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The Authoritative Voice of Contaminated Land Management from a Land Holders' Perspective

Category 4 Screening Levels Phase 2

Hannah White, Deputy Chair of Steering Group

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Defra Project SP1010

- 2012: Defra commissioned project to develop and test methodology to derive C4SL
- Project managed by CL:AIRE
- Steering Committee (Defra, Welsh Government, DCLG, HCA, FSA, EA, NRW, PHE, PHW)
- 3 x Stakeholder workshops (≈ 60 participants each)
- Project outputs reviewed by Committee of Toxicology, Committee of Carcinogenicity + peer reviews

- 2014: Defra publish methodology + C4SLs for six substances, with accompanying policy statement

SP1010 Project Approach

- Critically evaluate CLEA methodology to identify areas of conservatism that could be reduced
- Developed framework to derive C4SLs
  - CLEA with modified assumptions
    - Exposure modelling parameters
    - Toxicological benchmark (Low Level of Toxicological Concern (LLTC))
  - Two new land-uses (POS_{resi} and POS_{park})
  - Uncertainty assessment
  - Assessment of other factors in setting C4SLs

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C4SL Phase 2 Project

- Funded by industry through SAGTA
  - Also with in-kind support and Society of Brownfield Risk Assessment (SoBRA) grant
- Aim to produce a further 20 C4SLs, published in batches of 4 within next 2 years
- Process led

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Terms of Reference

- Terms of Reference:
  - All outputs completely unrestricted and freely available
  - Open, inclusive and transparent working
  - Knowledge transfer of exposure and toxicological processes to wider industry
  - Efficient and timely working
  - To support production of more C4SLs in line with published Framework and Policy and not to revisit debate over their use and/or existence

Developed framework to derive C4SL

1. Toxicological assessment

2. Derive LLTCs (mg kg^{-1} bw day^{-1})

3. Make (and justify) relevant modifications to CLEA

4. Use modified CLEA and LLTCs to derive **pC4SLs**

5. Use CLEA probabilistically to explore probability of exceeding LLTC when representative concentration = pC4SL

6a. Take account of uncertainties affecting the toxicological assessment

6b. Take account of sources of variability and uncertainty that are not quantified by probabilistic modelling.

6c. Take account of other relevant scientific considerations, including background concentrations, other routes of exposure, and epidemiological evidence

6d. Take account of any social or economic considerations that are thought relevant to setting an appropriate level of precaution

7. Is the pC4SL appropriately precautionary?

no

yes

STOP
C4SLs suitable for use
(final C4SLs)

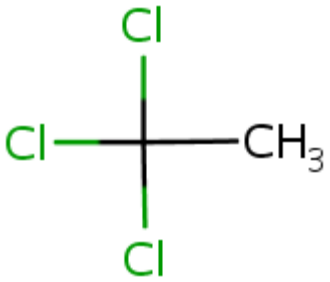
Phase 2 C4SL will use a simplified framework

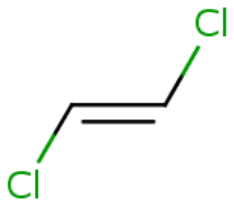
Priority Contaminant List

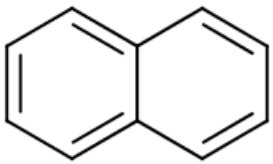
(Selected following 2015 consultation)

Free cyanide
Complex cyanide
Nickel
Vanadium
Beryllium
Chloroethene
Tetrachloroethene
Trichloroethene
1,1,1 Trichloroethane
Cis-1,2-Dichloroethene
Trans-1,2-Dichloroethene

1,2-Dichloroethane
Naphthalene
Toluene
Ethylbenzene
Xylenes (*o*, *m*, *p*)
1,3,5-Trimethylbenzene
1,2,4-Trimethylbenzene
1,2,3-Trimethylbenzene
Methyl tertiary butyl ether
Inorganic Mercury







