3	4	4	4	3	4	4	3	3			4	5	4	3	3	3	1	2	4	1	2	4	1
14	The proposed C4SL are they sufficiently	4	3	3	3	4	4	3	3	4	4	4			4	5	4	3	2	2	1	2	4	1	1	4	1
15	The proposed C4SL will be useful for	4	4	2	3	4	4	5	4	3	4	3			4	4	3	4	3	4		4	4	3	3	5	1
16	When using C4SLs in a risk assessment,	3	3	4	4	3	3	2	4	5	4	5			4	5	4	3.5	3	2	2	4	5	2	1	5	1

Committee on Toxicity

- Toxicological aspects submitted to the Committee on Toxicity (COT) on 14 May 2013, by Defra, for consideration, along with five specific questions.
- Minutes from this meeting are available online (http://cot.food.gov.uk/cotmtgs/cotmeets/).
- Selected sound-bites from the minutes:
  - *"One Committee Member, who was familiar with contaminated land policy, commented that the broad approach was reasonable."* (para 24)
  - *"Members agreed that the report was good"* (para 28)

Committee on Toxicity (cont)

- Defra Questions, COT answers and Defra responses (in green):

  i). Does the Committee have any comments regarding the use of a new term LLTC (Low Level of Toxicological Concern) that suitably reflects "low" concern in the context of deriving Category 4 Screening Levels for contaminants in contaminated land risk assessment?

  "The Committee felt that the "low level" in the new term, "Low Level of Toxicological Concern" (LLTC), that was proposed as part of the revised toxicological framework might be overlooked by the public, who would focus more on the "toxicological concern". Members recommended that sociological research on how the public would perceive the term would be useful."

  Although Defra hasn't commissioned any specific research, the Social Science Research Unit at the Food Standards Agency was contacted on this issue but is not aware of any specific work that has been undertaken in this area.

  There was a majority agreement at the first Stakeholder Workshop that this term was acceptable. More specifically there was agreement to:

  "Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing Category 4 Screening Levels that are "more pragmatic but still strongly precautionary" compared with existing Health Criteria Values."

Committee on Toxicity (cont)

ii). Does the Committee support the general approach taken in this research project and is the proposed methodology for developing LLTCs scientifically valid and robust given the role of LLTCs in assessing risk of exposure to contaminants in soil?

"Members commented that the approach adopted in the project was consistent with that applied in many other areas of toxicological risk assessment for chemicals. However, there was some concern about the proposed method for developing LLTCs, as regards setting and maintaining the margin between SGVs and Category 4 Screening Levels. It was also recommended that some of the current minimal risk HCVs should be revised to take account of newer data."

This would be for the Environment Agency to consider but there is currently no intention or funding to take this forward.

Committee on Toxicity (cont)

iii). Does the Committee think that the use of a chemical-specific margin (CSM), which parallels the MOE approach, is appropriate to derive a LLTC for non-thresholded chemicals? This could be either based on scientific uncertainties or be a policy chosen margin.

"The committee agreed that the use of a chemical-specific margin (CSM) approach, which paralleled the margin of exposure (MOE) approach, was appropriate to derive an LLTC for non-threshold chemicals. However, defining an acceptable margin entailed value judgements, and was not purely scientific. It involved an element of risk management, and careful consideration should be given as to how risk assessment and risk management could be brought together without the possibility of misuse. Specific criteria were needed by which to define the levels of margins, supporting the need for a central discussion rather than ad hoc local decisions. "

As recommended, the Committee on Carcinogenicity (COC) was approached in September 2013 and did not disagree with the approach of using an Excess Lifetime Cancer Risk higher than 1 in 100,000 to define a Low Level of Toxicological Concern but concluded there was no scientific basis for using a default margin smaller than those recommended by COC to derive a Low Level of Toxicological Concern. In general the Committee on Carcinogenicity works towards a minimal risk approach whereas the approach being taken for Category 4 Screening Levels is 'low risk'.

The majority of stakeholder workshop feedback was to set a higher Excess Lifetime Cancer Risk than 1 in 100,000 when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).

Therefore Defra recommends that for the purposes of deriving Category 4 Screening Levels, a risk estimate of 1 in 50,000 could be specified as 'low risk' and this would be a generic level used for all human genotoxic carcinogens.

