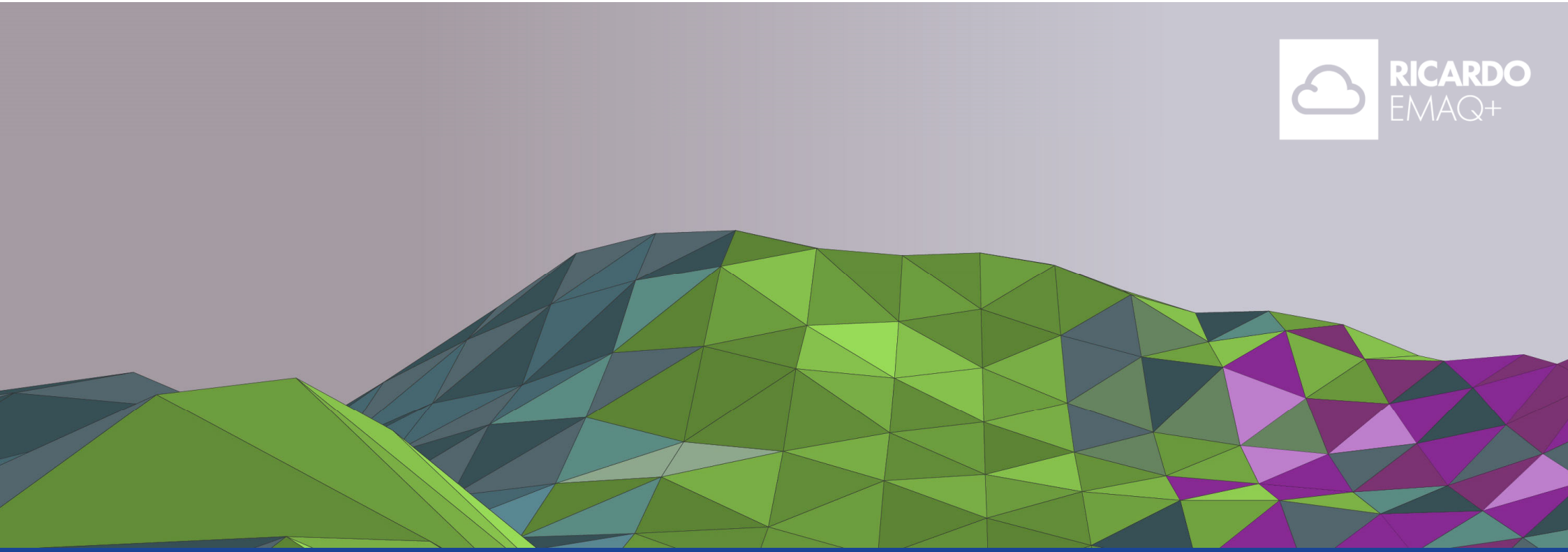

Essentials of CLM 3

Risk Assessment

July 2024

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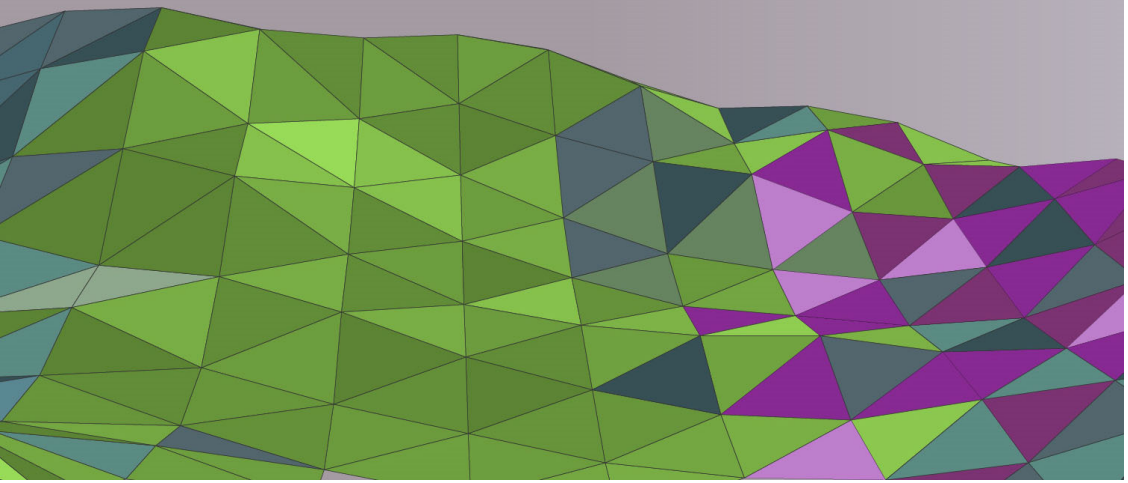

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AECOM

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The Scottish Government

Programme of the day

July 2024

Session 1: Introduction to Human Health risk assessment

Session 2: Introduction to Controlled Water Risk Assessment

Session 3: HHRA: Unpacking Toxicology

Session 4: Unpacking Exposure Assessment

Session 5: Generic Assessment Criteria

Session 6: Introduction to DQRA

Air Quality Monitoring

At Ricardo we have a dedicated team of AQ specialists and look forward to helping you with any of your air quality challenges:

- ISO 17025 UKAS accredited **QA/QC audits** – required by LAQM TG (22)
- **Data management**, data collection, checking, validation, ratification etc
- **Local site operations**, calibrations/call outs
- **Web reporting**
  http://www.airqualityengland.co.uk/
- **Routine data reporting** –
  weekly, monthly, quarterly, annual – for example
  http://www.airqualityengland.co.uk/assets/reports/291/KensingtonChelsea_month_2019_01.html
- **Short term monitoring surveys**
  (site installation/decommissioning through to reporting)
- Long term station hire
- Free advice on station installation and best practice
- Procurement of analysers and installation to LAQM TG (22) or AURN standards

- **Low cost sensor measurements**, network management
- **Real world vehicle emissions monitoring**
  aiding Action Planning
- **Mobile Monitoring**
  for point source and concentration contour mapping
- **Diffusion tube surveys**
- **Air quality forecasting** and public dissemination
  (via sms text, email, web, social media etc.)
- Air quality reporting
- LAQM TG (22) Annual Status Reporting (ASR), Detailed Assessment
- CAZ/LEZ consultancy
- Expert witness and Expert Advice
- Air Quality Modelling

For further information please get in touch with David Madle

07968707279

david.madle@ricardo.com

Judith Nathanail

Director of Land Quality Management Ltd

Environmental Consultant > 30 years

Experienced in all aspects of contaminated land management, PRA, site investigation, risk assessment and remediation.

Peer review of reports for various Local Authorities

Trainer with EMAQ since 2005

01235 753620

emaq@ricardo.com

Essentials of Contaminated Land Management

- 5 “stand-alone” seminars/webinars that, together, comprise a complete ‘Essentials of CLM’ Training Course
- A partnership between an individual and his sponsoring authority or organisation
- Curriculum based on the EMAQ Essentials Syllabus and government guidance
- Combines knowledge with practical experience of contaminated land management to:
  - Provide evidence of an individual’s ability to implement Contaminated Land Management (CLM) requirements;
  - Build the individual confidence to operate effectively.

Essentials of Contaminated Land Management

KEY ELEMENTS

1. Register and identify a “supervisor”
2. Attend the seminars\webinars
3. Demonstrate an understanding of the seminar\webinar material – via an on-line knowledge check,
   (A CLM credit will then be issued in addition to the CPD certificate that all those attending will receive.)
4. Agree a development programme with a supervisor (or mentor) which, by the end of the five seminar\webinar programme, will show evidence of having satisfactorily undertaken the following practical operations of CLM:

   - Procedural / Legal
   - Practical / Technical
   - Management

   (supervisor to verify attainment)

Essentials of Contaminated Land Management

A Certificate in Contaminated Land Management will be issued to those who have:

- Registered and paid the fee
  - Contact EMAQ for current fee
- Gained all 5 credits
- Successfully sat the on-line ‘Proficiency Test' designed to show a co-ordinated knowledge of all the aspects of CLM programme
- Whose Supervisor has:
  - verified the bona fides of the candidate and that the test was undertaken under the required conditions
  - confirmed that the candidate has had experience of the practical elements of CLM listed in their development plan

Essentials of Contaminated Land Management: Mechanics

- Online: instructions, registration, testing, record updating, certificate production
- Register – via the EMAQ+ website
    - include the name and contact details of supervisor
- Attend live seminars or view webinars on-line
- Obtain CLM credit via on-line ‘Knowledge Check’ 20 multi-choice questions which are to be completed on-line within one unbroken 2 hour period, gain a pass by getting 75% or more correct
    - Knowledge Check opens same time as webinar and delegates have 3 opportunities to pass
    - Proficiency Test, 20 multi-choice questions, drawn from the entire syllabus
    - When logging on, supervisor will be asked first to verify the candidate’s identity
    - Supervisor to verify practical experience
    - 20 test questions which must be undertaken within an unbroken two hour period
    - Successful candidates must correctly answer 75% of the questions. Candidates will have 2 opportunities to pass

Essentials of Contaminated Land Management: Modules

1. Introduction to Land Contamination Risk Management
2. Site Characterisation
3. Risk Assessment
4. Remediation & Brownfield Redevelopment
5. Peer Reviewing Third Party Reports

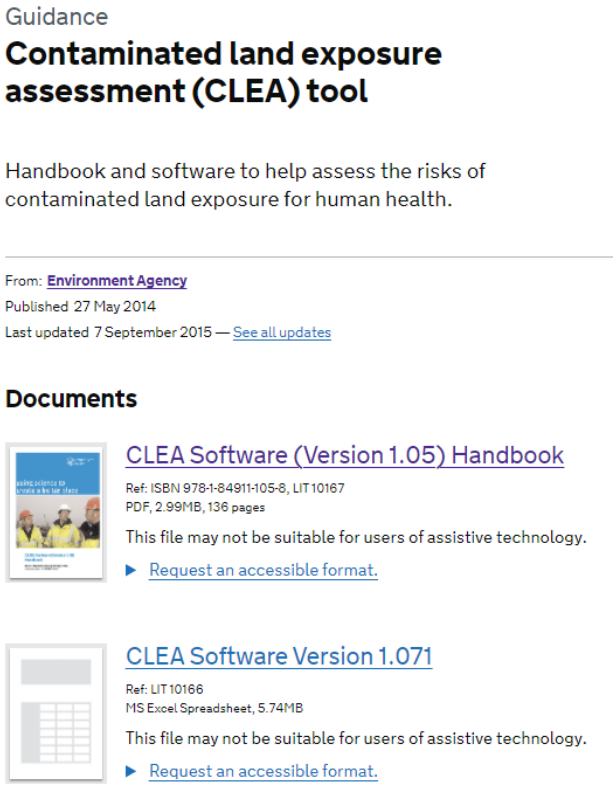
Activities

- There are some formal activities discussed within the videos where you should pause the video, do the activity and restart the video to listen to the answer

- There are also numerous links to other information and suggestions of things to look at – following these up will help you deepen your understanding

Download CLEA spreadsheet

- https://www.gov.uk/government/publications/contaminated-land-exposure-assessment-clea-tool



Guidance

Contaminated land exposure assessment (CLEA) tool

Handbook and software to help assess the risks of contaminated land exposure for human health.

From: Environment Agency
Published 27 May 2014
Last updated 7 September 2015 — See all updates

Documents

CLEA Software (Version 1.05) Handbook

Ref: ISBN 978-1-84911-105-8, LIT 10167
PDF, 2.99MB, 136 pages

This file may not be suitable for users of assistive technology.

▶ Request an accessible format.

CLEA Software Version 1.071

Ref: LIT 10166
MS Excel Spreadsheet, 5.74MB

This file may not be suitable for users of assistive technology.

▶ Request an accessible format.

Session 1: Introduction to Human Health risk assessment

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3 Tiers of RA - LCRM

- Stage 1
  - Tier 1
  - Tier 2
  - Tier 3

3 Tiers of RA - LCRM

- Stage 1
  - Tier 1: Preliminary risk assessment (PRA)
    - develops the outline conceptual model (CM)
    - establishes whether there are any potentially unacceptable risks

Qualitative RA

LCRM

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3 Tiers of RA - LCRM

- Stage 1
  - Tier 1: Preliminary risk assessment (PRA)
    - develops the outline conceptual model (CM)
    - establishes whether there are any potentially unacceptable risks
  - Tier 2: Generic quantitative risk assessment (GQRA)
    - using generic assessment criteria and assumptions to estimate risk.
  - Tier 3: Detailed quantitative risk assessment (DQRA)
    - carried out using detailed site-specific information to estimate risk.

LCRM

Qualitative RA

Quantitative Risk Assessment

Sound science: Defensible decisions

HHRA outline

- PRA – initial CSM
- Suitable and sufficient site investigation data characterising:
  - Source (location, depth, concentration and properties)
  - Pathways
- Updated Conceptual Site Model (including uncertainties)
- GQRA
  - Objectives of HHRA
  - Identify appropriate GAC or derive new ones
  - Compare site concentrations with chosen GAC
- DQRA
  - Objectives of HHRA
  - Develop SSAC
  - Compare site concentrations with SSAC

DAY 1

DAY 2

Tier 2 GQRA

Tier 3 DQRA

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Tier 2 – GQRA - objectives of risk assessment

- State objective of GQRA eg:
  - use GAC to evaluate whether there is a risk to future residents from arsenic and cadmium at the site in the planning context

Tier 2 - GQRA
Identify appropriate GAC

- GAC
  - Derived using standard set of generic assumptions about behaviour of SPR
  - Derived for selected land uses
- Available UK GAC for **human** receptors
  - LQM/CIEH S4ULs
  - C4SLs
  - (Atkins AtRisk - withdrawn)
  - SGV
  - EIC GAC
- Risk assessors can derive GACS using RA model and standard set of generic assumptions
  - Justify **input parameters** eg chemical properties, tox values
  - Assessment should use **generic assumptions**

Are the GAC appropriate for your site?

GAC = conservative

Requires specialist knowledge and experience

Sound science:
Defensible decisions

Example GACs for Schools

- Relevant inputs for any school eg schools building program
  - Age class ?primary
  - Time at school ?based on secondary schools
  - = GAC

- Relevant inputs for particular school
  - Ages of children at that schoOl
  - Time at school based on that school
  - = DQRA

GAC need to take account what happens at the site. Eg muddy school playing fields

Sound science:
Defensible decisions

GAC - Generic Land Use Scenarios

- Land use affects
  - Relevant exposure pathways
  - Receptors present and their behaviour
- UK has generic land uses for which risk based AC are available
  - Residential with/out homegrown produce
  - Allotment Gardens
  - Commercial
  - POS

GAC only appropriate for your site if land use scenario is sufficiently similar to CSM

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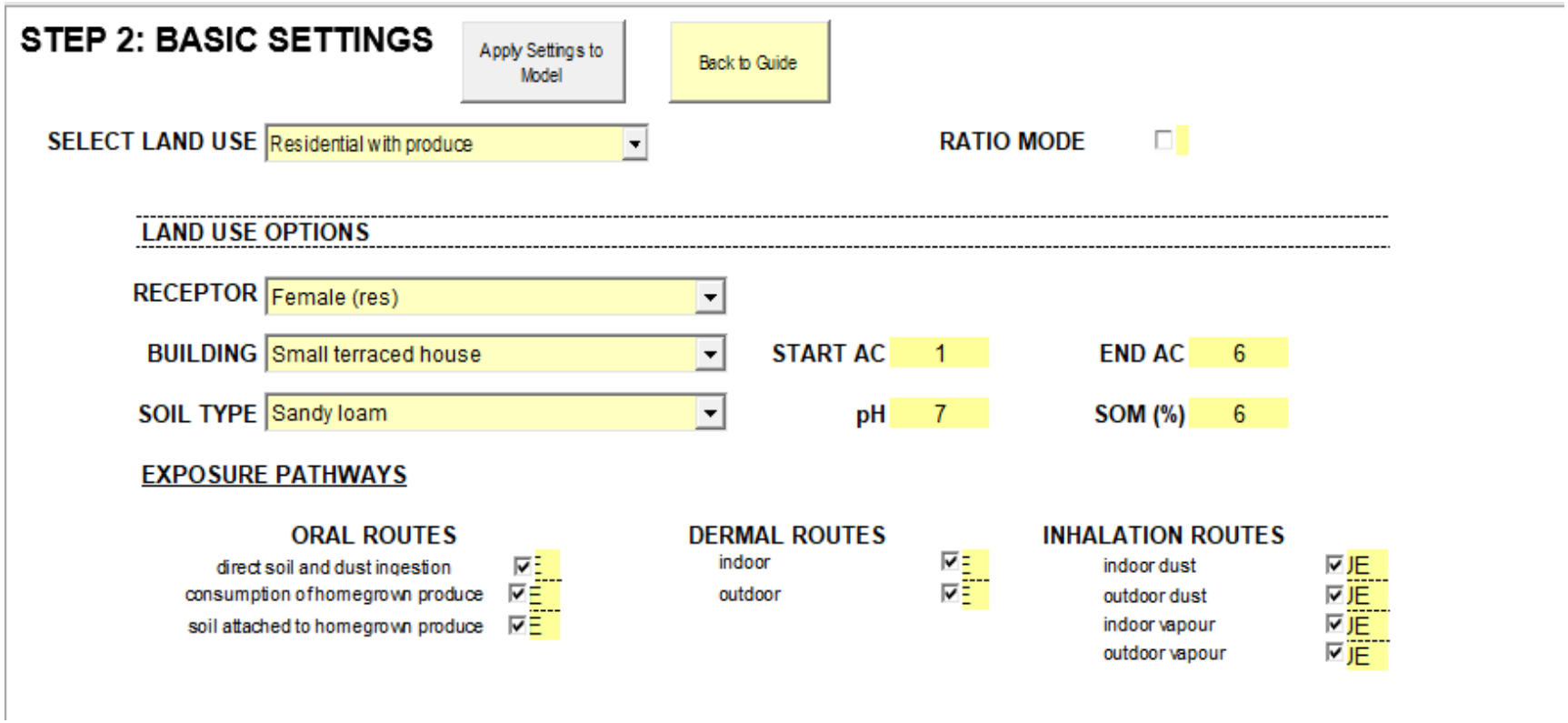
Look at land uses in CLEA spreadsheet



Sound science:
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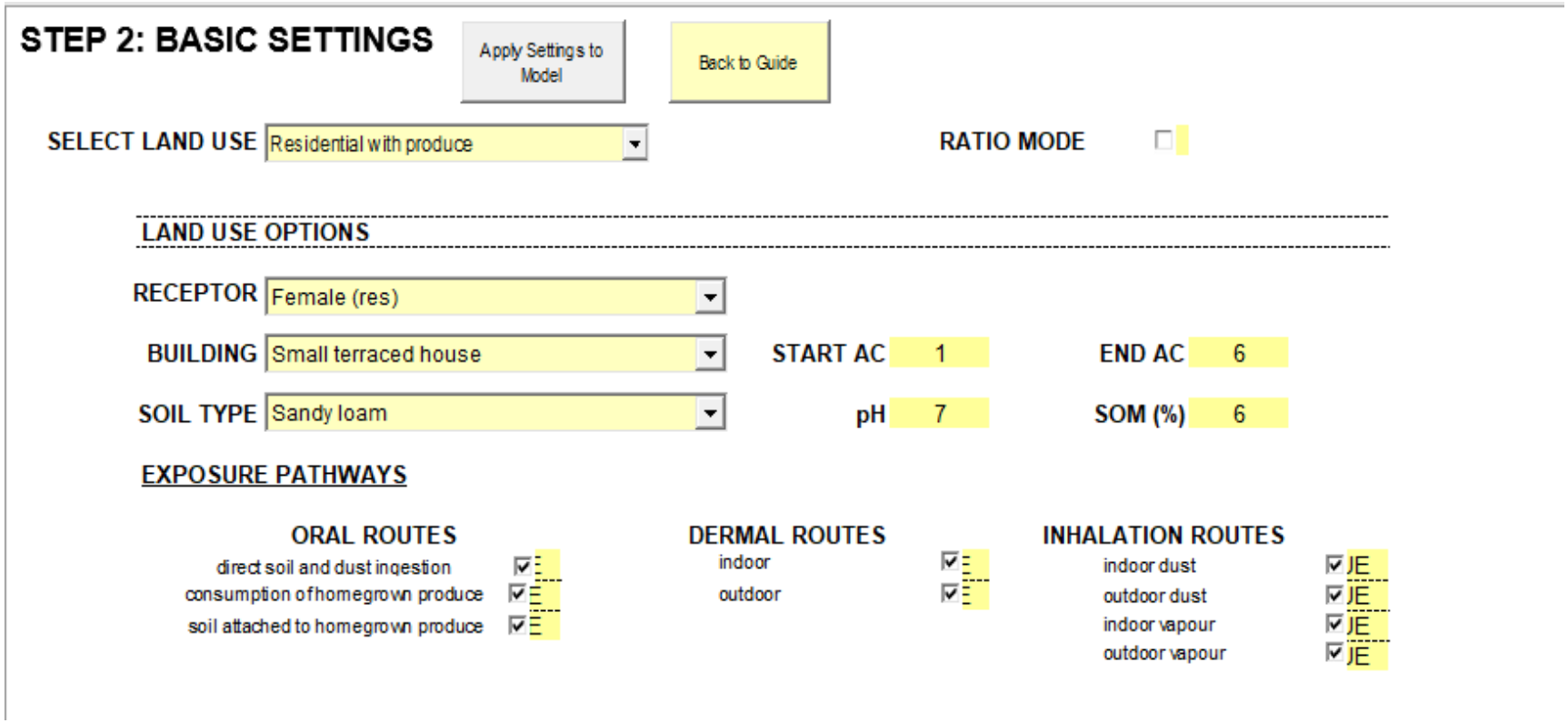
Look at land uses in CLEA spreadsheet