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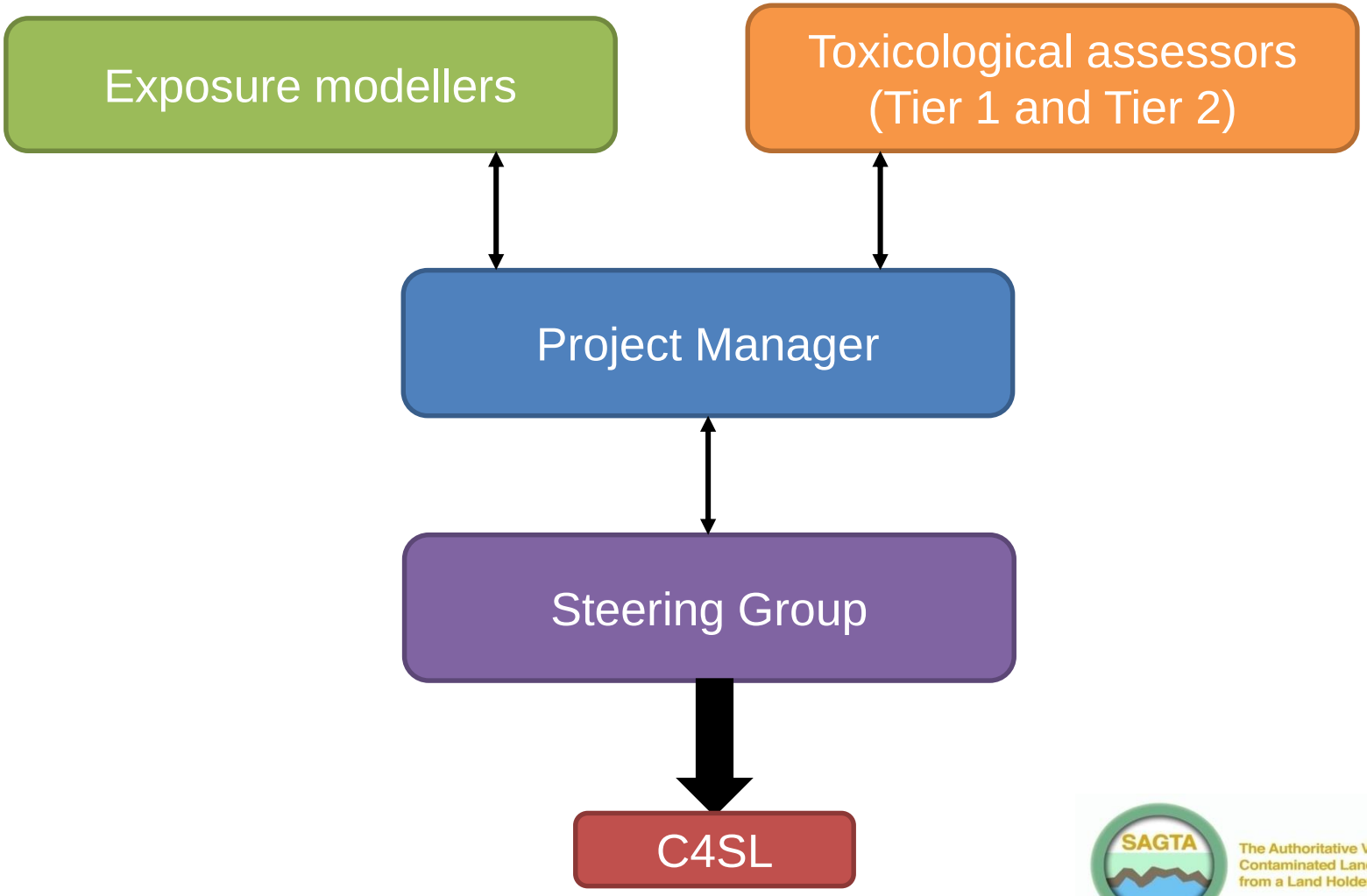
Project Organisation



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Steering Group

- SAGTA
- AGS
- Defra
- Environment Agency
- EIC
- EPUK
- Food Standards Agency
- Homes England (formerly Homes and Communities Agency)
- House Builders Federation
- Lancaster City Council
- Yorkshire and Lincolnshire Pollution and Advisory Council
- Mole Valley District Council
- NHBC
- National Resources Wales
- Public Health England *
- Public Health Wales *
- SoBRA
- Welsh Contaminated Land Group
- Welsh Government
- Wiltshire Council

- Led by SAGTA
- Steering Group shall oversee the production of further C4SLs, ensuring consistency and agreement with the provided Framework and Policy
- Steering Group shall seek decisions through consensus or where there is no consensus, through a simple majority vote
- Consequently the views and opinions of individual member organisations or experts may differ from the formal position of the Steering Group.

** central oversight of the development of the values as outlined in the Defra policy companion document*

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Role of Project Management Team

- Arrange workshops
- Manage work of exposure modellers / toxicologists
- Manage preparation, QA/QC and finalisation of deliverables
- Attend SG meetings
- PM team = Consortium of Nicola Harries (CL:AIRE), Simon Firth and Naomi Earl

Role of Tier 2 Toxicologists

- Collate and initially assess toxicological data
- Complete proforma
- Suggest if sufficient evidence exists to derive an LLTC, or if a minimal risk value is to be used
- Suggest the critical effect/study/point of departure
- Suggest uncertainty factors or margins
- Suggest the LLTC for use in modelling
- Write summary report (as advised by Tier 1 toxicologist)
- Check another T2s work

