

Progress with the development of the new Category 4 Screening Levels



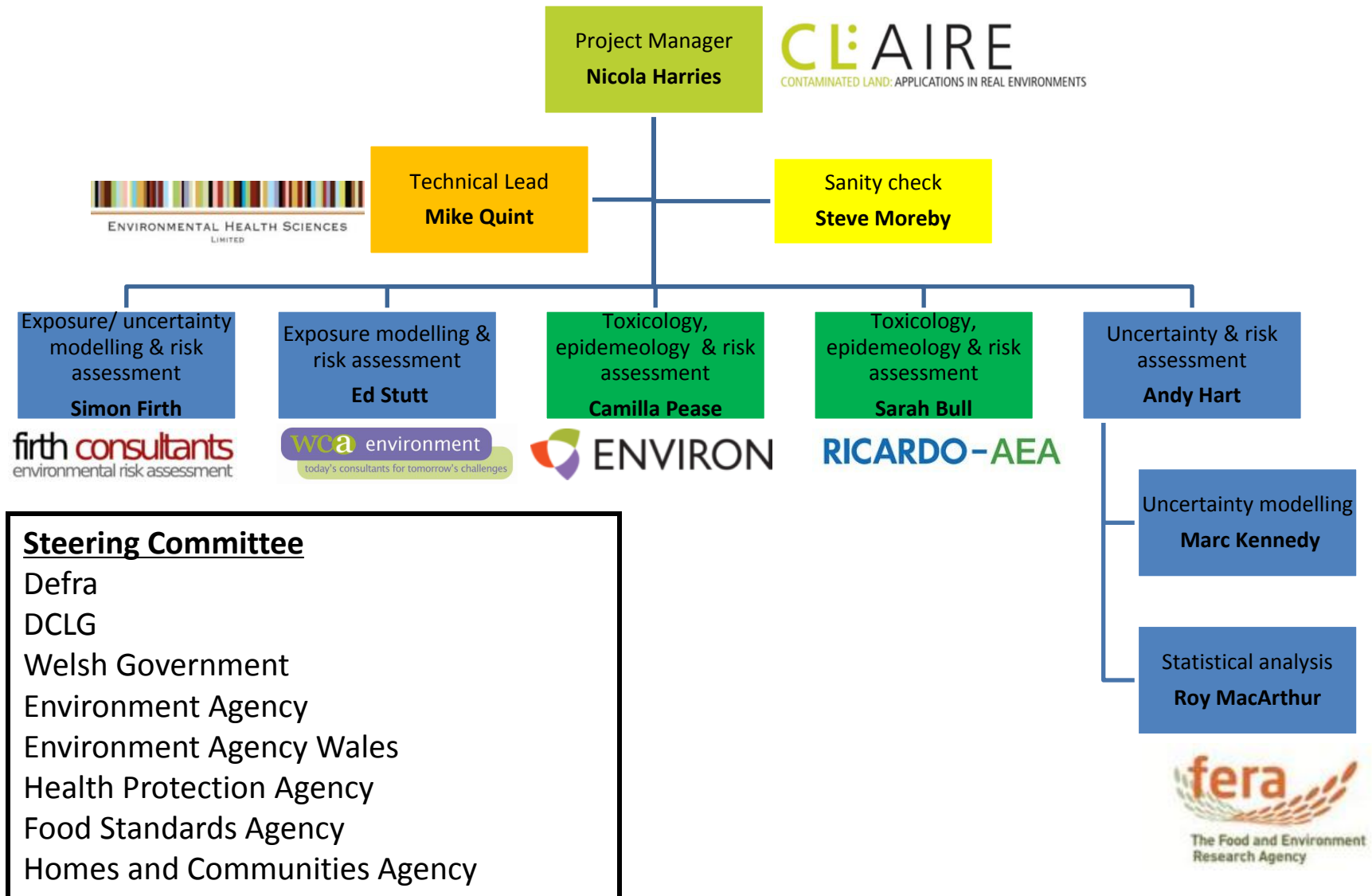
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Introduction

- Project team
- Project objectives
- What are C4SLs?
- Work conducted in Work Package 1
- Proposed methodology for deriving C4SLs

Project Team



Project Objectives

- To develop a methodology to derive C4SLs for 4 generic land-uses:
 - Residential
 - Allotments
 - Commercial
 - Public Open Space