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STEP 2: BASIC SETTINGS

Apply Settings to Model

Back to Guide

SELECT LAND USE: Residential with produce

RATIO MODE ☐

LAND USE OPTIONS

RECEPTOR: Female (res)

BUILDING: Small terraced house

START AC: 1

END AC: 6

SOIL TYPE: Sandy loam

pH: 7

SOM (%): 6

EXPOSURE PATHWAYS

ORAL ROUTES

- ☑ direct soil and dust ingestion
- ☑ consumption of homegrown produce
- ☑ soil attached to homegrown produce

DERMAL ROUTES

- ☑ indoor
- ☑ outdoor

INHALATION ROUTES

- ☑ indoor dust JE
- ☑ outdoor dust JE
- ☑ indoor vapour JE
- ☑ outdoor vapour JE

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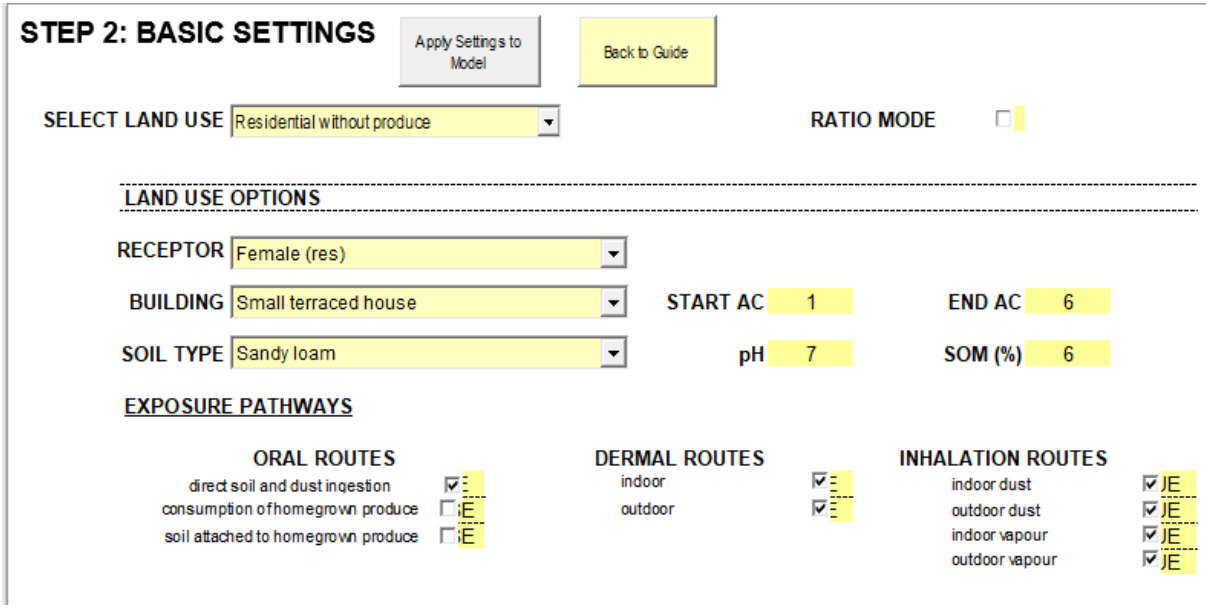
RwoHP



- PW removed:
  - Consumption homegrown produce
  - Soil attached to homegrown produce

Apply settings to model

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Look at land uses in CLEA spreadsheet

- What are the pathways for the following landuses?
  - Allotments
  - Commercial

- Ignore
  - Lifetime exposure
  - C4SL

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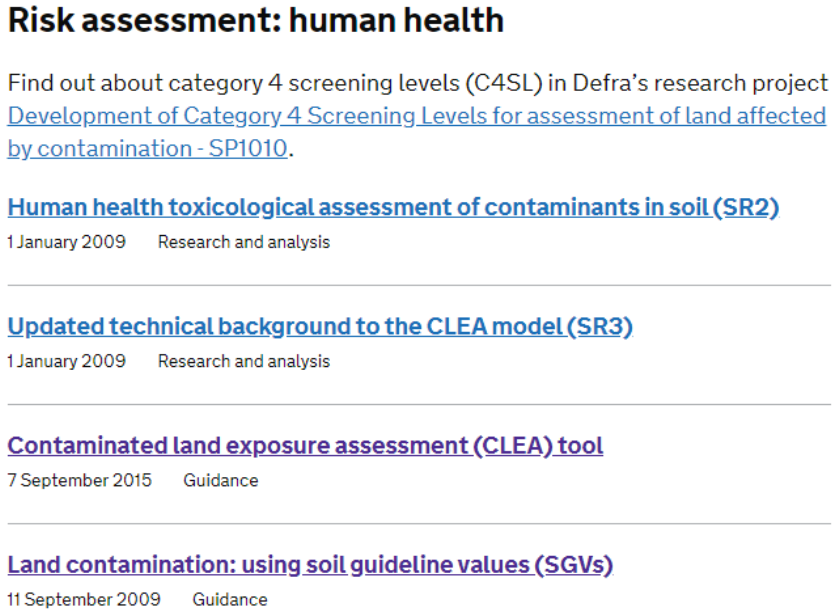
Current UK guidance - HHRA

- The guidance on human health risk assessment has changed over time
  - Keeping up to date is essential
- Currently includes:
  - SR2 – Toxicological guidance (2009)
  - SR3 – CLEA technical guidance (2009)
    - Tox and SGV reports
  - SR4 – CLEA handbook (2009)
  - SP1010 Defra's C4SL Project (2014)



Risk assessment: human health

Find out about category 4 screening levels (C4SL) in Defra's research project Development of Category 4 Screening Levels for assessment of land affected by contamination - SP1010.

Human health toxicological assessment of contaminants in soil (SR2)
1 January 2009 Research and analysis

Updated technical background to the CLEA model (SR3)
1 January 2009 Research and analysis

Contaminated land exposure assessment (CLEA) tool
7 September 2015 Guidance

Land contamination: using soil guideline values (SGVs)
11 September 2009 Guidance

Environment Agency

using science to create a better place

Human health toxicological assessment of contaminants in soil

Science Report – Final SC050021/SR2

SCHO0508BNQY

Environment Agency

using science to create a better place

Updated technical background to the CLEA model

Science Report: SC050021/SR3

Environment Agency

using science to create a better place

CLEA Software (Version 1.05) Handbook

Better Regulation Science Programme
Science report: SC050021/SR4

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HHRA - summary

- PRA, SI, CSM
- Identify/ develop GAC SSAC
- Risk estimation
  - GQRA
    - GAC
    - Generic Land uses
  - DQRA
- Risk Evaluation

Risk estimation

Toxicology

Exposure assessment

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Session 2: Controlled Waters Risk Assessment

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Session 2: Introduction to Controlled Water Risk Assessment

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Key references: Controlled waters

- EA policy on groundwater protection Version 1.2 (2018). Available via https://www.gov.uk/government/publications/groundwater-protection-position-statements
- EA GPLC (2010). Available via https://www.claire.co.uk/home/news/index.php?option=com_content&view=article&id=192&catid=41&Itemid=256
- RTM Guidance (2006). Available via https://www.gov.uk/government/collections/land-contamination-technical-guidance
- Good practice for the development of conceptual models … (EA 2001). Available via https://www.claire.co.uk/projects-and-initiatives/information-centre/index.php?option=com_content&view=article&id=183&catid=41&Itemid=256
- 'Land contamination groundwater compliance points: quantitative risk assessments'. Available at https://www.gov.uk/guidance/land-contamination-groundwater-compliance-points-quantitative-risk-assessments
- 'SEPA Assigning Groundwater Assessment Criteria for Pollutant Inputs' https://www.sepa.org.uk/media/152662/wat_ps_10.pdf

Sound science:
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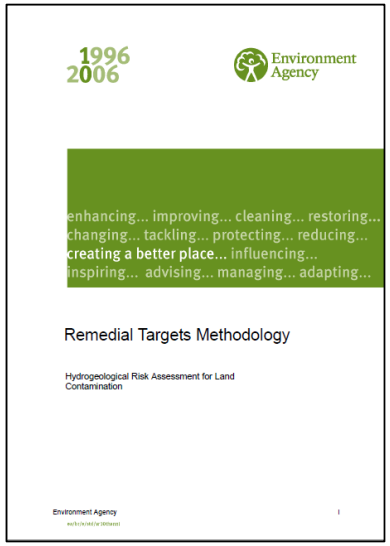
Controlled Waters Risk assessment Guidance

- "Remedial Targets Methodology: Hydrogeological Risk Assessment for Land Contamination" (RTM)
- Released in 2006
  - Includes an spreadsheet tool
- Describes a phased approach to deriving site specific remedial objectives for contaminated soils and/or groundwater to protect the aquatic environment
- Applies to soils & groundwater that are already contaminated and original source has ceased



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Hydrogeological risk assessment framework

- Define the Conceptual Model
  - Sources, pathways and receptors
- Selection of target concentration
- Selection of compliance point
- Derivation of remedial targets
  - Level 1, Level 2, Level 3, (Level 4)
  - Soil – assumes there is the potential for pollution of surface water or groundwater
  - Groundwater – contamination already occurred.

Described in the Remedial Targets Methodology (RTM) Guidance

Sound science:
Defensible decisions

Conceptual Site Model

- CSM in context of Hydrogeological Risk Assessment:
  - *"…must identify the crucial factors influencing groundwater flow and contaminant transport; whether the observed behaviour appears to be predictable; and whether mathematical approximations can be used to describe its behaviour"*

Environment Agency (2001). Guide to good practice for the development of conceptual models and the selection and application of mathematical models of contaminant transport processes in the subsurface. National Groundwater and Contaminated Land Centre Report NC/99/38/2 (Solihull, Environment Agency)

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Defensible decisions

Defining the Source Term

- History & timing of the release
- Contaminant concentrations
- Contaminant type
  - Inorganic
  - organic

- Contaminant properties
  - Solubility
  - Density
  - Leachability
  - Volatility
  - Degradation potential

- Source Geometry
  - Area
  - Depth

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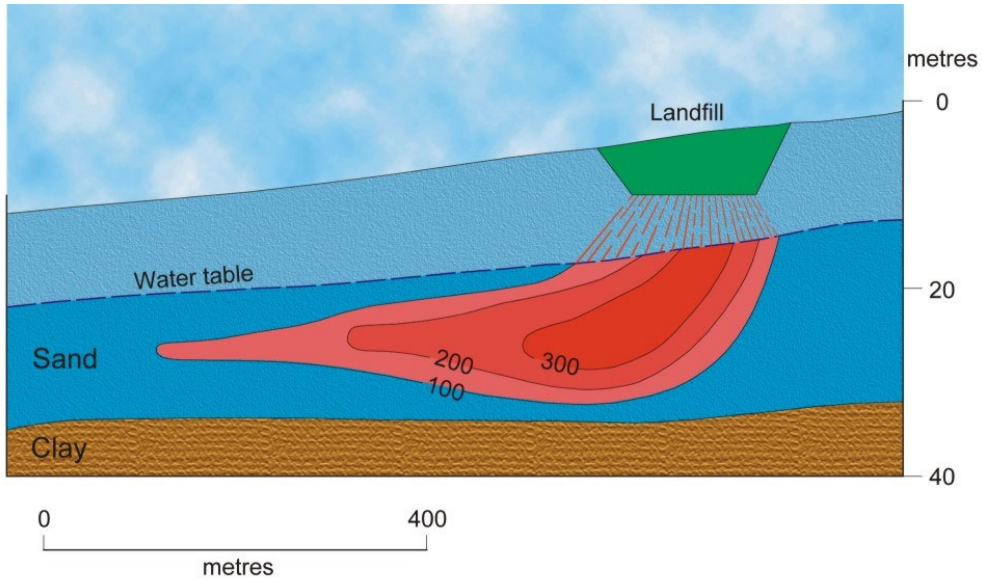
Defining the Source Term

- Types of Source
  - Soil / made ground containing contaminants
  - Unlined landfill, Tank, Soakaway – point source
  - Non Aqueous Phase Liquids (LNAPL/DNAPL)
- Contaminant phase
  - Solid
  - Aqueous
  - Sorbed
  - vapour



UK Groundwater Forum

Sound science:
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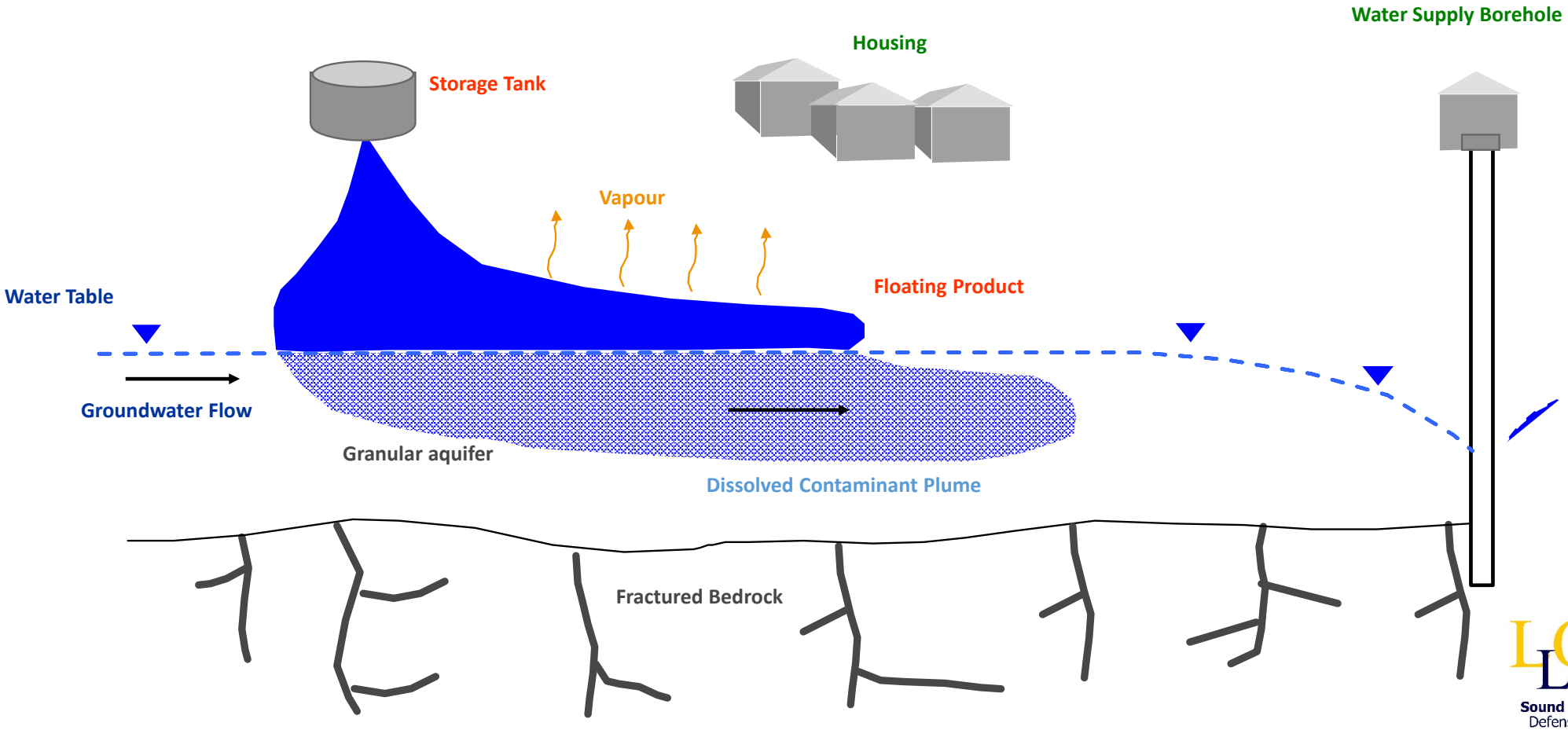
Defining the Source Term:
Light non-aqueous phase liquid (LNAPL)



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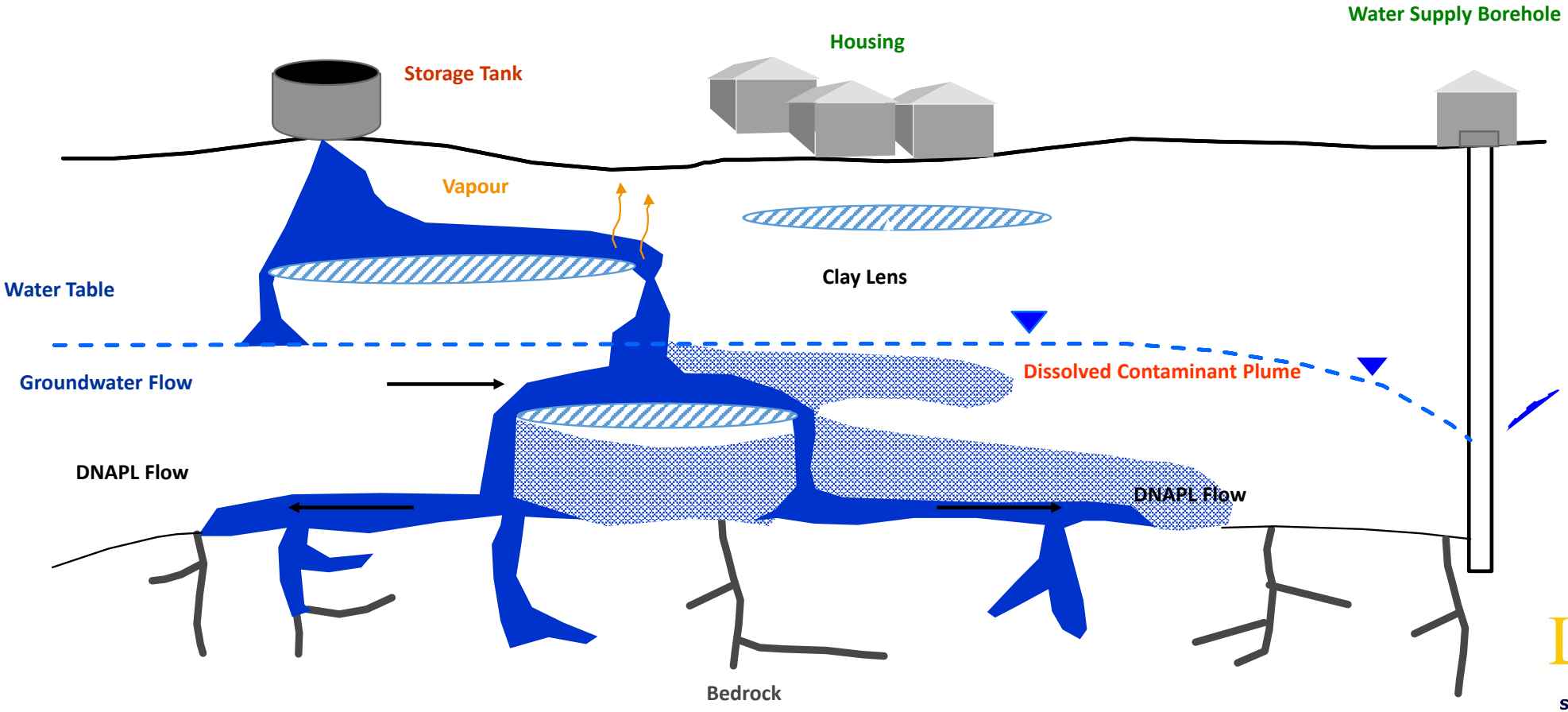
Defining the Source Term:
Dense non-aqueous phase liquid (DNAPL)



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Defining the Pathways

- Potential Sub-Surface Pathways
  - Transport through unsaturated zone
  - Transport through saturated zone
  - Transport through artificial pathways (e.g. drains, mine-workings, adits)

Not covered by RTM

- Potential Surface Pathways
  - Surface runoff (overland flow)
  - Flooding

Not covered by RTM

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Defensible decisions

Defining the Receptors

- Any protected water (i.e. protected from pollution under Water Resources Act (WRA) 1991)
- Surface waters:
  - Territorial waters (extending seaward for 3 miles)
  - Coastal waters
  - Inland freshwaters
- Groundwater (contained in underground strata):
  - Most common receptor in hydrogeological risk assessments for land contamination
  - May also be a pathway to other Controlled Waters (e.g. inland freshwater – rivers, streams, wetlands)
  - Present in geological formations (aquifers) directly beneath the source
  - Very difficult to clean once polluted from land contamination

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Defining the Receptors: Aquifer importance

- EA use aquifer designations that are consistent with the Water Framework Directive:
  - Principal
  - Secondary A
  - Secondary B
  - Secondary undifferentiated
- Designations based on ability of aquifer to:
  - Provide a drinking water resource
  - Support surface water flows and wetland ecosystems
- Based on geology
  - Defra Magic Map
  - Available for Superficial (drift) and Bedrock

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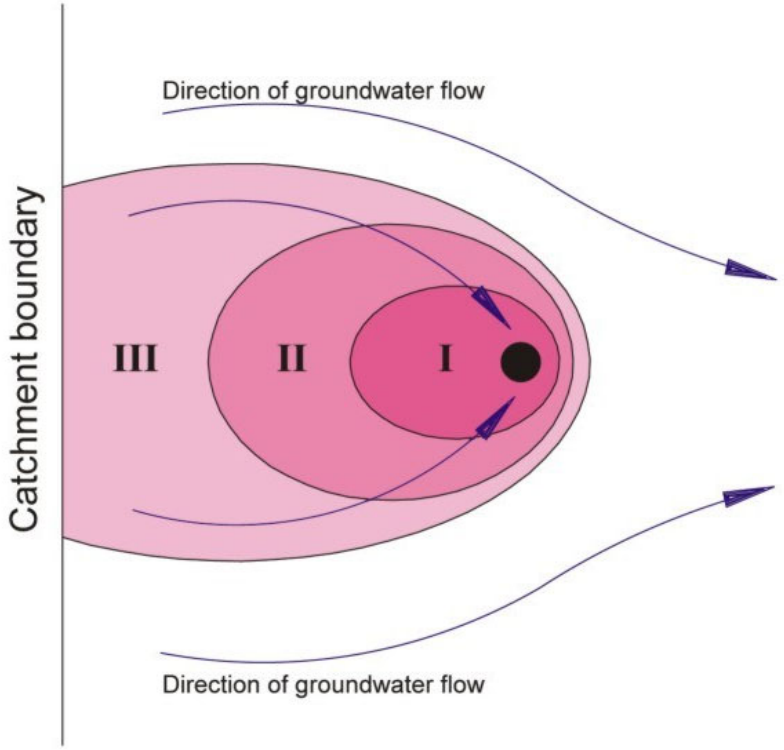
Defining the Receptors: Source Protection Zones (SPZs)

- Defined by EA for groundwater sources (e.g. wells, boreholes, springs)
- SPZ1 – Inner Protection Zone: 50 day travel time from any point below the water table to the source. Minimum radius of 50 m around the source
- SPZ2 – Outer Protection Zone: 400 day travel time from any point below the water table to the source. Minimum radius of 250 m around the source
- SPZ3 – Source Catchment Protection Zone: area around a source with which all groundwater recharge is presumed to be discharged at the source



UK Groundwater Forum

Sound science: Defensible decisions

What is a Target Concentration?