Tier 2 Toxicologist Team

- Joanna Wilding and Laura Aspinwall (RSK)
- Simon Cole (AECOM)
- Melinda Evans (SoilFix)
- Gareth Wills (WSP)
- Kate Baker (Leap Environmental)
- Duncan Grew, Peter Sheppard, Adam Symonds (Advisian)
- Alison Mackay (Leapmoor LLP),
- Sonja Trewavas, Natasha Glynn, Andrew Fellows (Atkins)
- Barry Mitcheson (Wood)
- Meera Cush (Ramboll)

Role of Tier 1 Toxicologists

- Support the assessment of toxicological data
- Determine whether sufficient evidence exists to derive a LLTC, or if a minimal risk value is to be used
- Review the critical effect/study/point of departure
- Review, uncertainty factors or margins
- Recommend LLTC for use in modelling
- Peer review the summary report
- Tier 1 Team
  - Sarah Bull
  - George Kowalczyk
  - Camilla Alexander-White
  - Steve Ruckman

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What goes into toxicological evaluation to derive LLTC?

- LLTC derived using similar framework to SR2 but with additional/refined interpretation:
- Take account of all critical health effects – not just the most sensitive
- Use of Benchmark Dose Modelling (BMD) to set Point of Departure (POD) where possible
- Avoid the use of default UFs – use scientifically based chemical specific adjustment factors (CSAF), or policy based adjustment factors or margins
- Consider moving above Excess Lifetime Cancer Risk of 1 in 100,000 (e.g. 2 in 100,000) for carcinogens with human epidemiological data
- Consider using receptor specific physiological parameters
- Other considerations (combination of different entry routes, lifetime averaging, bioavailability)

Toxicological evaluation to derive an LLTC

- What is the toxicological hazard within each study and do the effects constitute harm (according to Part 2A)?
- What Health Based Guidance Value was derived by each authoritative body and how robust is the scientific basis?
- What pivotal study should be chosen, considering sensitivity and relevancy of endpoints, adequacy of dose response data, POD?
- What Benchmark Dose Response should be chosen?
- How do you derive a CSAF considering toxicokinetics and toxicodynamics?
- What ELCR should be selected based on chemical specific considerations?
- Are effects specific to route of entry or systemic?
- Are default receptors appropriate?
- If LLTC is derived from a policy-based air or water guideline, should adjustments be made for intake for non-adult receptors?

Role of Exposure Modellers

- Work in duplicate to provide input parameters for CLEA Model for PM review
- Conduct CLEA Modelling
- Write summary report
- Exposure modeller team
  - Dave Brooks (SIRIUS)
  - Gareth Barns (WYG)
  - Rob Reuter (Wardell Armstrong)
  - James Lymer (Wardell Armstrong)
  - Catherine Cussell (RSK)
  - Lucy Burn (Advisian)

Sources of Phys-Chem Data - Organics

- SR7 parameters:
  - SGV reports
  - SR7 report
  - CL:AIRE, EIC & AGS GAC report
  - SLR, 2009 GAC for Petroleum Hydrocarbons report
  - SR7 approach
- Other parameters:
  - Dermal Absorption Factor (DAF): use values in SR3
  - Soil to plant CFs: model (unless empirical values available)
  - Soil to dust transport factor: use 0.5 (unless chemical specific values available)
  - Soil to indoor air correction factor: use 10 for hydrocarbons
  - Top 2: use CLEA & calculate

Sources of Phys-Chem Data - Inorganics

- General parameters:
  - DAF: use values in SR3 (use 0 where no data available)
  - Soil to dust transport factor: use 0.5 (unless chemical specific values available)
- Soil to plant concentration factors
  - Use empirical factors from literature where possible (support from Cranfield and Newcastle universities: use search terms that EA used in the supplementary SGV reports for Hg, Ni & Se
- Values required for PRISM model
  - Solubility & Kd: Check same sources EA used in the supplementary SGV reports for Hg, Ni & Se
  - Soil-plant availability factor (δ): refer to SR3 & Thorne, 2005
  - Correction factors between plant compartments (f_{int}): refer to SR3 & Thorne, 2005