WP1

- To derive C4SLs for 6 substances:
 - Benzo(a)pyrene
 - Cadmium

WP2

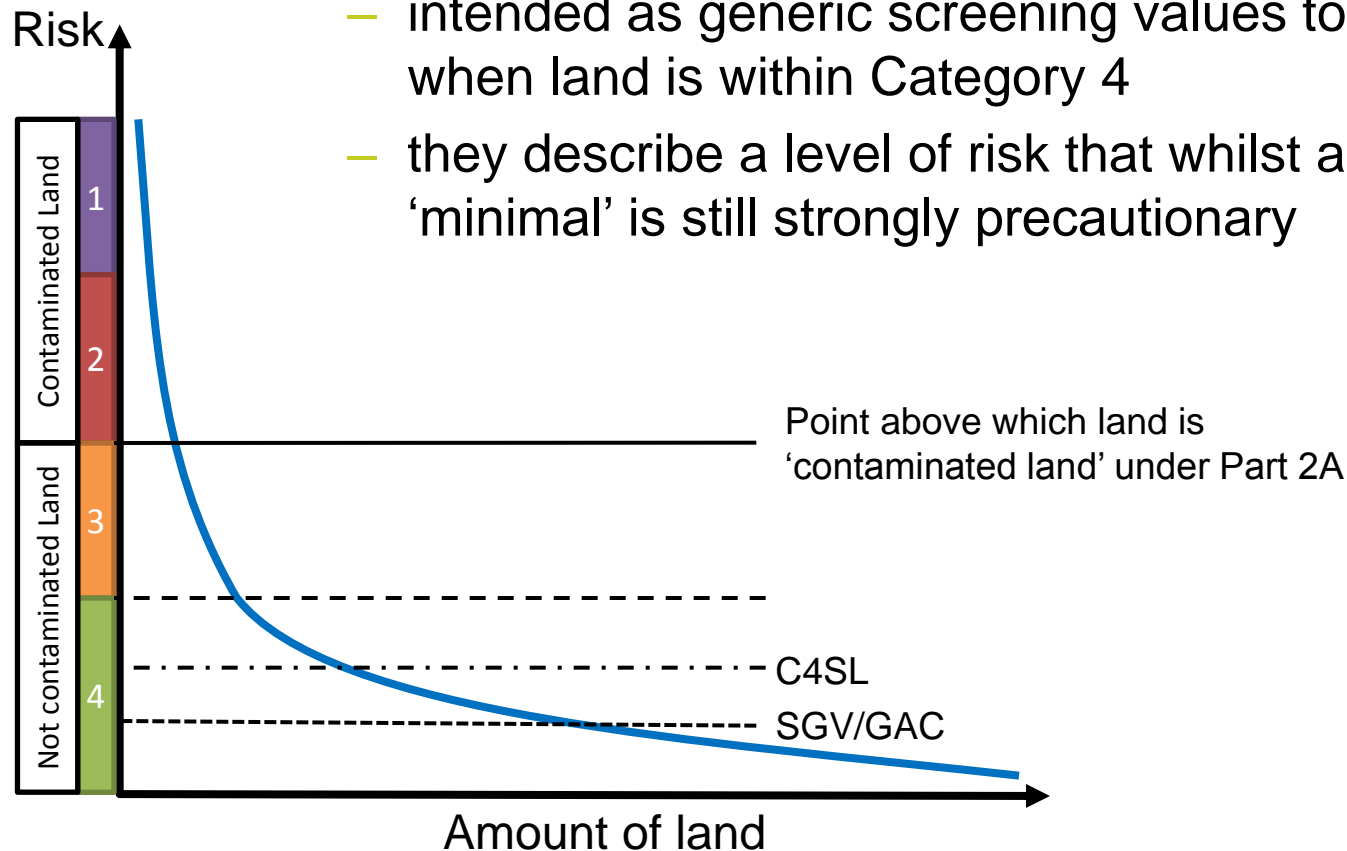
- Arsenic
- Benzene
- Hexavalent chromium
- Lead

WP3

What are C4SLs?

- Category 4 land
 - Land that is definitely not contaminated land
 - Land where there is no risk or where the level of risk posed is low
- C4SLs are