- The concentration at the compliance point that should not be exceeded
  - Usually based on a water quality standard (WQS) or background water quality
    - Environmental Quality Standards (EQS)
    - Drinking water standards (DWS)
- Remains constant at each level of the assessment process

Environment Agency (2006). Remedial targets Methodology: Hydrogeological Risk Assessment for Land Contamination

a concentration

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What is a compliance point?

- *"the point along the contaminant pathway where the target concentration should not be exceeded as this would represent an unacceptable risk of harm to the receptor"*

Environment Agency (2006). Remedial targets Methodology: Hydrogeological Risk Assessment for Land Contamination

- Varies at each level of the assessment process

a location

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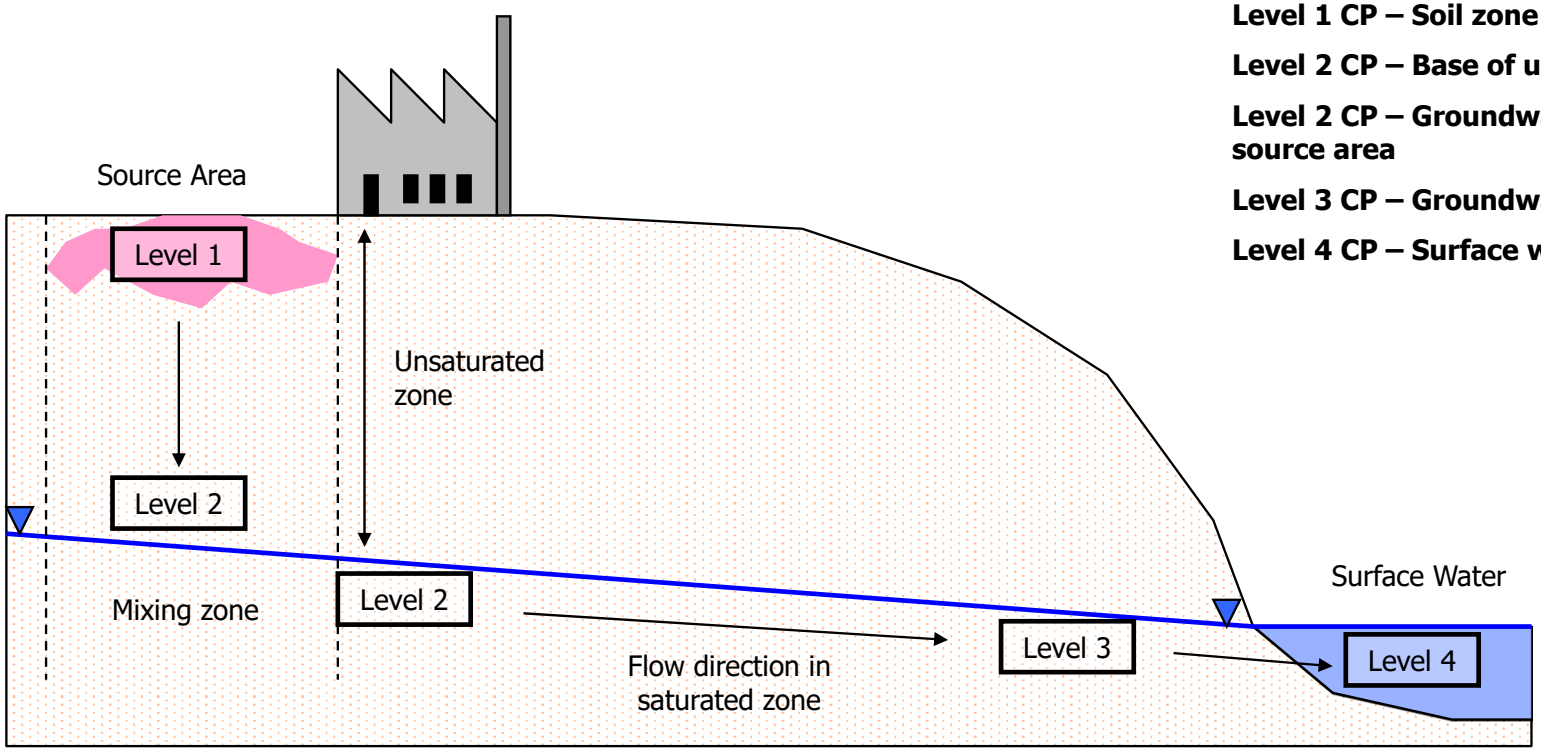
Remedial Target Levels



Level 1 CP – Soil zone (source)

Level 2 CP – Base of unsaturated zone

Level 2 CP – Groundwater immediately downgradient of source area

Level 3 CP – Groundwater downgradient of source area

Level 4 CP – Surface water body or abstraction point

Level 1 **= Level 1 compliance Point**

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Deriving a Remedial Target

- Now we know:
  - What the target concentration should be (i.e. C_T)
  - Where C_T should be achieved (i.e. compliance point)

a concentration

- We can use equations, spreadsheet models or risk assessment software to calculate the maximum source concentration that will not result in the target concentration being exceeded at the compliance point (ie the remedial target)
  - This is quantitative hydrogeological risk assessment for land contamination

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Uncertainties

- Examples:
  - Source geometry?
  - Concentrations of contaminants?
  - Depth to groundwater?
  - Direction of flow?
  - Presence of preferential flow paths?
  - Hydraulic connectivity?
  - Rate of flow?
  - Attenuation of contaminants?
  - Depth (OD) to base of river

Uncertainties form the basis of site investigation objectives

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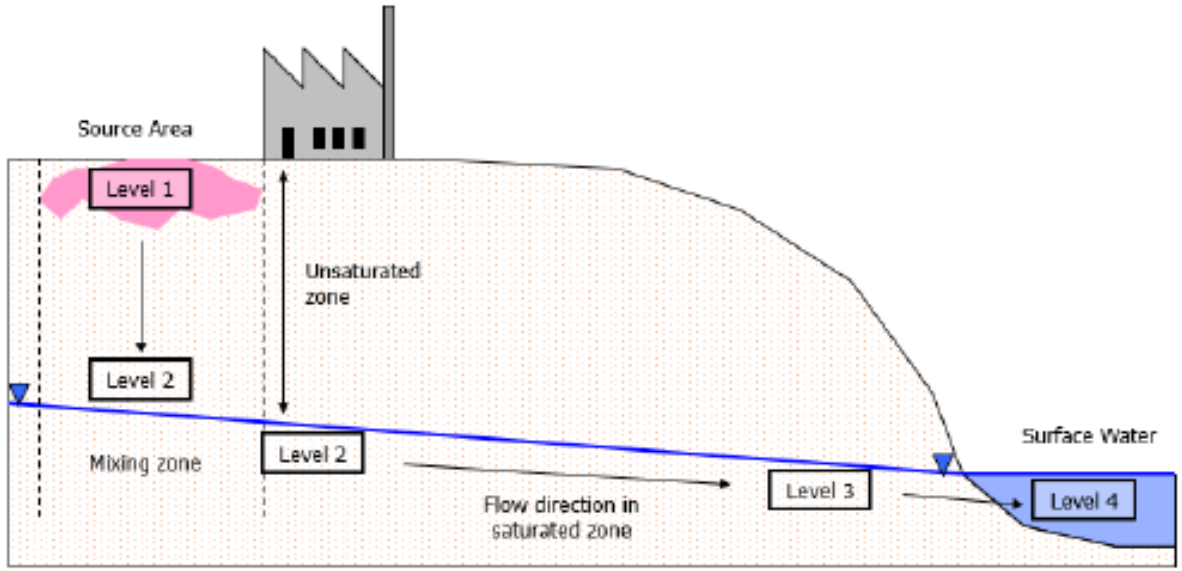
Groundwater hazardous substances

- JAGDAG
- England and Wales
  - https://wfduk.org/sites/default/files/Media/JAGDAG/2018%2001%2031%20Confirmed%20hazardous%20substances%20list_0.pdf
- Scotland (updated 2023)
  - https://www.sepa.org.uk/regulations/water/groundwater/#Contaminated_land



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Sobra Guidance – Controlled Waters and Climate Change

- Considers effect of climate change on controlled wters risk assessment
- Guidance on Assessing Risk to Controlled Waters from UK Land Contamination Under Conditions of Future Climate Change
- Version 1.0, August 2022

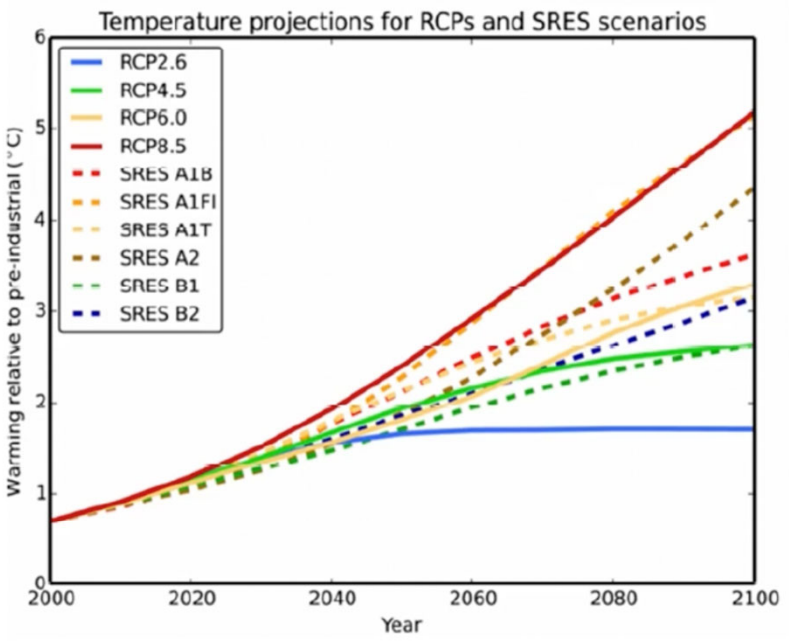
Sobra guidance: take account of changed Climate in controlled waters risk assessment

BS 21365 – take account of climate change in CSM

BS EN ISO 21365:2020

Sobra – Controlled Waters and Climate Change

- Climate change projections
  - Met Office UK Climate Projections (UKCP18)
  - Precipitation
  - Temperature
  - Sea Level
  - Groundwater, surface water
- Choosing Scenarios
- How to use in CWRA



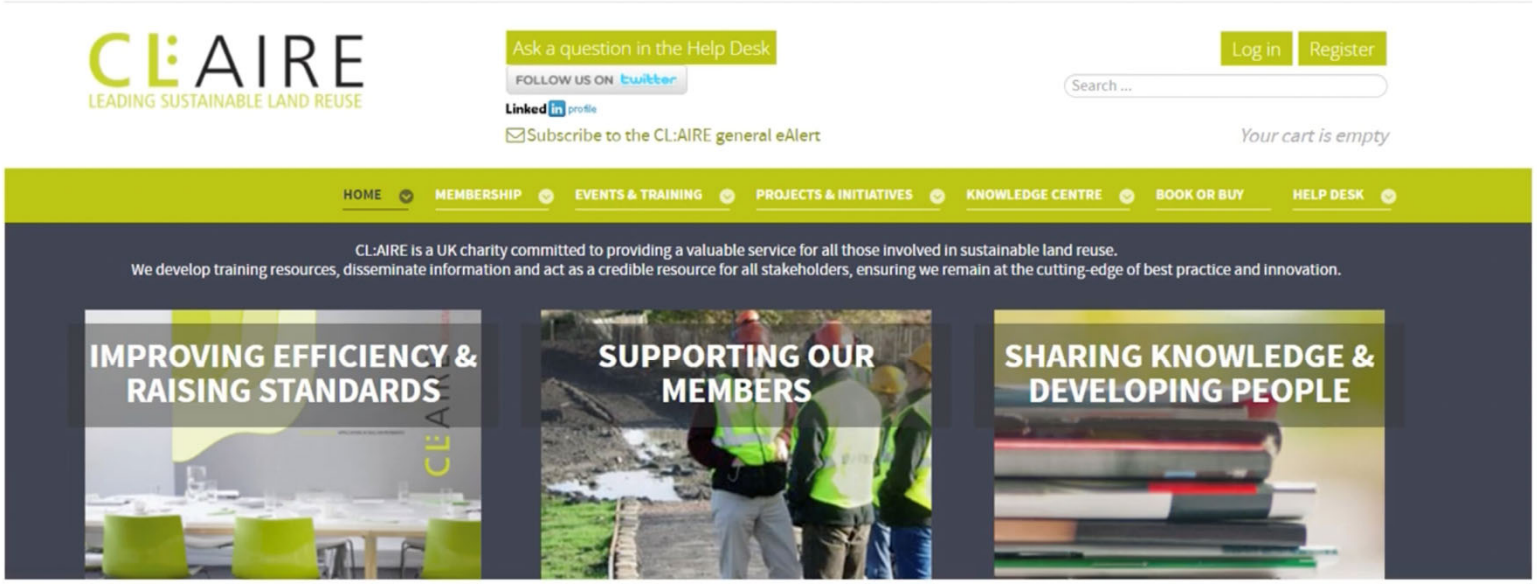
Temperature Projections for different scenarios (Figure A3-1)

UKCP	UK Climate Projections
RCP	Representative Concentration Pathway

Coming soon

Update to RTM spreadsheet and guidance

Date ???



Summary CWRA

- CSM to understand site
- Choose model
- RTM models 2 pathways
  - Migration unsaturated zone
  - Migration saturated zone
- Choose appropriate target concentration eg DWS
- Decide on compliance point for assessment
- Calculate a remedial target
- If concentration on site > RT → move CP downstream

Session 3: HHRA: Unpacking Toxicology

RICARDO EMAQ+

LQM
Sound science:
Defensible decisions

Content

- What is toxicology
- Current UK approach
  - SR2, SP1010
- Concepts and Terminology
  - Threshold and non-threshold effects
  - Uptake and intake
  - Point of Departure
  - Local and systemic effects
- Calculating tox values – HCVs, LLTCs
  - Tolerable Daily Intakes (TDIs)
  - Mean Daily Intakes (MDIs)
  - Index Doses (IDs)
- Published UK Tox Values

Toxicology

- Study of adverse effects of chemicals on living organisms
  - Nature of adverse effects
  - How chemicals cause harm
  - Mode/mechanism of action

Paracelsus

- The Dose Makes the Poison
- *“Sola dosis facit venenum”*
- "All things are poison, and nothing is without poison; the dosage alone makes it so a thing is not a poison."

1494 –1541

Sound science: Defensible decisions

Man dies from eating more than a bag of liquorice a day

24 September

Studies have found that eating too much liquorice can cause a dangerous drop in potassium levels

https://www.bbc.co.uk/news/world-us-canada-54269144

RICARDO EMAQ+

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Toxicological Assessment

- A toxicological assessment is used to derive appropriate toxicological values eg HCV, LLTC
- Toxicological assessment
  - Considers the adverse effects of chronic exposure of a human to a chemical based on the currently available toxicological data
  - Adverse effects may vary depending on:
    - Chemical form (CrVI vs CrIII); and
    - Route of exposure (Oral vs inhalation)
- Level of knowledge available is variable
  - Some chemicals are well studied
  - Little is known about others

Importance of Tox data

- To assess the risk to humans:
  - How is the receptor exposed to the contaminant?
  - How much contaminant is the receptor exposed to?
    - Calculated Average Daily Exposure expressed as mg contaminant/ kg body weight/day
  - Is this exposure acceptable?
  - Decision made using toxicological value adopted based on the contaminant's toxicological properties

Exposure Assessment

Tox

Toxicological values are the most critical parameters used in human-health risk assessment

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Case Study Martinique – result of drawing wrong conclusions form toxicology study

Chlorodecone

- BBC 20 Nov 20
- https://www.bbc.co.uk/news/stories-54992051
- Powder under banana trees
- Other names
  - Kepone
  - IUPAC name
    - decachloropentacyclo[5.3.0.$0^{2.6}$.$0^{3.9}$.$0^{4.8}$]decan-5-one[1]

Sources of Toxicological Data

Sources of toxicological data

- Animal data
- Human data
  - Epidemiological studies
  - Occupational studies
- Significant levels of uncertainty
  - Which needs to be considered when deriving toxicological values
- Human data preferred
  - Quality depending

Current UK approach

- **Environment Agency 2009 'Human health toxicological assessment of contaminants in soil' (Science Report SC050021/SR2)**
  - describes how the toxicity of chemical soil contaminants should be assessed to derive toxicological values called 'Health Criteria Values' (HCVs) that represent a "*level of long term human exposure to individual chemicals in soil that are tolerable or pose a minimal risk.*"

SGVs
S4ULS
EIC GACs

- **Defra 2013 'Development of Category 4 Screening Levels for assessment of land affected by contamination' (SP1010)**
  - Describes a different toxicological assessment framework to derive toxicological values called "Low Levels of Toxicological Concern" (LLTCs) defined as the "*concentration of a contaminant that would pose a **low** risk to human health … that definitely does not approach an intake that could be defined as causing a Significant Possibility of Significant Harm to human health.*"

C4SLs

Health Criteria Values (HCVs)

- Tox values derived using framework in SR2
- Represent levels of exposure protective of human health
  - Minimal or tolerable risk for long term exposure to chemicals in soil
  - HCVs
    - Tolerable Daily Intake TDI – threshold
    - Index Dose, ID non threshold
- Used to set
  - SGVs, S4ULs, EIC GACs, Atkins AtRisk

GACs

- GACS = the soil concentration where the Average Daily Exposure (ADE) from soil sources by a particular exposure route equals the HCV for that route

In USA tox values = REFERENCE VALUES: RfD RfC

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Minimal or tolerable risk

- Minimal risk
  - intake dose that is considered to be associated with a negligible risk of cancer over a specified duration of exposure – usually lifetime
  - Used for non threshold chemicals
- Tolerable risk
  - Used for threshold chemicals
  - [NB allowable risk = from food additives]

Non-threshold chemicals = minimal risk

Threshold chemicals = tolerable risk

Low level of toxicological concern:

- Tox values used to set C4SLs
- SP1010 moved away from toxicological values representing “minimal or tolerable risk”
  - eg Health Criteria Values derived in line with SR2, which follows international norms used to set air, food and drinking water standards
- SP1010 instead defines a toxicological value called a “low level of toxicological concern” (LLTC)
  - The definition is complex, but in general an LLTC will be approximately 2xHCV
  - For example, for carcinogens a HCV is aimed at an Excess Lifetime Cancer Risk of 1:100,000 but an LLTC represents 1:50,000
- These toxicological changes account for most of the difference between SGVs (and other GACs) and the C4SLs
  - GAC based on LLTCs are usually more than twice a comparable GAC based on HCVs

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Deriving Toxicological Values

Deriving toxicological values

- Most HHRA based on toxicological values published by others, such as Environment Agency TOX reports
- Deriving toxicological values from 1st principals is very complex; requires
  - considerable technical and scientific experience (toxicologist?)
  - significant effort and time (days or weeks) to undertake and evaluate a literature review that is:
    - Detailed, robust and comprehensive
    - Transparent and well documented
  - Any reporting should be as detailed as that published by the EA or Defra