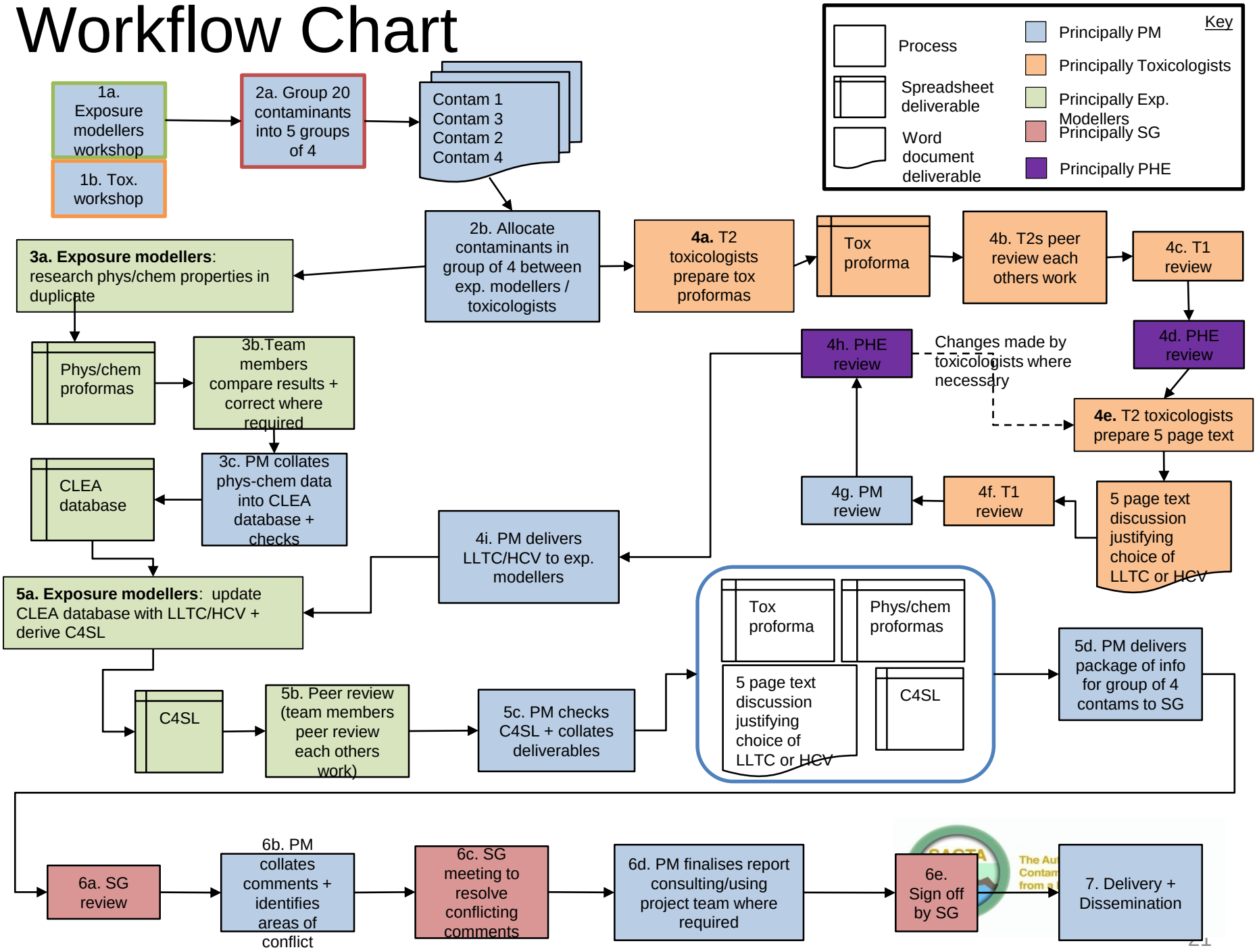
Reporting – Inputs and Results

- Explanation of toxicological decisions
- Tabulated Physical-Chemical Inputs with references and justification
- Explanation for choice of plant uptake factor/ decision to model, choice of dermal absorption factor, and choice of sub-surface soil to indoor air correction factor
- C4SLs for each land use
- How C4SL relates to vapour and solubility saturation limits
- Exposure Contributions for each pathway for each land use
- Risk driving pathway (e.g. Where inhalation of dust is risk driver even though very small % of exposure contribution because of very low inhalation LLTC)

Reporting – Further Considerations

- May need to consider wider context when setting the C4SL for a particular substance, e.g.:
  - Background soil concentrations
  - Background exposure from non soil sources
  - Epidemiological evidence
  - Whether ALARP should apply (non-threshold substances)
  - Laboratory limits of detection
  - Socio-economic considerations, e.g. the cost and proportionality in setting C4SLs so low as to always be exceeded
  - Comparison of C4SL with e.g. Sludge Regulations and PAS 100 Compost Specification
  - Sense check on whether there could be odour, phytotoxicity or visual acceptability issues or acute risks at the C4SL

Workflow Chart



Where are we now?

- Batch 1:
  - Chloroethene (vinyl chloride)
  - Trichloroethene
  - Naphthalene
  - Tetrachloroethene
- Batch 1 TOX Proformas being drip fed for PHE review
- Batch 1 CLEA Inputs ready for modelling
- Batches 2 and 3 started
  - cis-1,2-dichloroethene, trans-1,2-dichloroethene, 1,2-dichloroethane, 1,1,1-trichloroethane
- A project website provides regular updates and will publish findings as they are developed www.claire.co.uk/c4sl.

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Thank you

- Hannah.White@nationalgrid.com
- Richard.Boyle@homesengland.gov.uk
- www.claire.co.uk/c4sl