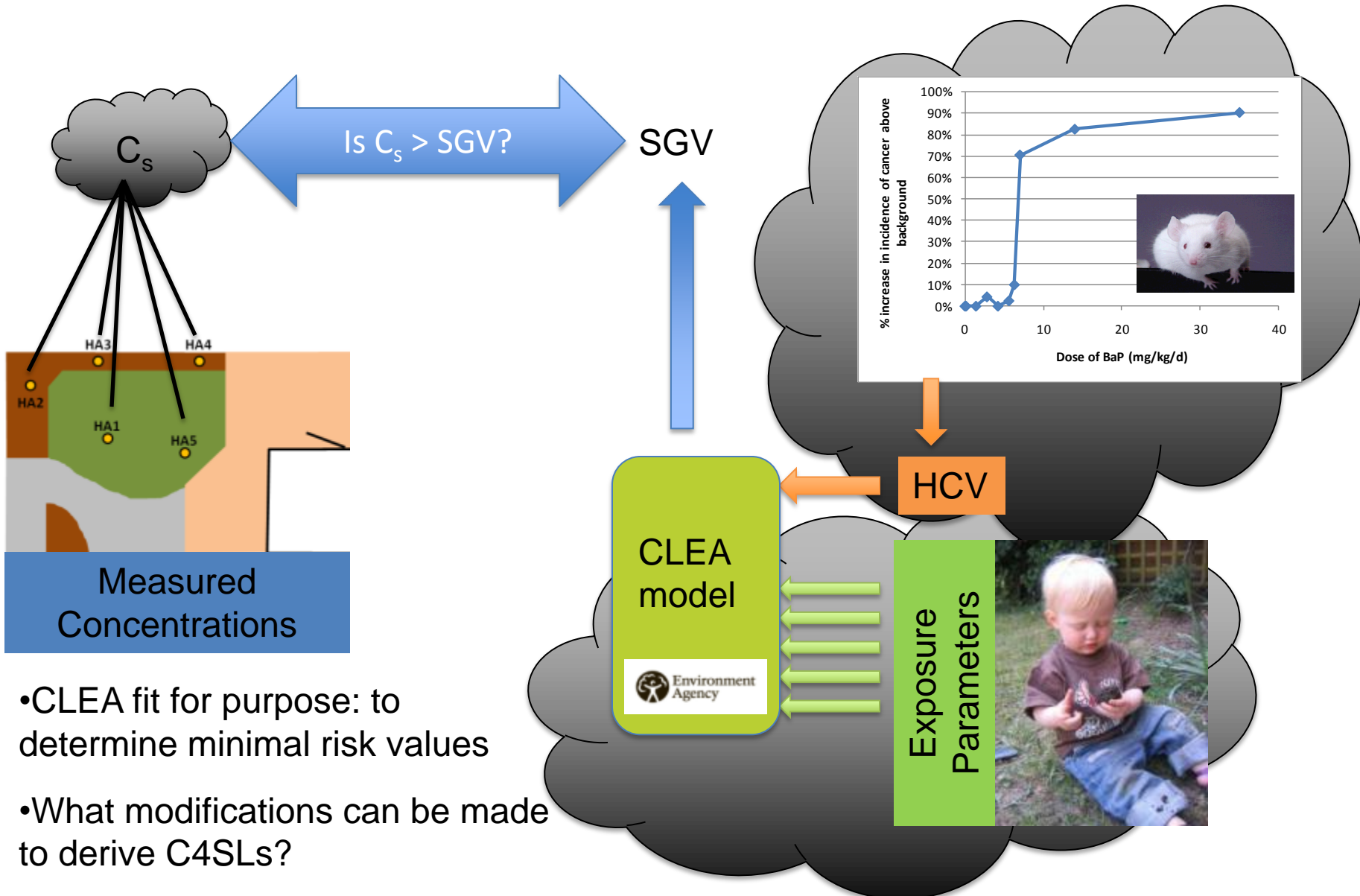
- intended as generic screening values to help show when land is within Category 4
- they describe a level of risk that whilst above 'minimal' is still strongly precautionary



Approach to WP1

1. Critical review of CLEA:
 - Exposure modelling aspects
 - Toxicological aspects
2. Development of framework
 - Proposed modifications to existing CLEA framework
3. Preparation of draft WP1 report for Steering Committee Review
4. Stakeholder workshop
 - Presented proposed modifications
 - Collated feedback
5. Finalisation of WP1 report
 - Taking on board comments received from Steering Committee/Stakeholders

The CLEA paradigm



- CLEA fit for purpose: to determine minimal risk values
- What modifications can be made to derive C4SLs?

Exposure Modelling

- Updating parameter values, e.g.
 - Produce consumption rates
 - Respiration volume
- Reasonable maximum exposure
 - e.g. Dermal contact
 - Child assumed to wear shorts + T shirt and get filthy in garden 365 d/yr
 - Propose to use CT estimate for soil adherence in combination with worst case skin area, 170 d/yr
- Receptor specific intake values
 - Currently, $HCV_{inh} \text{ benzene} = AQO (5 \text{ ug/m}^3) \times 20 \text{ m}^3/\text{d} / 70\text{kg}$
 - Applied to a 13 kg child who breathes $8.8 \text{ m}^3/\text{d}$ (average AC 1-6)
 - Results in an acceptable indoor air conc of 1.5 ug/m^3 (<AQO)
 - Calc receptor-specific $LLTC_{inh}$, i.e. based on child for resi land use