Seek specialist assistance

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Deriving toxicological values

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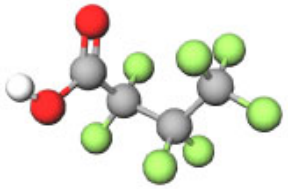
PFAS



Perfluorobutanoic acid (PFBA) (C4)

Seek specialist assistance

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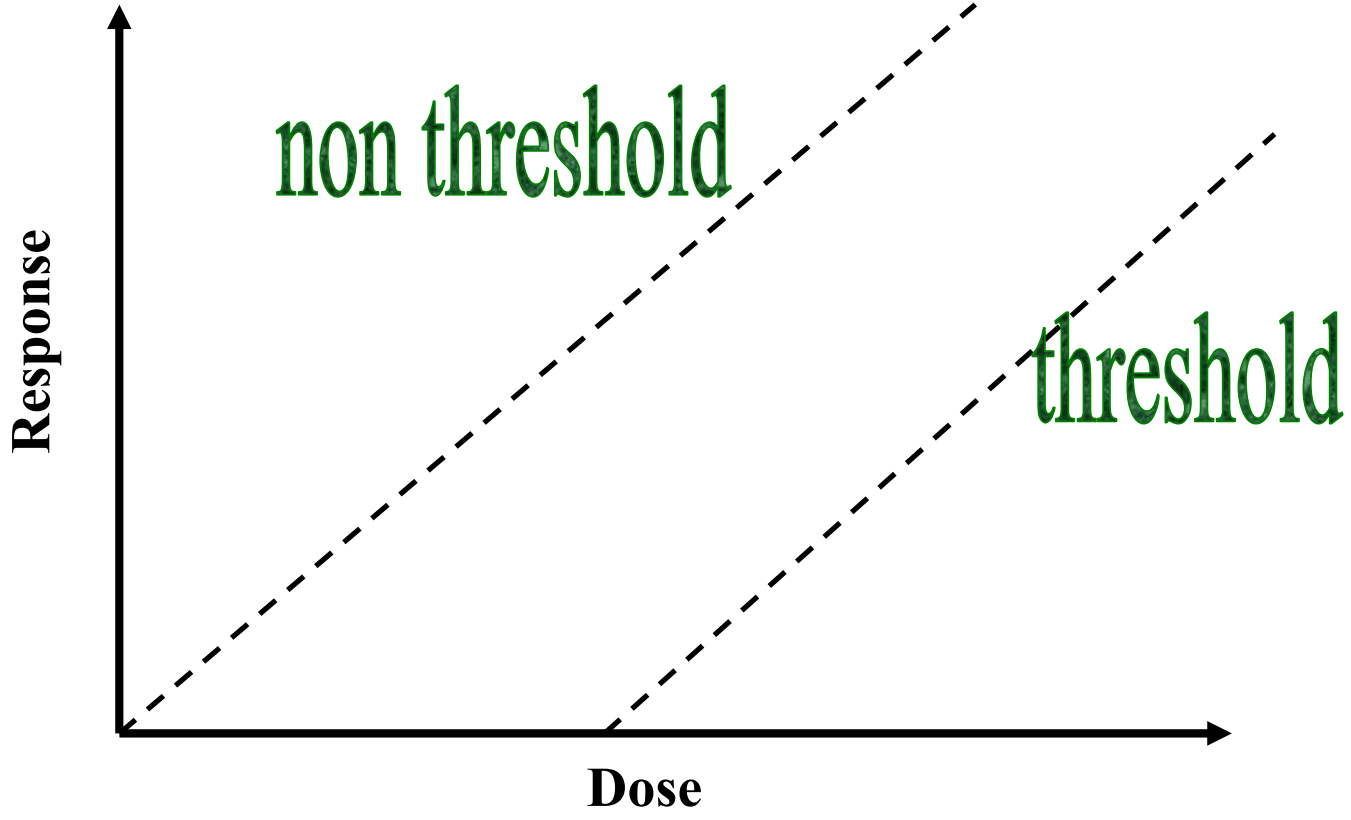
Concepts and Terms

Concepts and terminology: Local vs systemic toxicity

- Local toxicity
  - health effect occurs at the point of contact eg:
    - Inhaled asbestos causes lung cancers
    - Benzo[a]pyrene on the skin can cause skin cancers
    - Nickel in jewellery can cause skin irritation and sensitization
- Systemic toxicity
  - Health effect occurs after the contaminant has been absorbed by the body, usually to an organ not at the point of contact eg:
    - benzene via inhalation (blood and bone cancers)
    - Arsenic via ingestion (skin cancers)
    - Lead by ingestions (kidney, heart and foetal effects)
- Some substances can have both local and systemic effects
  - This needs to be considered in deriving a toxicological value

Concepts and terminology: Threshold vs non-threshold toxicity



dose response curve

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Concepts and terminology: Non-threshold toxicity

- Usually relates to mutagens and genotoxic carcinogens that damage DNA and genetic material
- In these cases there is no basis to assume a threshold exists
  - So any exposure will carry some level of risk
- UK policy is to apply the ALARP principle:
  - Each source of exposure should be reduced to a level that is 'As Low As Reasonably Practicable'
  - Exposure from each source (eg ambient air, drinking water, food and land contamination) are treated independently

Mutagen: physical or chemical agent that changes the genetic material, usually DNA, -increases the frequency of mutations above the natural background level
Genotoxic: chemical that damages cellular DNA, resulting in mutations or cancer.

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Concepts and terminology: Threshold and non-threshold toxicity

- But its more complicated!
- A substance may behave differently via different routes of entry e.g. chromium
  - Oral exposure to chromium – Threshold effects (intestinal and blood disease)
  - Inhalation exposure to chromium – Non-threshold effects (lung cancer)
- Substances may display both threshold and non threshold effects via one route of entry
  - Both need to be considered in deriving a toxicological value
  - Identify which is the critical effect

Deriving Toxicological values: Threshold Toxicity

- Identify the critical study (chronic exposure) from the toxicological assessment, usually by selecting a high quality study that identified adverse effects at low doses
- NOAEL
  - "No Observable Adverse Effect Level" – highest dose in the study at which no adverse effects were observed
- LOAEL
  - If adverse effects were observed at the lowest dose studied a NOAEL cannot be derived
  - In these cases, the "Lowest Observed Adverse Effect Level" is used but there is more uncertainty for a larger UF is applied

NOAEL or LOAEL may be used as Point of Departure (POD)

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Dose Response Curve

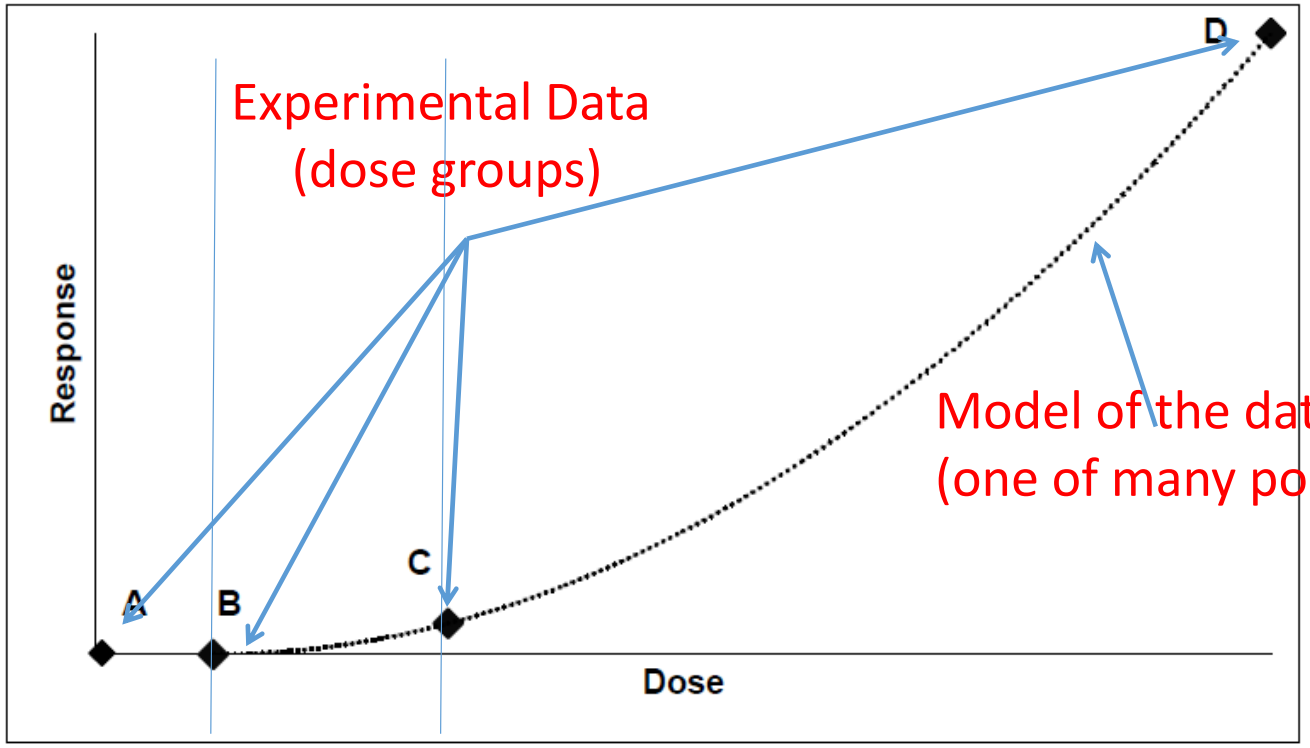

Figure 2.1 Typical dose-response data

SR2

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Calculating Tox Values

- Tox Value = Point of departure/Uncertainty Factor

$$TDI = \frac{POD}{UF}$$

HCV

Where: POD = point of departure (e.g. NOAEL, LOAEL, BMDL)
UF = uncertainty factor

SR2

SP1010 uses LLTC as tox value

Figure 2.4 Derivation of the tolerable daily intake

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Deriving HCV values: Threshold Toxicity

- Toxicology Value = POD/UF
  - The Point of Departure (POD) may be a NOAEL, LOAEL or BMD/BMDL for chronic exposure.
  - Uncertainty factors (UF), usually set at 10, are used to account for different sources of uncertainty, for example
    - For animal studies, x10 for differences between animal model and humans (interspecies variation)
    - X10 for variability between individuals within a species (intraspecies variation)
    - Plus further factor (x10) for data gaps, use of LOAEL rather than a NOAEL, poor quality studies)
    - Total UF = 1000
  - SP1010 uses a similar concept referred to as a 'chemical-specific adjustment factor' in deriving LLTCs for threshold effects

Deriving Health Criteria Values: Non-Threshold Toxicity

- More complicated that for threshold effects
- Approach 1 – quantitative risk assessment (QRA)
  - Use models to predict 'slope factors' or excess lifetime cancer risks (ELCR) from cancer incidence observed in studies and select a dose that equates to a minimal cancer risk
  - This approach is not endorsed in UK for animal studies, but may be applied where human cancer incidence data is available
    - Eg Arsenic and asbestos
- Approach 2 – non quantitative extrapolation
  - Preferred by UK authoritative bodies for animal data
  - Identify lowest dose where carcinogenic effect is observed and apply uncertainty factors based on expert judgement to derive a dose that should pose minimal cancer risk
- SP1010 uses combination of approaches

Deriving toxicological values: Benchmark Dose modelling

- NOAEL & LOAEL – relate to a single dose from a single study
- It would be more robust to derive a POD based on all the data derived from one or more studies
- Benchmark dose modelling uses statistics and curve fitting techniques the data from one or more studies to estimate a dose (benchmark dose BMD) that would result in a predetermined change in response (BMR). For example:
  - Threshold: a 10% increase in kidney damage or 5% weight loss. (or cancer incidence)
  - Non-threshold: 5% increase in liver tumour incidence
- Uncertainty can be taken into account by calculating 95% confidence limits for the BMD – referred to as BMDLs

BMR = Benchmark Response

Deriving toxicological values: Benchmark Dose modelling

SR2

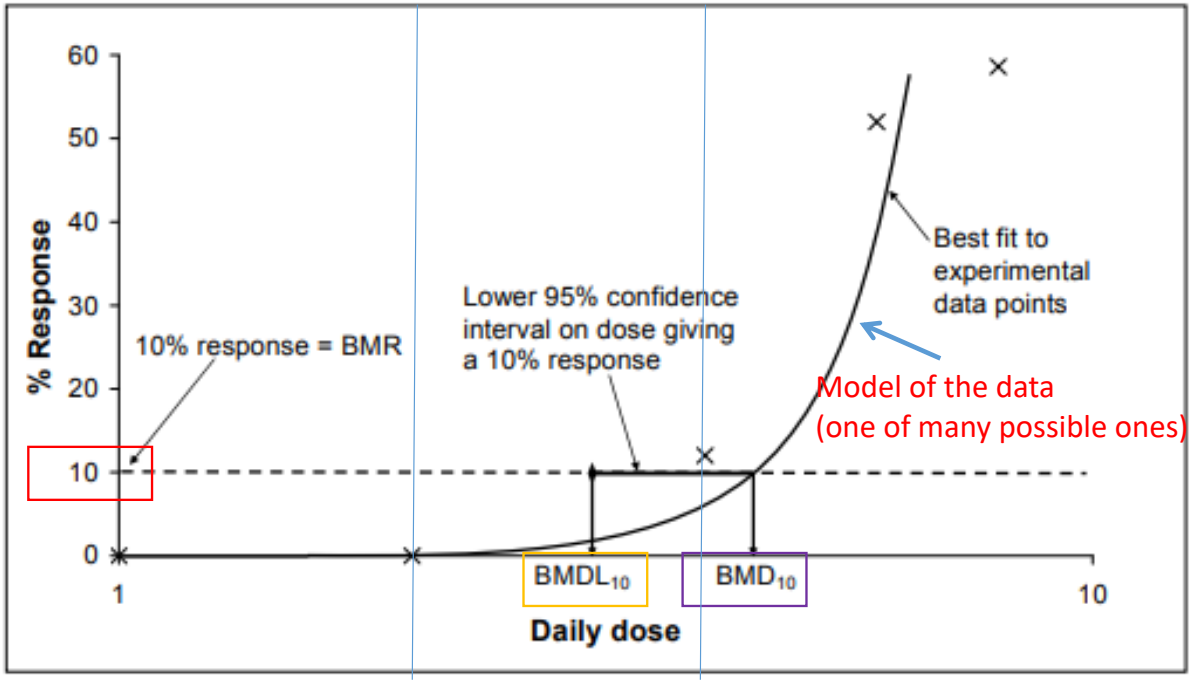
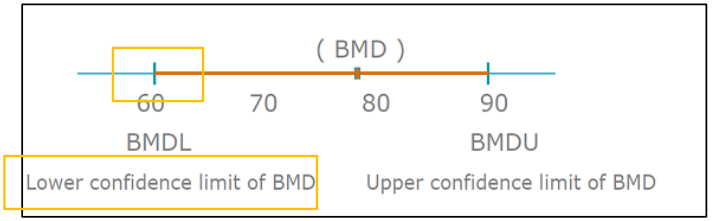


Figure 2.2 The benchmark dose (modified from EFSA, 2005a)



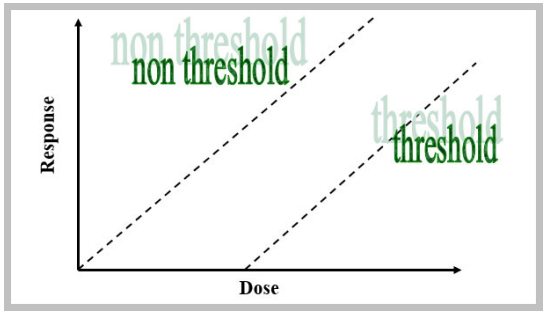
https.com/Topics/CRA/What_Is_Benchmark_Dose_(BMD)_and_How_to_Calculate_BMDL.html://www.chemsafetypro

BMDL = POD

BMR = Benchmark Response

Now we know difference between Threshold and non threshold toxicity

- Non Threshold
  - TOX value = ALARP
    - ID or LLTC



- Threshold
  - TOX value =
    - TDI = POD/UF
    - LLTC

- Next step is to compare the tox value with the predicted exposure

- Different approaches for T and NT tox
  - Threshold behaviour takes into account background exposure

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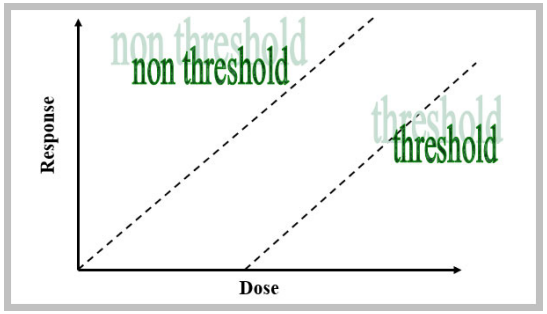
Land contamination assessments: Non-threshold behaviour

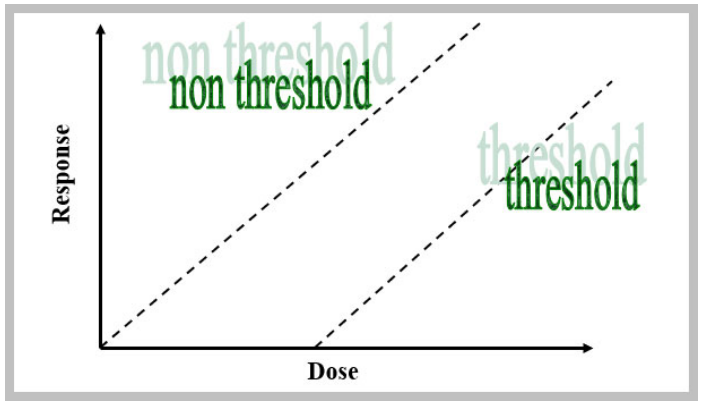
- **Type of toxicological value**:
  - SR2: Index Dose (ID) or
  - SP1010: LLTC
- ALARP applies to exposure from all other non-soil sources (ie background exposure). So background exposure is not be considered
- **Risk estimation**: compares predicted exposure directly with ID or LLTC



Land contamination assessments: Threshold behaviour

- **Type of toxicological value:**
  - SR2: Tolerable Daily Intake (TDI) or
  - SP1010: LLTC
- Background exposure must be considered and is estimated as a Mean Daily Intake (MDI), which includes exposures from:
  - Food (e.g. FSA UK Total Diet studies)
  - Water (e.g. Drinking water inspectorate)
  - Ambient air (e.g. UK air quality surveys)
- **Risk estimation:** compares predicted exposure with the Tolerable Daily Soil Intake (TDSI)

TDSI = TDI (or LLTC) - MDI



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Land contamination assessments: Threshold behaviour - MDI

- Mean Daily Intake (MDI) - Average adult background exposure of UK population including:
  - Food (e.g. FSA UK Total Diet studies)
  - Water (e.g. Drinking water inspectorate)
  - Ambient air concentrations (e.g. UK air quality surveys)
- Units
  - MDI is quoted in mg per day so needs converting **before** calculating TDSI (mg/kg body weight/day)
    - Divide by body weight (70 kg for adult)
    - Further adjustments for child receptors (eg residential landuses)
      - Reduced dietary intake
      - Higher respiration rates
    - These conversions and adjustments are done automatically within CLEA

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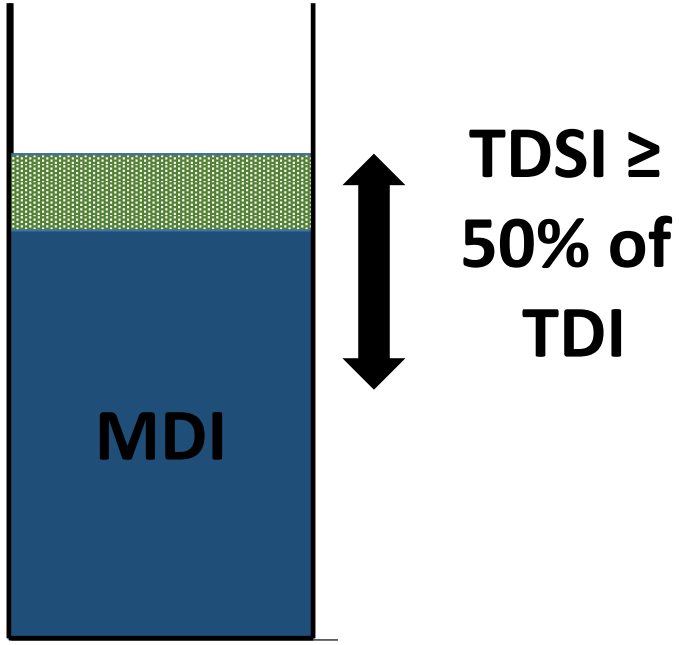
The 50 % Rule

Land contamination assessments: 50% Rule

- Calculating TDSI by TDI (or LLTC) - MDI is appropriate when TDI is much greater than MDI
- But if TDI is similar to or less than MDI?
  - TDSI will be close to or less than zero!
  - Meaning soil can contain no contamination or must absorb it from the environment!
  - This is the case for some contaminants, eg cadmium
- So SR2 makes the policy that the TDSI must be at least half of the TDI
  - This is called 'The 50% rule'
  - CLEA will automatically apply this rule