To avoid disproportionately targeting soils compared with other media such as water or air, the LLTC may be associated with a higher ELCR. In such cases, a toxicologically-based LLTC could be derived, which would then be over-ridden by a policy-based LLTC recommended elsewhere .

Committee on Toxicity (cont)

iv). Does the Committee think that, in the context of cancer, the use of an Excess Lifetime Cancer Risk (ELCR) higher than 1 in 100,000 is appropriate when defining a LLTC using quantitative dose-response modelling (based on human data)?

"In the context of cancer and the use of an Excess Lifetime Cancer Risk (ELCR) higher than 1 in 100,000 to define a LLTC, the Committee commented that a level of exposure associated with a 1 in 100,000 excess risk could not be established scientifically, and therefore it was necessary to consider margins on exposures that caused larger effects. The Committee recommended that further advice on this should be sought from the Committee on Carcinogenicity (COC). ELCRs were used by other bodies internationally and so could not be ignored. However, it is a risk management decision to define an acceptable level of risk. Members agreed that it was important that transparency be maintained in making such decisions."

There has been a significant amount of peer review undertaken. The reports in their entirety have been reviewed by experts specialising in toxicology and risk/exposure assessment; a summary of their comments is being published separately. Additionally, the two independent scientific committees approached to review certain toxicological aspects of the report (the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Committee on Carcinogenicity (COC)) are public meetings with minutes available on their respective websites.

Committee on Toxicity (cont)

v). Does the Committee have any comments that it would like the project consortium to take into account in finalising this research project?

"The Committee advised that in finalising this research project, differences in the absorption of contaminants from different routes of exposure should be accounted for in the toxicological assessment rather than the exposure assessment."

This project was designed with the intention that one of the outputs would be an agreed and tested methodology that would then be available for the sector to develop further Category 4 Screening Levels for additional contaminants as necessary. It is Defra's view that sufficient guidance is provided in the final reports from the project together with this Policy Companion Document for additional Category 4 Screening Levels to be developed with confidence by those in the sector, bearing in mind the need for specialist toxicological input into the derivation of the Low Level of Toxicological Concern. However, Defra recognises the potential value in there being some central oversight of additionally developed C4SLs and will consider this further but, in any case, endorses significant stakeholder input into the derivation of additional C4SLs.

Committee on Carcinogenicity (COC)

- Toxicological aspects (and especially the approach to dealing with non-threshold carcinogens) submitted to the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) on 19 September 2013, by Defra, for consideration.
- Minutes from this meeting available online (see http://www.iacoc.org.uk/meetings/index.htm).
- Selected sound-bite:
  - *"In general, COC work towards a minimal risk approach and would not like to see the threshold go higher than 1 in 100,000 ELCR." (para 19)*

Peer Reviewers

- Defra received comments from two peer reviewers.
- Selected comments from Peer Reviewer 1:

"In summary, I think it must be recognized that the challenge of balancing the competing goals of being "strongly precautionary" while avoiding being "over cautious" is substantial. Because such a balance requires technical and policy considerations, identification of the optimal balance point is highly subjective and it is safe to say that it would be impossible to develop screening levels that would have unanimous support."

"The project team accepted a substantial challenge and provided a very well thought out and well documented approach, and they clearly identified the scientific uncertainties, as well as the fact that policy considerations are important in the derivation of any soil screening levels. Because the approach proposed by the project team is based on conservative human health risk assessment methods and acceptable risk policies, the provisional screening values produced by the proposed process are virtually certain to be "strongly precautionary.""

Peer Reviewers (cont)

- Selected comments from Peer Reviewer 2:

  "Given the policy requirements and context, this appears to be a reasonable approach to the development of Category 4 Screening Levels (C4SLs)"

  "Probabilistic approaches have been used effectively to explore exceedences of the average daily exposure at the LLTC and the soil concentration at the provisional C4SL."

Other

- Land Forum discussions (see www.claire.co.uk)
- Jiscmail discussion (ongoing)
- Trade journal articles (eg, ENDS, Brownfield Briefing, Contaminated Land Bulletin)

Conclusions

- Project consortium has delivered a considerable amount of research that should be useful for years to come.
- Defra project team should be commended for grasping the complexity of the subject, listening to the diverse opinions around it, responding to specific issues as they arose, understanding the limitations of the science and making policy-based decisions (where required).
- Steering group, expert committees, peer reviewers and stakeholder bodies / representatives should all be thanked for their important inputs.

Thanks for listening!

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