Toxicity Assessment

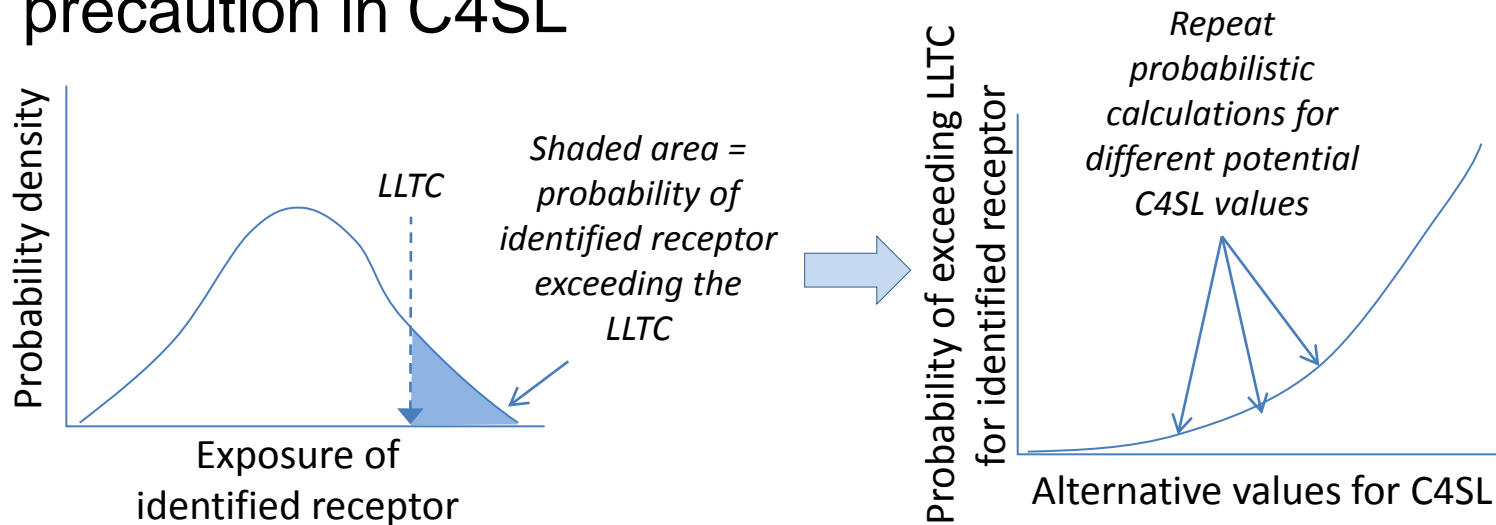
- $SGV = \text{soil concentration at which estimated exposure to critical receptor} = HCV$
- HCV describe a level of risk at which substances might pose either **no appreciable risk** or a **minimal risk** to human health
- HCV derived using protocol in CLEA SR2:
 - Threshold substances
 - $HCV = \text{Point of departure} / \text{Uncertainty Factor (UF) (Variable)}$
 - Point of departure (POD) = NOAEL, LOAEL or BMDL
 - Non threshold genotoxic carcinogens
 - Animal data $HCV = \text{POD (BMDL}_{10}) / \text{UF (10,000)}$
 - Human epidemiological data $HCV = \text{dose that results in ELCR of 1 in 100,000}$

Toxicity Assessment

- C4SLs describe a higher level of risk than SGVs
- C4SL = soil concentration at which estimated exposure to critical receptor = Low Level of Toxicological Concern (LLTC)
- LLTC derived using similar framework to SR2 but with reinforcement/modification in certain areas:
 - Use of BMD modelling to set POD where possible
 - Avoid the use of default UFs – use scientifically based chemical specific adjustment factors/margins, where possible
 - Consider moving above ELCR of 1 in 100,000 (e.g. 2 in 100,000) for carcinogens with human epidemiological data

Setting the C4SL

- C4SL = soil concentration at which estimated average daily exposure = LLTC
- Use probabilistic modelling/qualitative uncertainty assessment to ensure there is sufficient level of precaution in C4SL



- Consider other lines of evidence, e.g.
 - Background exposure/concentrations
 - Degree of precaution in LLTC

Take home messages

- This is work in progress – nothing is finalised!
- The intention is that C4SLs describe a level of risk that whilst higher than SGVs is still suitably protective
 - Subject to them being used appropriately
- Existing CLEA model will be used to derive C4SLs
 - But behind the scenes probabilistic modelling will be conducted in WP2 (& WP3) to help finalise a suitable set of parameter values
- C4SLs will be used in GQRA in the same way as SGVs
 - But work is progressing on how site measurement uncertainty is best considered

Thank you



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