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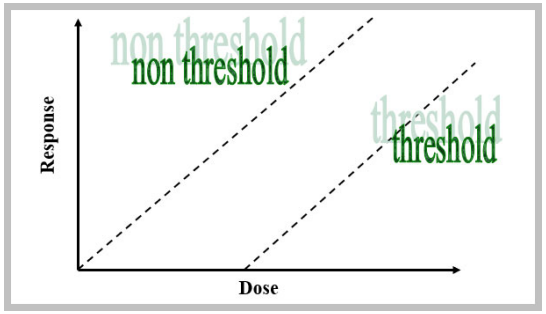
REMINDER: Threshold vs Non Threshold terminology (SR2)

- **T**hreshold
  - **T**olerable Risk
  - HCV = **T**DI (LLTC)
  - Background exposure, 50% rule

SP1010 = LLTC



- Non Threshold
  - Minimal risk
  - HCV = Index dose (LLTC)
  - ALARP

SP1010 = LLTC

Published UK Toxicology Values

‘Old’ Environment Agency TOX reports

TOX 1 Arsenic (Replaced by ‘new’ report)

TOX 2 Benzo(a)pyrene

TOX 3 Cadmium (Replaced by ‘new’ report)

TOX 4 Chromium

TOX 5 Inorganic cyanide

TOX 6 Lead (withdrawn)

TOX 7 Mercury (Replaced by ‘new’ report)

TOX 8 Nickel (Replaced by ‘new’ report)

TOX 9 Phenol (Replaced by ‘new’ report)

TOX 10 Selenium (Replaced by ‘new’ report)

TOX 11 Benzene (Replaced by ‘new’ report)

TOX 12 Dioxins, Furans and Dioxin-Like PCBs (Replaced by ‘new’ report)

Minimal or tolerable risk

TOX 14 Toluene (Replaced by ‘new’ report)

TOX 16 1,1,2,2 tetrachloroethane & 1,1,1,2 tetrachloroethane

TOX 17 Ethylbenzene (Replaced by ‘new’ report)

TOX 18 Vinyl Chloride

TOX 19 Xylenes (Replaced by ‘new’ report)

TOX 20 Naphthalene

TOX 21 Carbon Tetrachloride

TOX 22 1,2 Dichloroethane

TOX 23 Tetrachloroethene

TOX 24 Trichloroethene

TOX 25 1,1,1 Trichloroethane

Published 2002-2006 based on CLR9

Sound science: Defensible decisions

Published toxicological values: 'Old' Environment Agency TOX reports

Number	Substance	Status
TOX 1	Arsenic	Replaced by 'new' report
TOX 2	**Benzo(a)pyrene**	based on CLR9
TOX 3	Cadmium	Replaced by 'new' report
TOX 4	**Chromium**	based on CLR9
TOX 5	**Inorganic cyanide**	based on CLR9
TOX 6	Lead	withdrawn
TOX 7	Mercury	Replaced by 'new' report
TOX 8	Nickel	Replaced by 'new' report
TOX 9	Phenol	Replaced by 'new' report
TOX 10	Selenium	Replaced by 'new' report
TOX 11	Benzene	Replaced by 'new' report
TOX 12	Dioxins, Furans and Dioxin-Like PCBs	Replaced by 'new' report
TOX 14	Toluene	Replaced by 'new' report
TOX 16	**1,1,2,2 tetrachloroethane & 1,1,1,2 tetrachloroethane**	based on CLR9
TOX 17	Ethylbenzene	Replaced by 'new' report
TOX 18	**Vinyl Chloride**	based on CLR9
TOX 19	Xylenes	Replaced by 'new' report
TOX 20	**Naphthalene**	based on CLR9
TOX 21	**Carbon Tetrachloride**	based on CLR9
TOX 22	**1,2 Dichloroethane**	based on CLR9
TOX 23	**Tetrachloroethene**	based on CLR9
TOX 24	**Trichloroethene**	based on CLR9
TOX 25	**1,1,1 Trichloroethane**	based on CLR9

Minimal or tolerable risk

BOLD – older tox reports, based on CLR9 methodology, not withdrawn or replaced. Still useful for understanding chemical toxicity but may not be suitable for deriving HCVs as more recent toxicology information may be available.

Published 2002-2006 based on CLR9

Sound science: Defensible decisions

Published toxicological values: 'New' Environment Agency TOX reports

- Arsenic
- Cadmium
- Mercury (withdrawn)
- Nickel (withdrawn)
- Selenium

Published in 2009 based on SR2 and replace any earlier 'old' TOX report

- Benzene
- Toluene
- Ethylbenzene
- Xylenes
- Phenol
- Dioxins, Furans & Dioxin-like PCBs

Minimal or tolerable risk

Sound science: Defensible decisions

Example Tox Values

- Selenium
  - TDI_{oral}
  - No TDI_{inh}

HCV and MDI values for selenium

Parameter		Oral	Inhalation
MDI	(μg day^{-1})	35	0.06
MDI for 70 kg adult	(μg kg^{-1} bw day^{-1})	0.5	0.0009
MDI for 20 kg child	(μg kg^{-1} bw day^{-1})	1.3 [a]	0.002 [a]
TDI	(μg kg^{-1} bw day^{-1})	**6.4**	**Not derived**

[a] see Environment Agency (2009a) for details of MDI conversion factors.

- Arsenic
  - ID_{oral}
  - ID_{inh}

Table 6.1 ID and MDI[a] values for inorganic arsenic

Parameter	Units	Oral	Inhalation
MDI	μg day^{-1}	5	0.014
MDI for 70-kg adult	μg kg^{-1} bw day^{-1}	0.07	0.0002
MDI for 20-kg child	μg kg^{-1} bw day^{-1}	0.19 [b]	0.0005 [b]
ID for deriving SGV	**μg kg^{-1} bw day^{-1}**	**0.3 [c]**	**0.002**

[a] Note: the MDI is not accounted for in deriving SGVs based on IDs.
[b] See Environment Agency (2009a) for details of MDI conversion factors.
[c] Oral value based on equivalence to the UK drinking-water standard for arsenic.

For full details = see Tox reports

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Defensible decisions

Published toxicological values: Defra's SP1010

- Phase 1
  - Arsenic
  - Benzene
  - Benzo[a]pyrene (as a surrogate marker for PAHs)
  - Cadmium
  - Chromium (VI)
  - Lead

Low level of toxicological concern

- Phase 2
  - Tetrachloroethene
  - Trichloroethene
  - Vinyl chloride
  - 1,2-Dichloroethane (v1.1)
  - cis 1,2 Dichloroethene and trans
  - Napthalene
  - PFAS

https://claire.co.uk/projects-and-initiatives/category-4-screening-levels

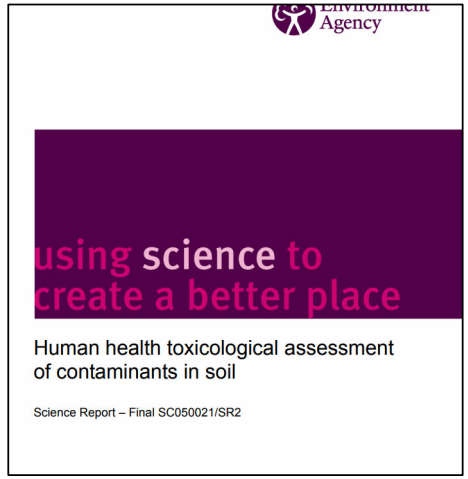
Sound science: Defensible decisions

Reminder of key terminology

Health Criteria Value (HCV)

- Generic term to describe the toxicological value derived using SR2 and representing 'minimal or tolerable risk'

- Threshold Effects
  - Tolerable Daily Intake (TDI)
  - Background exposure referred to as Mean Daily Intake (MDI)
  - Tolerable Daily Soil Intake (TDSI) = TDI-MDI or 0.5xTDI
- Non threshold effects
  - Index Dose (ID) – ALARP applies so MDI not needed



Low Level of Toxicological Concern (LLTC)

- In SP1010, the term LLTC is used for both threshold and non-threshold effects.

But they must be entered into CLEA as TDIs or IDs

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Activity: Look up some Toxicological Inputs

Find the toxicological input for toluene published by EA

- What is the oral HCV
- What is the inhalation HCV
- Is there a dermal HCV
- For each pathway is toluene a threshold or non threshold substance?
- https://webarchive.nationalarchives.gov.uk/201403[illegible].environment-agency.gov.uk/scho0309bpqq-e-e.pdf

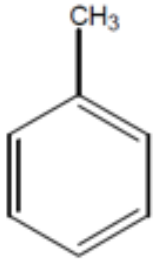

Figure 2.1 Structure of toluene

Find the toxicological input for toluene

- What is the oral HCV
  - TDI = 223 µg kg-1 bw day-1
- What is the inhalation HCV
  - TDI = 1400 µg kg-1 bw day-1
- Is there a dermal HCV
  - NO
  - it is reasonable to assume that the oral HCV value can be used for a conservative rudimentary dermal risk assessment.
- For each pathway is toluene a threshold or non threshold substance
  - Threshold for all pathways

HCV and MDI values in CLEA spreadsheet

HCV values in CLEA spreadsheet

ADVANCED SETTINGS

Parameter	Units	Oral	Inhalation
MDI	µg day^{-1}	10	520
MDI for 70-kg adult	µg kg^{-1} bw day^{-1}	0.14	7.4
MDI for 20-kg child	µg kg^{-1} bw day^{-1}	0.37 [a]	19.3 [a]
TDI	µg kg^{-1} bw day^{-1}	**223**	**1,400**

[a] See Environment Agency (2009) for details of MDI conversion factors

Chemical Name	Chemical type	Type	µg kg^{-1} BW day^{-1}	Compare with: Oral exposure	Compare with: Dermal exposure	Compare with: Inhalation exposure	Type	µg kg^{-1} BW day^{-1}	Compare with: Oral exposure	Compare with: Dermal exposure	Compare with: Inhalation exposure	Combine oral and inhalation AC	
Toluene	organic	TDI	2.23E+02	Yes	Yes	No	TDI	1.40E+03	No	No	Yes	Yes	1.00

Sound science:
Defensible decisions

MDI values in CLEA spreadsheet

Parameter	Units	Oral	Inhalation
MDI	µg day^{-1}	10	520

ADVANCED SETTINGS

Restore Defaults | Back to Menu

Chemical Name	Chemical type	Oral HCV					Inhalation HCV					Combine oral and inhalation AC	Oral MDI for adults	Inhalation MDI for adults
		Type	µg kg^{-1} BW day^{-1}	Compare with			Type	µg kg^{-1} BW day^{-1}	Compare with					
				Oral exposure	Dermal exposure	Inhalation exposure			Oral exposure	Dermal exposure	Inhalation exposure		µg day^{-1}	µg day^{-1}
Toluene	organic	TDI	2.23E+02	Yes	Yes	No	TDI	1.40E+03	No	No	Yes	Yes	1.00E+01	5.20E+02

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Summary Toxicology

- Different toxicology values
  - Based on chemical eg TDI and ID
  - Based on approach SR2/3, SP1010
- Non threshold = ID
- Threshold = TDI
  - Account for MDI
- Where tox values and MDI go in CLEA spreadsheet

Optional Extension

- Select another contaminant for which a tox report is available
- Find the oral and inhalation HCV
- For each route is the substance T or NT
- Use the CLEA spreadsheet to load chemical data and remind yourself where tox values are input

Session 4: Unpacking Exposure Assessment

RICARDO EMAQ+

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Content

- What is exposure assessment
- Concepts and Terminology
  - Exposure pathways
  - Intake and uptake
  - Critical receptor
  - General risk estimation process
- Input data required
- Calculating exposure

Input data:
- Critical receptor
- Contaminant
- Site
- Soil

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What is exposure assessment

Exposure assessment is "*the process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the risk assessment*" (IPCS, 2004).

- CLEA model estimates exposure to chemicals from soil sources
  - In units which can be compared to tox value eg HCV
  - Typically amount of chemical per kilogram body weight per day
    - Mg kg^{-1} bw day^{-1}

IPCS = International Programme on Chemical Safety

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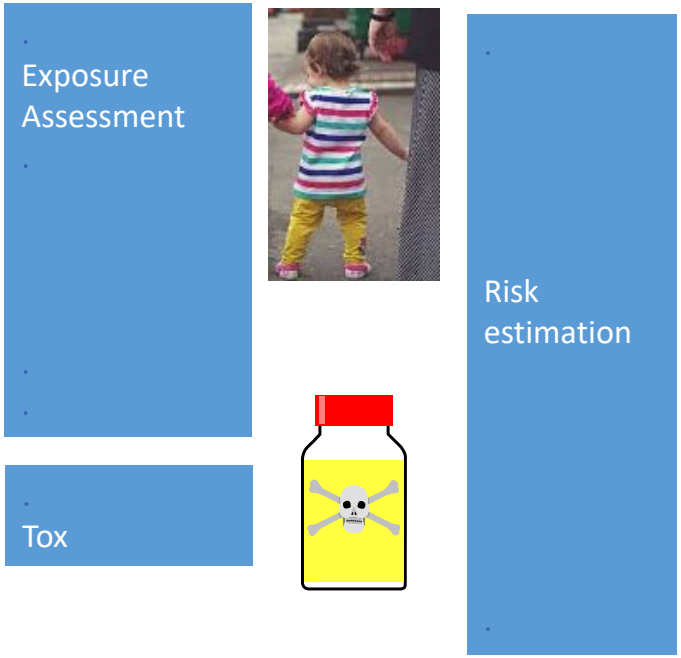
Exposure Assessment is part of Risk Estimation

- Identify exposure routes
  - Soil (contaminated site)
  - Other sources eg food
- Estimate exposure from each route
- Calculate total intake from all routes
  - How much contaminant is the receptor exposed to?
- Determine Toxicological Value
  - How much contaminant is a risk to health?
- Compare total intake to Toxicological Value
  - Is there unacceptable risk to human health?



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Exposure Assesment

- Identify exposure routes
  - Based on land use scenario
- Calculate intake from soil from each route
  - Based on defined exposure scenario
- Sum intake from all routes
  - → estimate exposure

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Exposure Routes

- The main routes of entry into body for soil contaminants are:
  - Ingestion (via mouth)
  - Inhalation (via nose and mouth)
  - Dermal (via skin)

  - [ocular, injection, breaks in skin]

- Dermal exposure is usually added to either oral or inhalation exposure because:
  - Toxicological data for dermal exposure is rarely available
  - Dermal exposure is rarely a significant exposure route

Defining exposure: Intake vs uptake

- Daily exposure to the soil contaminant via each route is estimated using equations
- But there is a difference between:
  - Intake – amount that is ingested, inhaled or touches the skin, and
  - Uptake – amount that enters the body
    - **Absorption** via the lungs, gastrointestinal tract or skin
    - depends on site-specific bioavailability and other complexities, and so is more difficult to measure or calculate.
- In general in the UK, GQRA considers **intake** as a cautious estimate of actual exposure (some exceptions e.g. lead C4SL)
  - Bioavailability may be considered during DQRA

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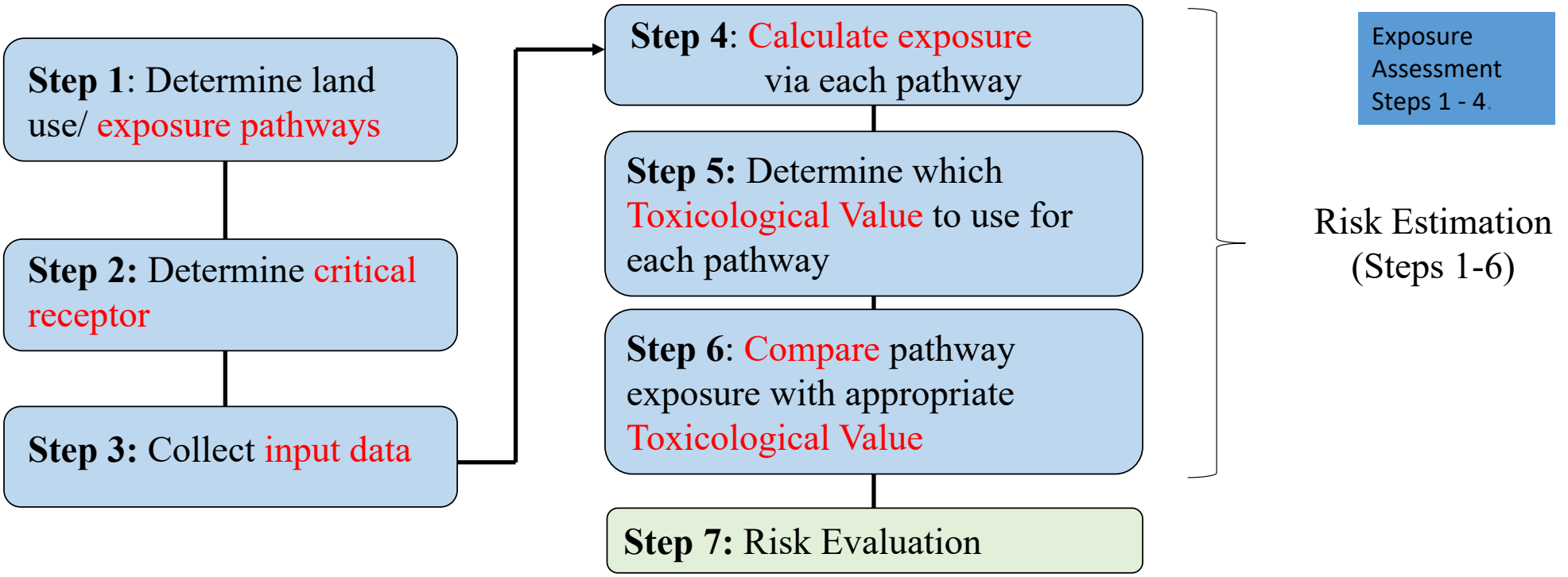
Risk Assessment Process



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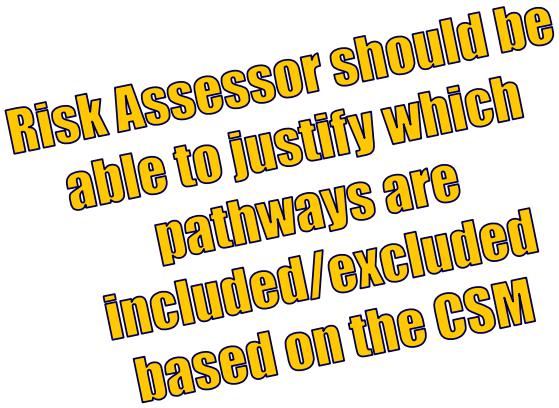
Step 1: Land Use and exposure pathways

- Land use
  - determined by the conceptual model
  - will dictate exposure pathways
- Does the site conceptual model match a generic land use ?
  - SR3 generic land uses: Residential (with/out homegrown produce), allotments, commercial
  - Defra SP1010 (2014) introduced 2 different Public Open Space land uses
- Advanced skills and careful selection of methods and inputs needed for:
  - Non-standard land uses (e.g. schools, hospitals)
  - Presence of additional pathways
    - Food [eggs, chickens], groundwater, showering

CLEA Exposure Pathways

- 10 in total
- Soil and dust ingestion (direct and indirect)
- Consumption of homegrown produce (vegetables and fruit)
- Ingestion of soil attached to homegrown produce
- Skin contact (outdoor & indoor)
- Inhalation of dust (outdoor & indoor)
- inhalation of vapours (outdoor & indoor)
- **Note:**
  - On a site specific basis there may be other exposure pathways requiring consideration e.g. chickens, livestock or on-site water source?
  - For inhalation of vapours from groundwater see “Development of Generic Assessment Criteria for Assessing Vapour Risks to Human Health from Volatile Contaminants in Groundwater” (SoBRA 2017)



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Step 2: Critical Receptor

- The individual or subgroup of the population most likely to be exposed and/or susceptible to the presence of soil contamination
- Women have lower body weights than males
- Children have:
  - greater intake of food, water, air and soil per body weight than adults
  - Larger skin area per unit volume than adults
  - (Generally) More susceptible physiology than adults

Risk Assessor should be able to justify the critical receptor based on the CSM

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Step 3: Input data for critical receptor

- Characteristics vary from year to year due to growth and changes in behaviour e.g.
  - Body weight
  - Body height (breathing zone)
  - Soil ingestion rates
  - Likely exposed skin area
  - Consumption rates for homegrown produce etc.

Risk Assessor should be able to justify all inputs (even for Generic Assessment Criteria)

What is the critical receptor like?

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Step 3: Input data for critical receptor

Table 4.6: Mean weight and height by sex and age class from the 2003 Health Survey for England (after Jeffries 2009)

Age class	Female		Male	
	Weight (kg)	Height (m)	Weight (kg)	Height (m)
1	5.6	0.7	6.9	0.7
2	9.8	0.8	10.5	0.8
3	12.7	0.9	13.2	0.9
4	15.1	0.9	15.8	0.9
5	16.9	1.0	17.6	1.0
6	19.7	1.1	19.6	1.1
7	22.1	1.2	22.8	1.2
8	25.3	1.2	25.4	1.2
9	27.5	1.3	28.0	1.3
10	31.4	1.3	33.2	1.3
11	35.7	1.4	35.6	1.4
12	41.3	1.4	40.2	1.4
13	47.2	1.5	43.7	1.5
14	51.2	1.6	49.8	1.6
15	56.7	1.6	58.8	1.6
16	59.0	1.6	61.2	1.7
17	70.0	1.6	83.2	1.8
18	70.9	1.6	82.7	1.7

Step 3: Input data for critical receptor

- Exposure duration ED (*ie* number of years over which the chemical intake is likely to occur)
  - SR3 Residential: 0-6yrs
- Exposure frequency EF (*ie* number of days/year exposure event is likely to occur)
  - May vary with age.
  - SR3 Residential:
    - young children (<5 yrs) assumed to inhale dusts in the home 365 days/year
- Occupancy Periods (*ie* number of hours per day spent indoors and outdoors*)*
  - Varies with age.
  - SR3 Residential:
    - young children (<5 yrs) assumed to spend 1 hr outdoors, 23 hrs inside the home.
    - Older children will attend school.

How does the critical receptor behave?

Step 3: Input data for contaminant

- Relevant Toxicological Value & background exposure (if appropriate) for each route of entry

Parameter	Units	Oral	Inhalation
MDI	µg day^{-1}	10	520
MDI for 70-kg adult	µg kg^{-1} bw day^{-1}	0.14	7.4
MDI for 20-kg child	µg kg^{-1} bw day^{-1}	0.37 [a]	19.3 [a]
TDI	µg kg^{-1} bw day^{-1}	**223**	**1,400**

[a] See Environment Agency (2009) for details of MDI conversion factors

Tox

- Physical-chemical properties such as
  - partition coefficients including K_d, K_{ow} and K_{oc}
  - molecular weight
  - vegetable/fruit concentration factors
  - vapour pressure
  - solubility etc

How does the contaminant behave?

Risk Assessor should be able to justify all inputs

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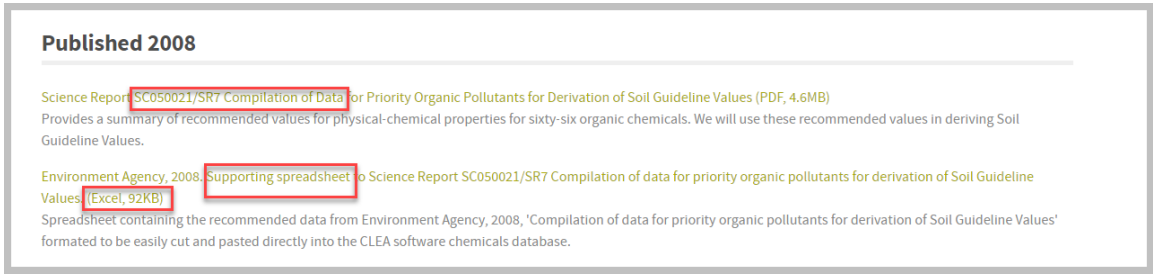
Step 3: Input data for contaminant

- Many possible sources:
  - Consider ‘authorititative’ness of the source
  - SR7 ‘Compilation of Data for Priority Organic Pollutants for Derivation of Soil Guideline Value’
    - Environment Agency, November 2008, SC050021/SR7
    - Recommended physical-chemical data consistent with SR3 for 66 organic chemicals
    - Download as Microsoft® Excel spreadsheet to import into CLEA
    - https://www.claire.co.uk/useful-government-legislation-and-guidance-by-country/77-risk-assessment-info-ra?start=10
  - Other reports, documents and scientific papers
  - Google or Wikipedia? – caution!



Published 2008

Science Report SC050021/SR7 Compilation of Data for Priority Organic Pollutants for Derivation of Soil Guideline Values (PDF, 4.6MB)
Provides a summary of recommended values for physical-chemical properties for sixty-six organic chemicals. We will use these recommended values in deriving Soil Guideline Values.

Environment Agency, 2008. Supporting spreadsheet to Science Report SC050021/SR7 Compilation of data for priority organic pollutants for derivation of Soil Guideline Values (Excel, 92KB)
Spreadsheet containing the recommended data from Environment Agency, 2008, 'Compilation of data for priority organic pollutants for derivation of Soil Guideline Values' formated to be easily cut and pasted directly into the CLEA software chemicals database.

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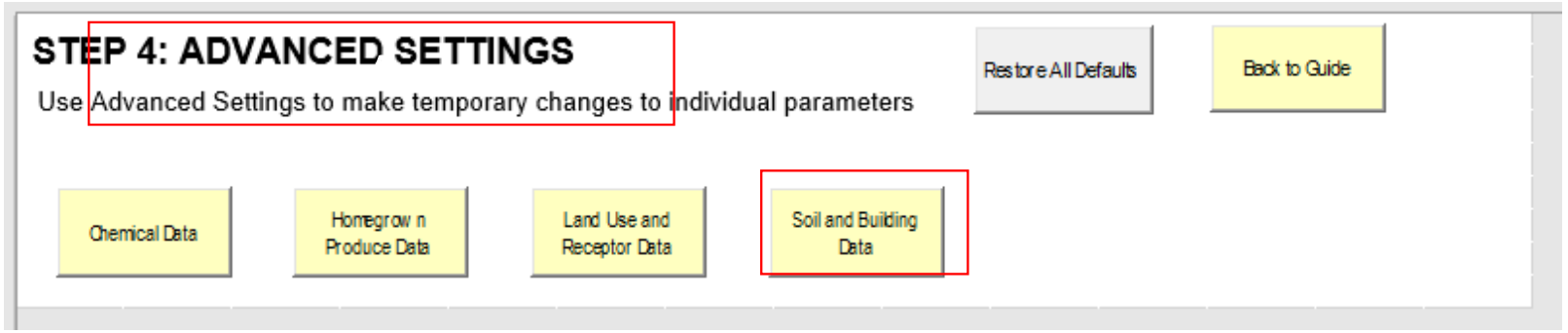
Step 3: Input data for site and soil

- Site parameters:
  - Size and depth of contaminated zone
  - Windspeed
- Soil properties:
  - Bulk density
  - Fraction of organic carbon
  - Soil type e.g. sandy/loam/clay or other
  - Porosity (total plus air- and water-filled)

Risk Assessor should be able to justify all inputs (even for Generic Assessment Criteria)



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SR3 soil properties

Table 4.4: Default properties according to soil type

Soil type [1]	Property							
	Bulk Density ($g\ cm^{-3}$)	Porosity ($cm^3\ cm^{-3}$)			Residual Water Content ($cm^3\ cm^{-3}$)	Saturated Hydraulic Conductivity ($cm\ s^{-1}$)	van Genuchten	
		Air	Water	Total			α (cm^{-1})	m (dimensionless)
Clay	1.07	0.12	0.47	0.59	0.24	9.93E-04	0.0385	0.2972
Silty clay	0.94	0.12	0.51	0.63	0.26	1.17E-03	0.0541	0.3155
Silty clay loam	1.07	0.12	0.46	0.58	0.21	1.17E-03	0.0291	0.3072
Clay loam	1.14	0.14	0.42	0.56	0.19	1.51E-03	0.0437	0.3039
Sandy clay loam	1.20	0.16	0.37	0.53	0.15	2.37E-03	0.0560	0.3098
Silt loam	1.09	0.14	0.44	0.58	0.18	1.58E-03	0.0375	0.3078
Sandy silt loam	1.19	0.14	0.38	0.52	0.15	2.20E-03	0.0410	0.3174
Sandy loam [2]	1.21	0.20	0.33	0.53	0.12	3.56E-03	0.0689	0.3201
Sand	1.18	0.30	0.24	0.54	0.07	7.36E-03	0.1221	0.3509

[1] Most exposed areas of residential and commercial sites (such as gardens and landscaped areas) will be covered by a layer of top soil. However, many former industrial sites may have limited/no top soil and care should be taken in applying the data in this table to subsoil horizons, made ground, and drift geology.

[2] Also includes data from loamy sand soils since it has a very narrow particle size range.

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Step 3: Input data for pathway

For example

- Soil ingestion rates
- Vegetable & fruit concentration factors
- Homegrown produce consumption rates
- Soil loading parameters
- Inhalation rates
- Dermal absorption rates
- Dilution ratio
- Temperature

Pathway Parameters: Dilution Ratio

- Estimating vapour intrusion into a building is highly complex
  - Multiple different mathematical models have been derived
  - CLEA utilises the Johnson and Ettinger Model

What proportion of vapour in soil gets into building

Pathway Parameters:
Temperature

- SR3: the UK average annual soil temperature at the soil surface can be assumed to be **10ºC**

Step 4: Calculate exposure

- Calculate Intake rate via each pathway
- Calculate total exposure
- Calculate average daily exposure
  - Affected by
    - Human behaviour
    - Chemical behaviour
    - Soil characteristics

Average Daily Exposure (ADE)

- average daily amount of a contaminant PER KG BODYWEIGHT that the **critical receptor** may take in over the duration of exposure

Equation 2.1

$$\text{ADE} = \frac{(IR_{ing} \times EF_{ing} \times ED_{ing})}{BW \times AT} + \frac{(IR_{inh} \times EF_{inh} \times ED_{inh})}{BW \times AT} + \frac{(IR_{derm} \times EF_{derm} \times ED_{derm})}{BW \times AT}$$

Where

ADE is the average daily human exposure to a chemical from soil, mg kg^{-1} bw day^{-1}

IR is the chemical intake/uptake rate, mg day^{-1}

EF is the exposure frequency, days $year^{-1}$

ED is the exposure duration, year

BW is the human body weight, kg

AT is the averaging time, days

The subscripts *ing*, *inh*, and *derm* apply to the inhalation, ingestion and dermal contact routes respectively. IR_{ing} and IR_{inh} are normally estimated as intakes. IR_{derm} is normally estimated as an uptake.

ADE units = mg/ kg bw /day

SR3

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Chemical intake/uptake rate (IR)

- Calculated from:
  - Concentration of contaminant in soil (or other media eg soil/water/food/air)
  - Daily human exposure to soil (or other medium)
- Eg
  - **Cadmium** intake rate by soil ingestion depends on
    - Concentration of **Cd** in soil
    - *amount of soil ingested* each day by critical receptor
  - **Benzene** intake rate by inhalation depends on
    - concentration of **benzene** in air
    - *amount of air inhaled* each day by critical receptor

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Averaging Time

- **Average** Daily Exposure is calculated over the Averaging Time
- In the UK, Averaging Time is assumed to be equal to exposure duration
  - Residential and allotments: 0-6 yrs (6yrs)
  - Commercial: 16-65 yrs (49 yrs)
- Important UK policy decision – not the same in all countries

Step 5: Toxicological Value

- Determine the type of toxicity (threshold or nonthreshold)
- Set an appropriate Toxicological Value for each route of entry
  - The single most critical input in any assessment
  - Doubling the Tox Value will double the Assessment Criteria
  - may be a:
    - Health Criteria Value (HCV), as defined in SR2; or
    - Low Level Of Toxicological Concern (LLTC), as defined in SP1010

REMEMBER – Tox values based on science AND policy

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Step 6: Comparison of ADE and Tox Value

- The ADE (**mg/kg bw/day**) for the relevant exposure pathway(s) is compared with Tox Value (**mg/kg bw/day**) for relevant route(s) of exposure
  - Some exceptions depending on the toxicology of the contaminant
  - In practice, it is a little bit more complicated than this!

- If ADE > Tox Value (ratio>1) there may be an unacceptable risk
- If ADE< Tox Value (ratio<1) an unacceptable risk is unlikely

Step 7 – Risk evaluation

- Significance of Risk
  - Legislative context
  - Uncertainties:
    - CSM
    - Data inputs

Breaking speed limit versus dangerous driving

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Exposure Assessment - Summary

- Estimates exposure of critical receptor to chemicals
  - CLEA model
  - Based on exposure routes relevant to land use scenario
  - Select inputs
    - CR characteristics and behaviour
    - Contaminant behaviour
    - Pathways …..
  - Calculate ADE and compare with tox

Optional Activity

- SR3
  - Tables of default input values for CLEA ET
    - Critical receptor eg weight, height, exposure duration
    - Soil characteristics eg Kd
- SR7
  - Chemical parameters for toluene

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Session 5: Generic Assessment Criteria

Remember all risk assessments must be site-specific!

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Contents

- GQRA
  - GAC
  - Comparing site concentrations results to GAC
  - Using Representative Site concentration
- UK GAC
  - How UK GAC derived
  - Generic assumptions for each land use

GQRA = Tier 2 of Stage 1

- **LCRM Stage 1**
  - **Tier 2: Generic quantitative risk assessment (GQRA)**
    - **Uses generic assessment criteria (GAC) exist**
    - **GACs may include SGVs, LQM/CIEH S4ULs, C4SLs, EIC/CL:AIRE GACs**
    - **GACs developed for specific land use scenarios**
  - Tier 3: Detailed quantitative risk assessment (DQRA)
    - If there is no suitable GAC or it is exceeded, deriving site specific assessment criteria (SSAC)

= majority of UK risk assessments

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GQRA

- Risk estimation
  - Select GAC
    - Use existing GAC
      - Scientifically based
      - Relevant
    - Develop GAC
      - Based on generic assumptions in CLEA guidance
      - NOT site specific
  - Compare site concentrations with GAC
- Risk evaluation
  - eg Part 2A - evaluate whether the contamination is causing significant harm /SPOSH

Off the peg suit

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Types of Generic assessment criteria

- In the UK, GAC are **generally** screening levels
  - Risks are not significant below these values
  - Further investigation or action **may** be needed above these levels
- But internationally some are action levels
  - Action **must** taken above this level
  - Eg Dutch Intervention Values (cf Dutch Target Values)

Generic assessment criteria: General assumptions

- Tend to be conservative & protective and based on a reasonable worst case scenario
- So are appropriate across a range of different site conditions & soil types
- Are a blend of authoritative science and UK policy judgements
- Are based on generic assumptions including:
  - Soil assumed to be relatively dry and porous
  - Contaminant is present at the soil surface
  - Contaminant is dispersed evenly in the soil (no free phase or 'lumps')
  - Soil concentration do not change (no losses due to biodegradation or leaching etc)
- The assumptions used for any published GACs will be presented in the relevant reports
  - Eg CLEA guidance (SR3 and SR4) and SP1010

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Deriving GAC

- Risk assessors can derive GACS
  - use RA model
  - use standard set of generic assumptions
  - applies to general land use type
  - assumptions based on general land use type
  - all inputs need to be justified
  - requires expertise

Comparing contaminant concentrations to assessment criteria

- Risk assessor chooses contaminant concentration to compare to assessment criteria
  - May use different contaminant concentrations for different parts of the site
    - Need to justify
- Starting point:
  - Compare Maximum concentration with GAC
    - Max < GAC → Pass
    - Max > GAC → ? Fail

Comparing site concentrations to assessment criteria

- Max > GAC → ? Fail
  - What proportion of results > GAC ?
  - How much above GAC?
  - Look at elevated contamination results together with other information
    - ?reasons for local high concentration
      - Site history
      - Logs – what are the materials,
    - Lab results ?problems ?TICs
  - Is additional sampling required to make a decision?

Planning

What about using “Representative Concentration”?

- Only appropriate in limited situations
  - Samples collected using statistically valid non targeted approach
  - No underlying spatial trend
- A representative concentration is defined by the risk assessor for a particular part of the site
- It could be:
  - **Maximum concentration**
    - Quickest, simplest, least contentious and most cautious – as long as sufficient samples
  - **Upper confidence limits of the population mean**

NB in calculation of UCL it is necessary to have a single population and outliers are identified – don’t forget those outliers – they are possible hotspots and considered separately

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Selecting a representative concentration

- Needs a thorough understanding of the site and data including:
  - Lateral and vertical distribution of contaminant
  - Correlations with materials types and descriptions
- Important not to mix populations
  - Concentrations in made ground likely to be a different population to concentrations in underlying clay
  - Concentrations within gas holder likely to be a different population to concentrations in other parts of the former gas works
- Decide if you are considering the results at the site for:
  - averaging zone
  - averaging area

Source based decision

Receptor based decision

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Averaging Areas

- Based on receptor exposure
- An Averaging Area :

Receptor based decision

"..is that area (together with a consideration of depth) of soil to which a receptor is exposed or otherwise contributes to the creation of hazardous conditions." (CLR7, 2002)

IE individual house plot

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Averaging Zones

- Ground investigations and data interpretation may be based on zones. For example, zones with:
  - Similar historical uses or contaminative uses
  - Similar geology/material type
- During data analysis always re-examine whether:
  - The data supports the proposed zones?
  - Are any “Hotspots” evident?
  - If necessary, rezone before choosing representative concentration

Source based decision

Sound science:
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Comparing contaminant concentrations to assessment criteria

- Summary
  - For most sites:
    - Compare max (for each part of the site) to GAC
    - Review contamination results together with other site data to make a decision
  - In limited situations
    - Representative Concentration (max, UCL)
      - For individual populations at a site
      - For averaging zone or averaging area

Area critical receptor exposed to

Risk Evaluation

- Describe the conceptual site model
  - Identify pollutant linkages
  - Identify the uncertainties and assumptions, justifications for any calculated GAC
  - Pull together all supporting lines of evidence
- Present and justify the conclusion drawn from the evidence
  - Remediation is required because the risk is unacceptable **in the legal context**
    - Not demonstrable safe
    - SPOSH
  - Remediation is not required **in the legal context**

Sound science:
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Deriving UK Generic Assessment Criteria

- **How UK Generic Assessment Criteria are derived and the generic assumptions that underpin them**

UK Generic Assessment Criteria …

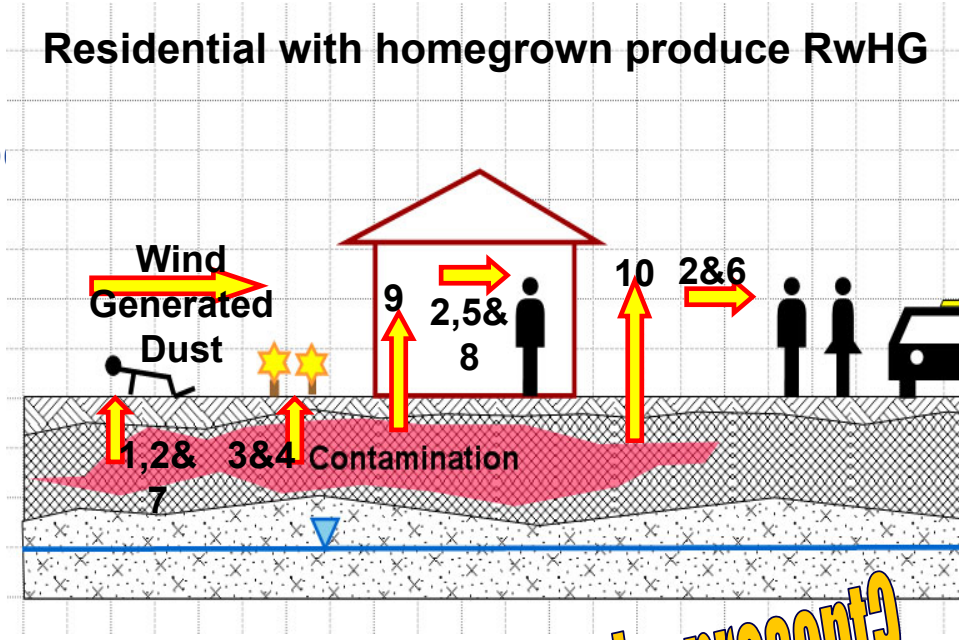
- Relate **only** to direct human health risks (Chronic exposures)
- They are **not relevant to**:
  - Acute/one-off exposures (Eg cyanides)
  - Ground or surface water protection
  - Ecosystem protection
  - Buildings and building materials effects
  - Protection of construction workers (occupational exposure)
- **Are not** intended to be remediation or clean-up criteria
- **Do not** indicate when land is Part 2A contaminated land
  - But can be used to screen out Category 4 sites

CLEA model

- Spreadsheet which estimates exposure to chemicals from soil sources
- Chronic
- Compares predicted exposure with tox values eg HCV
- Used to derive GAC (and calculate SSAC used in DQRA)

Generic UK Exposure Pathways

- 1 & 2. Direct soil and dust ingestion
- 3. Consumption of home-grown produce
- 4. Ingestion of soil attached to home-grown pro
- 5. Inhalation of dust (indoors)
- 6. Inhalation of dust (outdoors)
- 7. Dermal contact with soils
- 8. Dermal contact with dust (indoors)
- 9. Inhalation of vapours (indoors)
- 10. Inhalation of vapours (outdoors)



But other pathways may be present?

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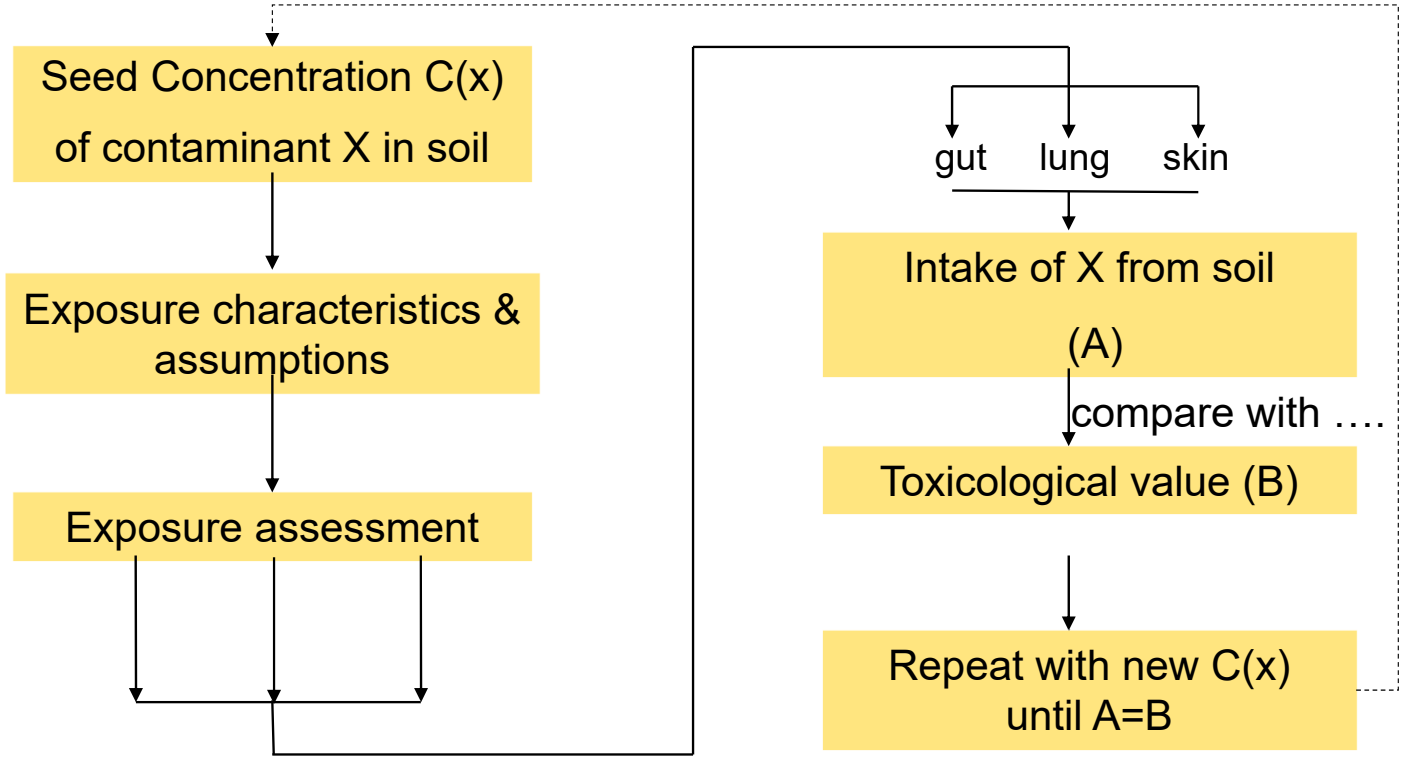
Derived using various versions of the CLEA model



So at a GAC:

ADE = TV or

$$\frac{ADE}{TV} = 1$$

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Generic Land Uses

- The land use dictates:
  - Critical receptor
  - Which exposure pathways are considered eg:
    - Indoor inhalation is considered for residential and commercial but not allotments
    - Consumption of homegrown produce is considered for residential(wHP) and allotments but not for commercial
  - Building type, if any
- SR3 describes three considers generic land uses:
  - Residential with/out homegrown produce
  - Allotment Gardens
  - Commercial
- SP1010 updates these and adds two Public Open Space (POS) land uses

Generic Land Uses: Residential Land Use

- Critical receptor - 0-6 year-old female child
- Exposure duration – 6 years
- 2 storey small terraced house (ground bearing slab) including a **private garden (lawn & small fruit & veg patch)**
- All pathways included:
  - Ingestion of soil & household dust
  - Indoor & outdoor inhalation of fugitive dusts
  - Indoor & outdoor inhalation of vapours
  - Dermal contact with soil & household dust
  - **Ingestion of contaminated homegrown produce and soil attached**

Described in SR3 and updated by SP1010

If no garden is present (flats and managed apartments) pathways can be turned off

Sound science: Defensible decisions

Generic Land Uses: Allotments

- Critical receptor - 0-6 year-old female child
- Exposure duration – 6 years
- Pathways included:
  - Ingestion of soil & household dust
  - Outdoor inhalation of fugitive dusts
  - Outdoor inhalation of vapours
  - Dermal contact with soil & household dust
  - Ingestion of contaminated homegrown produce and soil attached
- Pathways not included:
  - No indoor inhalation pathway - assumes no buildings on site
  - No livestock

Described in SR3 and updated by SP1010

Sound science: Defensible decisions

Generic Land Uses: Commercial

- Critical receptor - Adult female worker (16-65 years)
- Exposure duration – 49 years
- Assumes:
  - indoor working is passive activity (office or retail etc.)
  - 45 hour week (including lunch), 230 days/year for 49 years
  - Three storey office – (pre 1970s) with landscaped areas
- Pathways included:
  - Ingestion of soil & building dust
  - Indoor & outdoor inhalation of fugitive dusts
  - Indoor & outdoor inhalation of vapours
  - Dermal contact with soil & building dust

Described in SR3 and updated by SP1010

Sound science: Defensible decisions

Generic Land Uses: Public Open Spaces (POS)

- POS 1 (POS_{resi}) – grassed area close to housing
  - Track back into the home is included
  - Age classes 1-6 or Age classes 4-9

- POS 2 (POS_{park}) – park/playing field type open space
  - No track back into the home
  - Age class 1-6, based on allotment land use

Described in SP1010

Sound science: Defensible decisions

Summary - GQRA
Including deriving UK GAC

- GQRA = Tier 2
  - Uses GAC
    - Conservative
    - Published / Developed
  - Comparing site concentrations to assessment criteria
- Deriving UK GAC
  - Derived using CLEA model
  - GAC for 6 generic land uses

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Session 6: Introduction to DQRA

Requires specialist knowledge and experience

Introduction to DQRA

- DQRA involves calculating site-specific assessment criteria (SSAC)
  - that remove some of the conservatism present in GAC
  - Uses site-specific inputs and assumptions.
- DQRA should include in-depth reporting and justification of the:
  - Risk assessment tool (CLEA ?) used
  - The site-specific inputs used
- Modelling outputs should also be included in any DQRA report

= LCRM – Stage 1 Tier 3

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Introduction to DQRA

Made to measure suit

Sound science:
Defensible decisions

Detailed Quantitative Risk Assessment: Examples

- Updated toxicological values
  - based on more up-to-date research
- Changes to the inputs to better reflect the land use
  - Changes to the soil type or building type
  - Even defining a completely new land use – prison, school or nursey
    - NB new land use = GQRA if can apply to ANY P S N
    - NB new land use = DQRA if only applies to P S N at your site

Detailed Quantitative Risk Assessment: Examples

- More accurately reflecting the depth of the contamination
- Incorporating more detailed SI data:
  - Bioavailability/bioaccessibility measurements
  - Site-specific vegetable measurements
  - Site-specific soil vapour concentration measurements

Model if you must – measure if you can

Colin Ferguson

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Bioacessibility vs Bioavailability

- Bioaccessible fraction
  - Proportion of contaminant in soil that enters into human gastric and intestinal juices

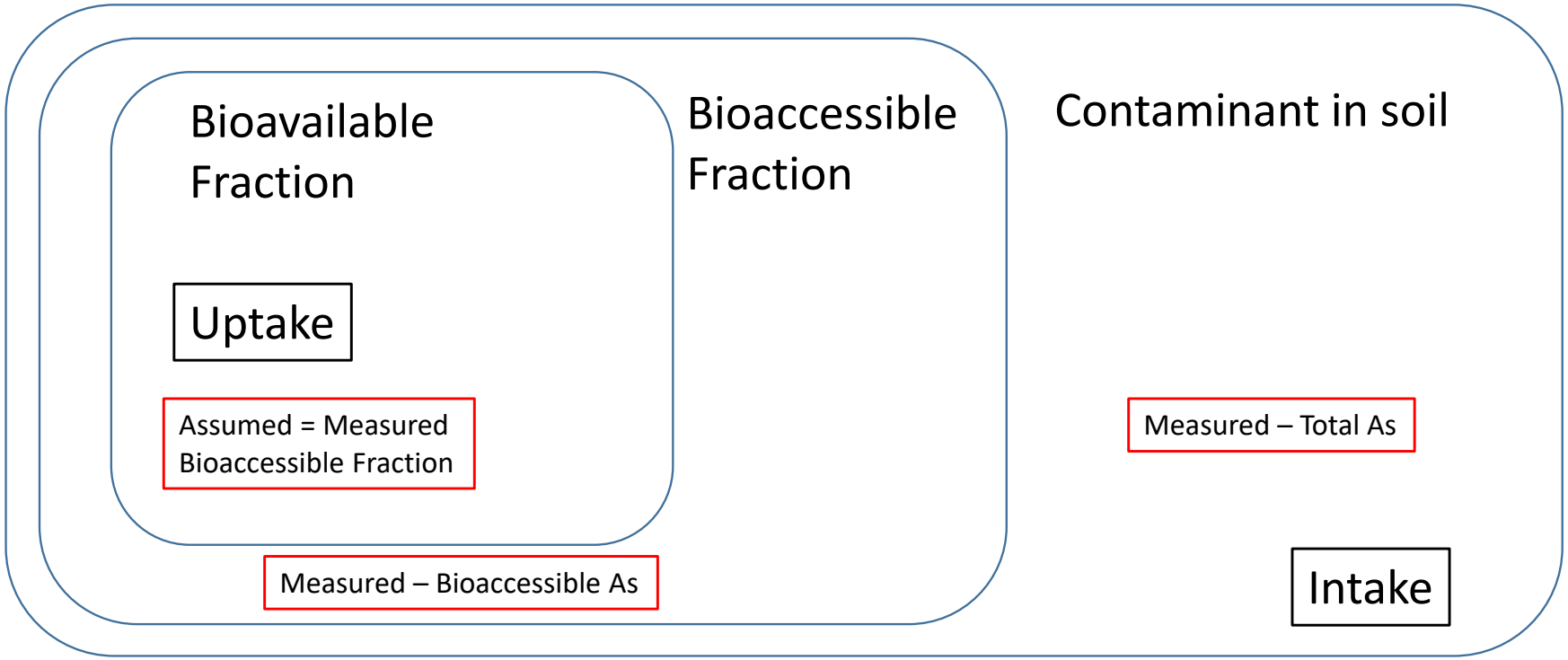
Measured – Bioaccessible Fraction

- Bioavailable fraction
  - Proportion of contaminant in soil that enters systemic circulation and is able to reach the target organ or system

Assumed = Measured Bioaccessible Fraction

Sound science:
Defensible decisions

Bioacessibility vs Bioavailability



Detailed Quantitative Risk Assessment: Risk assessment tools

- Anyone doing DQRA is likely to use a risk assessment tool or model
- In the UK this is likely to be the Contaminated Land Exposure Assessment model (CLEA)
- Other tools are available but do not comply with UK policy by default:
  - BP Risk
  - Csoil
  - RBCA

CLEA:
What is it?

- UK Risk Assessment Tool published by the Environment Agency
  - A non-statutory aid for risk estimation
- Complex Microsoft Excel® spreadsheet
  - Runs in most versions of Excel®
- Free to download and use
- Generally based on the contaminant modelling equations and generic assumptions presented in SR3
  - But also includes the changes and updated in SP1010
- Significant functionality but generally used to calculate generic (both SGVs and C4SLs) and site-specific assessment criteria for soil contaminants

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CLEA:
Version history

- CLEA v1.03 (beta) – released 2008
- CLEA v1.04 – released Jan 2009
- CLEA v1.05 – released Sept 2009
- CLEA v1.06 – released Oct 2009
- CLEA v1.07 – released Aug 2015
  - Issues identified by users
- **CLEA v.071 – released 4th Sept 2015**
  - CLEA v1.05 handbook still applicable

Sound science:
Defensible decisions

Input data available in software

- 4 Library databases
  - Buildings
  - Chemicals
  - Land uses
  - Soils
- Contain standard datasets e.g. different soil types (see SR3)
  - Can add user defined datasets (basic & advanced) or edit existing datasets (advanced)

Parameter Inputs

- Some inputs have hard-coded values for use in deriving GAC but these can be changed for deriving SSAC
  - e.g. receptor characteristics - body weight etc
- Other inputs need to be user defined for deriving both GAC and SSAC
  - e.g. soil organic matter
- Limited changes can be made in generic mode

Take Care

- CLEA Software has significant functionality
- Risk assessment tool is only as good as the user
- Understand the basis of the model
- Software inputs need to reflect site conceptual model
- All inputs should reflect UK policy & good practice
- When changes have been made – press ‘apply settings to the model’ button
- Always check the outputs very carefully
  - units

DQRA:
Risk Evaluation

- Like any risk estimation, a risk evaluation is needed to explain what it all means and what the conclusions are
- For DQRA, the Risk evaluation is likely to be more detailed and discuss:
  - Legislative context
  - Describe and justify the modelling approach
    - Discuss their uncertainties
  - Describe and justify the toxicological values
    - What level of risk to they represent?
  - Describe and justify the site-specific inputs
    - Discuss their uncertainties
- Will include output from the risk assessment tool(s)
  - but this alone does not constitute a risk evaluation
- Present a well documented, robust and informed decision that is supported by the available evidence

Sound science:
Defensible decisions

Practical

- Arsenic concentrations > C4SL
  - C4SL = 37
  - Site concentration = 50
- Is it worth doing bioavailability testing?
  - How low does our bioavailability need to be to be less than what we have on site?
- RwHP scenario

Relative Bioavailability	Result mg/kg	
1		
0.8		
0.6		
0.4		
0.2		

Relative Bioavailability	Assessment Criteria mg/kg	
1	37	
0.8	46	
0.6	59	
0.4	83	
0.2	142	

Site Concentration = 50

If our bioavailability was around 0.7, site concentration < SSAC

Sound science:
Defensible decisions

Summary - HHRA

- Risk estimation
  - Deriving tox values: HCV (TDI/ID); LLTC
  - Calculating exposure based on assumptions about generic land uses
  - Comparing ADE and tox values
- Risk evaluation
- GQRA, GAC, including UK GACs and UK generic land uses
- DQRA, SSAC

CLEA spreadsheet – Quick Look

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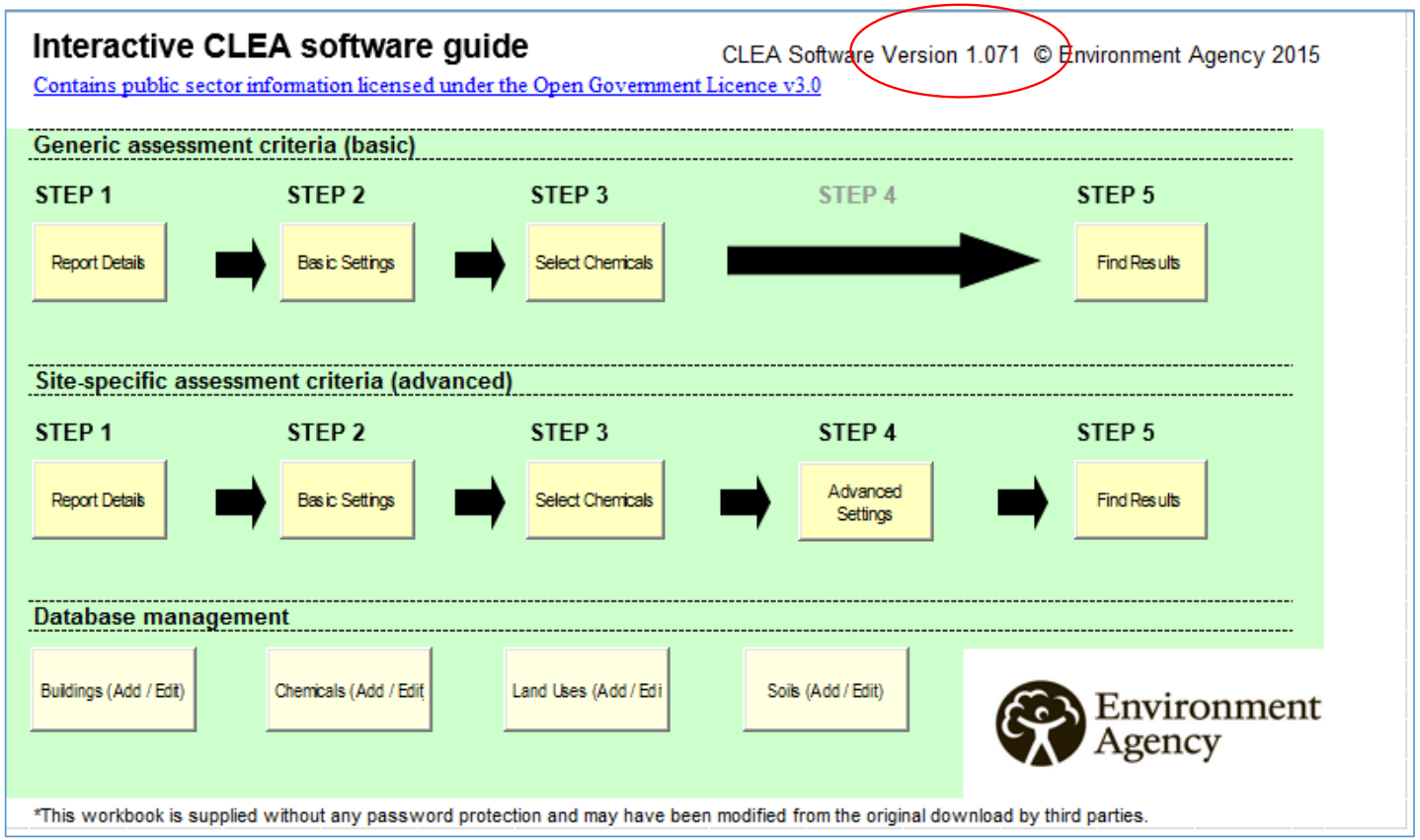
Check version number



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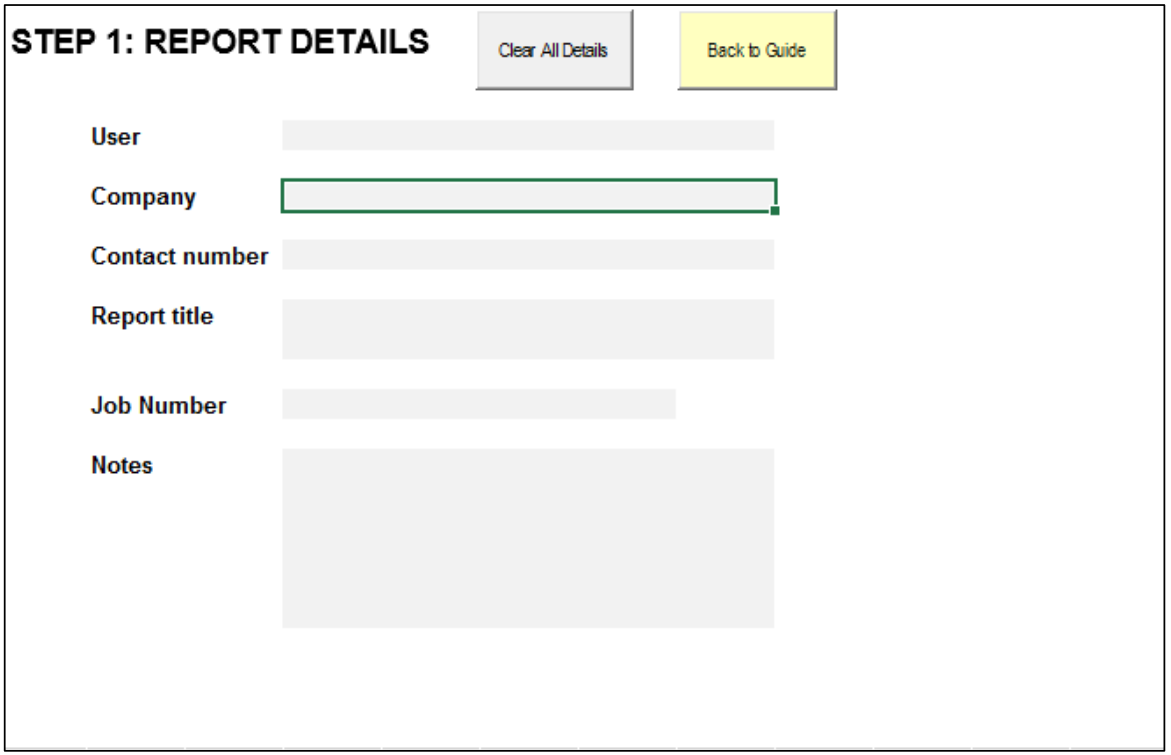
CLEA:
STEP 1 basic details



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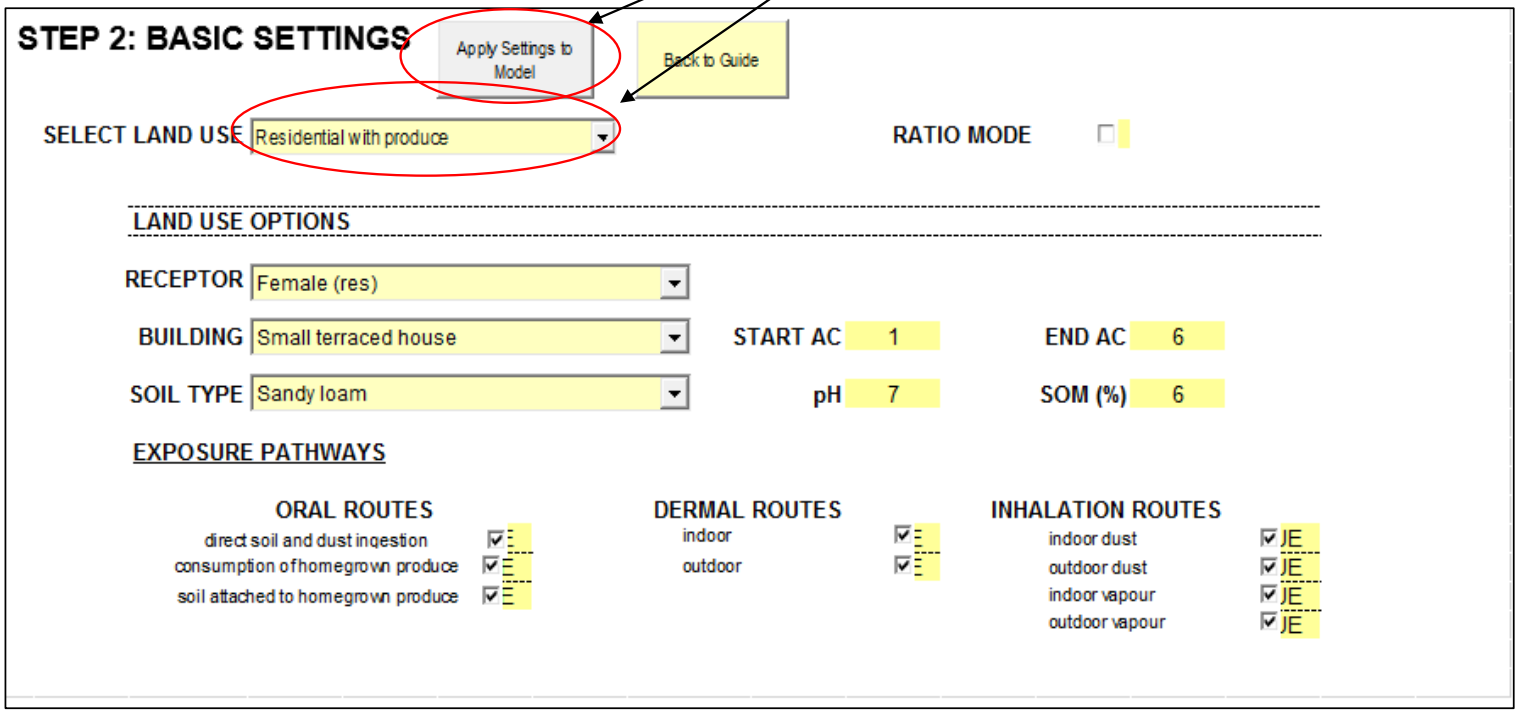
CLEA:
STEP 2 Select generic land use

Select land use and apply to model



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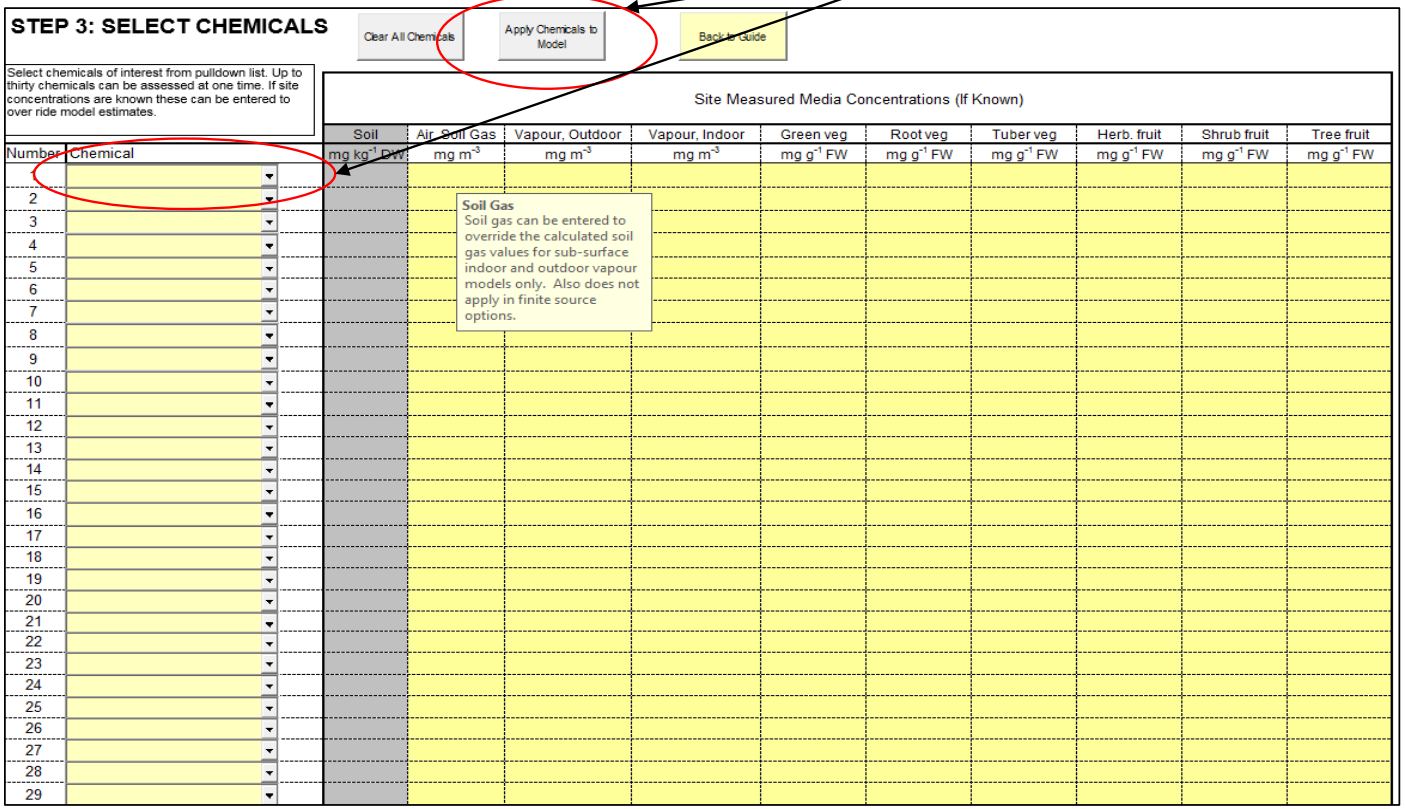
CLEA:
STEP 3 Select contaminants

Select contaminant(s) and apply to model

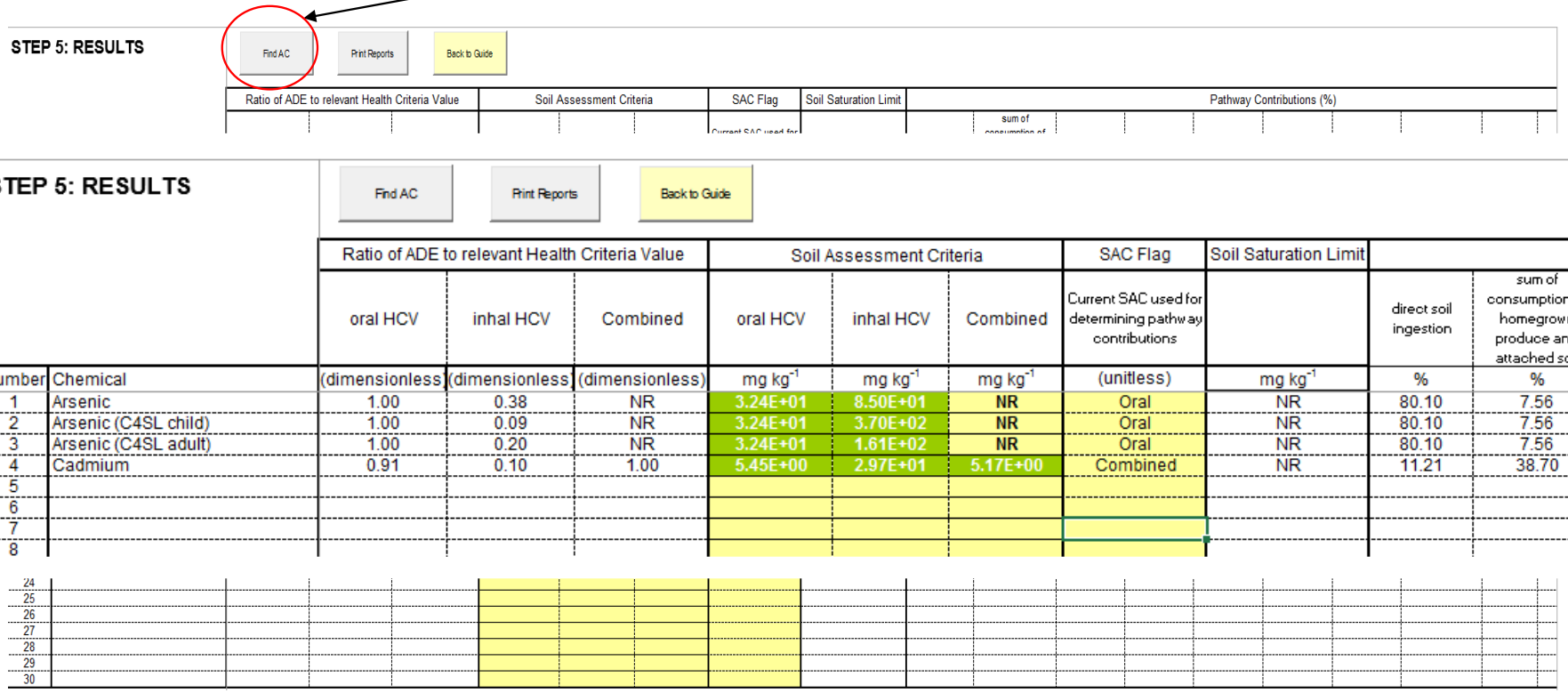


Note: limited chemical data (SGV & C4SL data only). For any other contaminant, all relevant data needs to be added into chemical database prior to Step 3

Sound science:
Defensible decisions

CLEA:
STEP 5 Calculate assessment criteria

Use ‘Find AC’ to generate results



STEP 5: RESULTS

Find AC | Print Reports | Back to Guide

		Ratio of ADE to relevant Health Criteria Value			Soil Assessment Criteria			SAC Flag	Soil Saturation Limit						
		oral HCV	inhal HCV	Combined	oral HCV	inhal HCV	Combined	Current SAC used for determining pathway contributions		direct soil ingestion	sum of consumption of homegrown produce and attached soil	dermal contact (indoor)	dermal contact (outdoor)		
Number	Chemical	(dimensionless)	(dimensionless)	(dimensionless)	mg kg^{-1}	mg kg^{-1}	mg kg^{-1}	(unitless)	mg kg^{-1}	%	%	%	%		
1	Arsenic	1.00	0.38	NR	3.24E+01	8.50E+01	NR	Oral	NR	80.10	7.56	0.45	11.90		
2	Arsenic (C4SL child)	1.00	0.09	NR	3.24E+01	3.70E+02	NR	Oral	NR	80.10	7.56	0.45	11.90		
3	Arsenic (C4SL adult)	1.00	0.20	NR	3.24E+01	1.61E+02	NR	Oral	NR	80.10	7.56	0.45	11.90		
4	Cadmium	0.91	0.10	1.00	5.45E+00	2.97E+01	5.17E+00	Combined	NR	11.21	38.70	0.00	0.06		
5															
6															
7															
8															

Sound science:
Defensible decisions

CLEA:
STEP 5 Print output

Print Reports

STEP 5: RESULTS

Find AC | Print Reports | Back to Guide

		Ratio of ADE to relevant Health Criteria Value			Soil Assessment Criteria			SAC Flag
		oral HCV	inhal HCV	Combined	oral HCV	inhal HCV	Combined	Current SAC used I determining pathw contributions
umber	Chemical	(dimensionless)	(dimensionless)	(dimensionless)	mg kg^{-1}	mg kg^{-1}	mg kg^{-1}	(unitless)
1	Arsenic	1.00	0.38	NR	3.24E+01	8.50E+01	NR	Oral
2	Arsenic (C4SL child)	1.00	0.09	NR	3.24E+01	3.70E+02	NR	Oral
3	Arsenic (C4SL adult)	1.00	0.20	NR	3.24E+01	1.61E+02	NR	Oral
4	Cadmium	0.91	0.10	1.00	5.45E+00	2.97E+01	5.17E+00	Combined
5								
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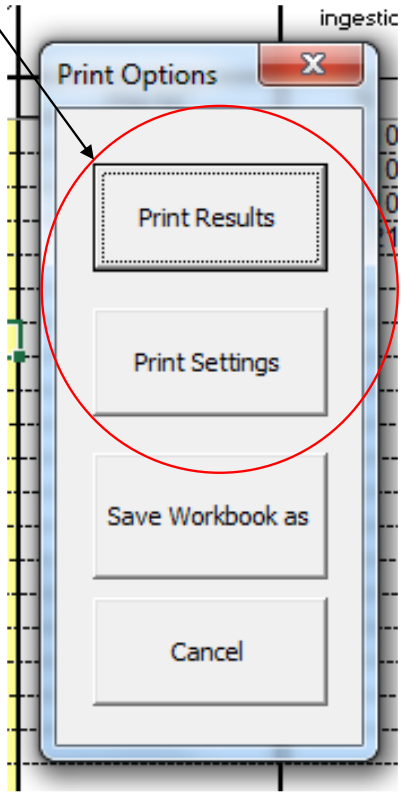

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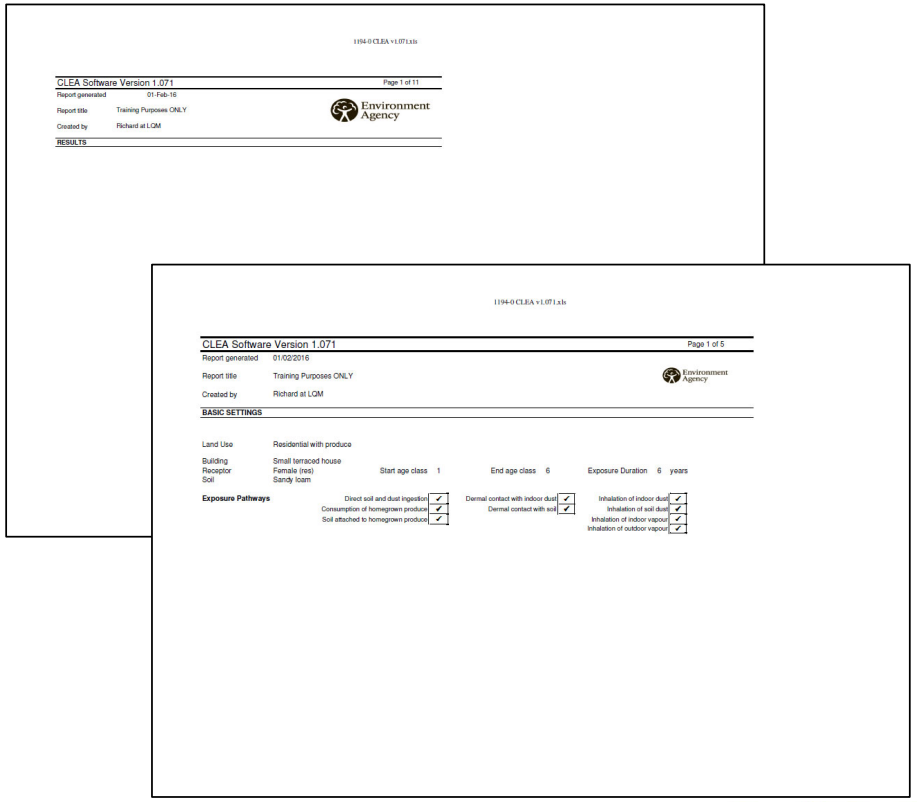
Defensible decisions

CLEA:
Output reports

- There are two output reports
  - You need both to understand the inputs and the outputs
- Results report (11 pages)
  - Contains the chemical inputs and the outputs, including the assessment criteria
- Settings report (5 pages)
  - Contains all the remaining inputs for the land use, receptor, building and soil type
- The reports have no title and look almost identical except for the **number of pages**



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CLEA output - Results

- Correct transcription of results?

Environment Agency

	Assessment Criterion (mg kg^{-1})			Ratio of ADE to HCV			Saturation Limit (mg kg^{-1})	50% rule?		Apply Top 2 Approach to Produce Group							
	oral	Inhalation	combined	oral	Inhalation	combined		Oral	Inhal	Top Two applied?	Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit	
Arsenic (C4SL child)	3.71E+01	5.26E+02	NR	#VALUE!	0.07	#VALUE!	NR	No	No	Yes	Yes	No	No	No	No	Yes	
Arsenic (C4SL child)	4.55E+01	5.26E+02	NR	#VALUE!	0.09	#VALUE!	NR	No	No	Yes	Yes	No	No	No	No	Yes	
Arsenic (C4SL child)	5.89E+01	5.26E+02	NR	#VALUE!	0.11	#VALUE!	NR	No	No	Yes	Yes	No	No	No	No	Yes	
Arsenic (C4SL child)	8.33E+01	5.26E+02	NR	#VALUE!	0.16	#VALUE!	NR	No	No	Yes	Yes	No	No	No	No	Yes	
Arsenic (C4SL child)	1.42E+02	5.26E+02	NR	#VALUE!	0.27	#VALUE!	NR	No	No	Yes	Yes	No	No	No	No	Yes	

Average Daily Exposure (mg kg^{-1} bw day^{-1})							Distribution by Pathway (%)							
Direct soil ingestion	Consumption of homegrown produce and attached soil	Dermal contact with soil and dust	Inhalation of dust	Inhalation of vapour	Background (oral)	Background (inhalation)	Direct soil ingestion	Consumption of homegrown produce and attached soil	Dermal contact with soil and dust	Inhalation of dust	Inhalation of vapour (indoor)	Inhalation of vapour (outdoor)	Background (oral)	Background (inhalation)

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Course summary

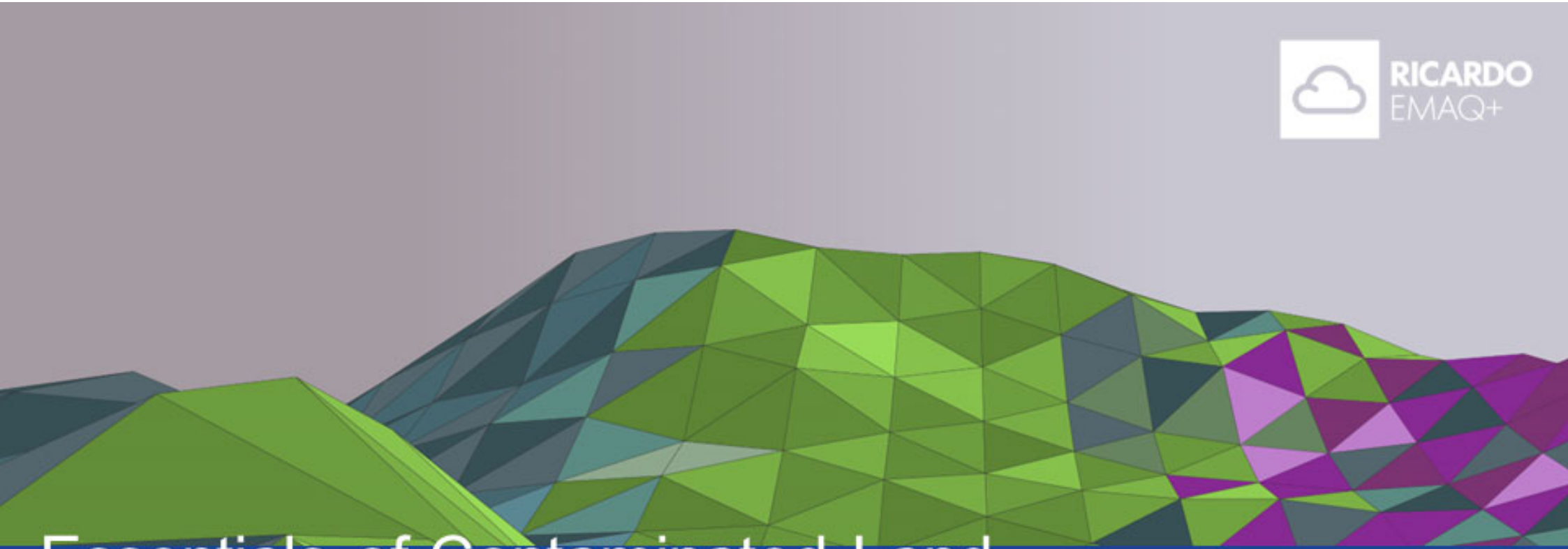
- Basics of CLEA spreadsheet
- Generic quantitative HHRA
- Detailed quantitative HHRA
- Toxicology
  - Choice of tox values
- Exposure assessment
  - Calculated ADE for each pathway
  - Compare tox values with ADE
- Risk evaluation

Risk Estimation

Read:

- SR2
- SR3
- SP1010

Sound science: Defensible decisions



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Essentials of Contaminated Land Management