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## Guidance on the attribution of cause and effect in ecological risk assessment

Science report SC070009/SR2e

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Steve Killeen

**Head of Science**

# Executive summary

This document provides guidance on decision-making activities at Tier 3 (the final tier) of the Ecological Risk Assessment framework for contaminated soils. This tier requires risk assessors to consider whether the adverse effects observed that signify harm at the site under investigation can be attributed to the contaminants measured in the soil.

The guidance sets out a structured approach for assessing the attribution of the cause to the effect, referred to as Hill's Causal Criteria (Hill, 1965), and also proposes a range of other options more commonly used in the aquatic environment that could potentially be developed for soils.

The structured consideration of cause-effect attribution is intended to allow sites where the harm in the ecosystem is due to a reason other than chemical contamination to exit the framework at Tier 3, or to increase the strength of the evidence where harm is likely to be attributable to those contaminants.

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# 1 Introduction

## 1.1 The purpose of this document

This document provides guidance when making decisions as to whether the adverse effects observed that signify harm (See Section 1.3) at the site under investigation can be attributed to the contaminants measured in the soil and therefore to the source of that contamination.

Prior to reaching this decision, the risk assessor will have moved through all of the previous tiers of the Ecological Risk Assessment (ERA) framework, which will have involved the development of a Conceptual Site Model (CSM), soil sampling and the measurement of the contaminants of potential concern at Tier 1 and the collection of evidence for harm using ecological surveys and /or bioassays at Tier 2.

The guidance in this document forms the final stage of a risk assessment of potentially contaminated land under Part 2A of the Environmental Protection Act 1990. The consideration of whether to attribute the adverse effects observed to the contaminants of concern is the activity required at Tier 3 of the ERA framework. It is intended to allow sites where the harm to the ecosystem is due to a reason other than chemical contamination to exit the framework, but also to increase the strength of the evidence where harm is likely to be attributable to those contaminants.

## 1.2 How this document fits into the Ecological Risk Assessment Framework

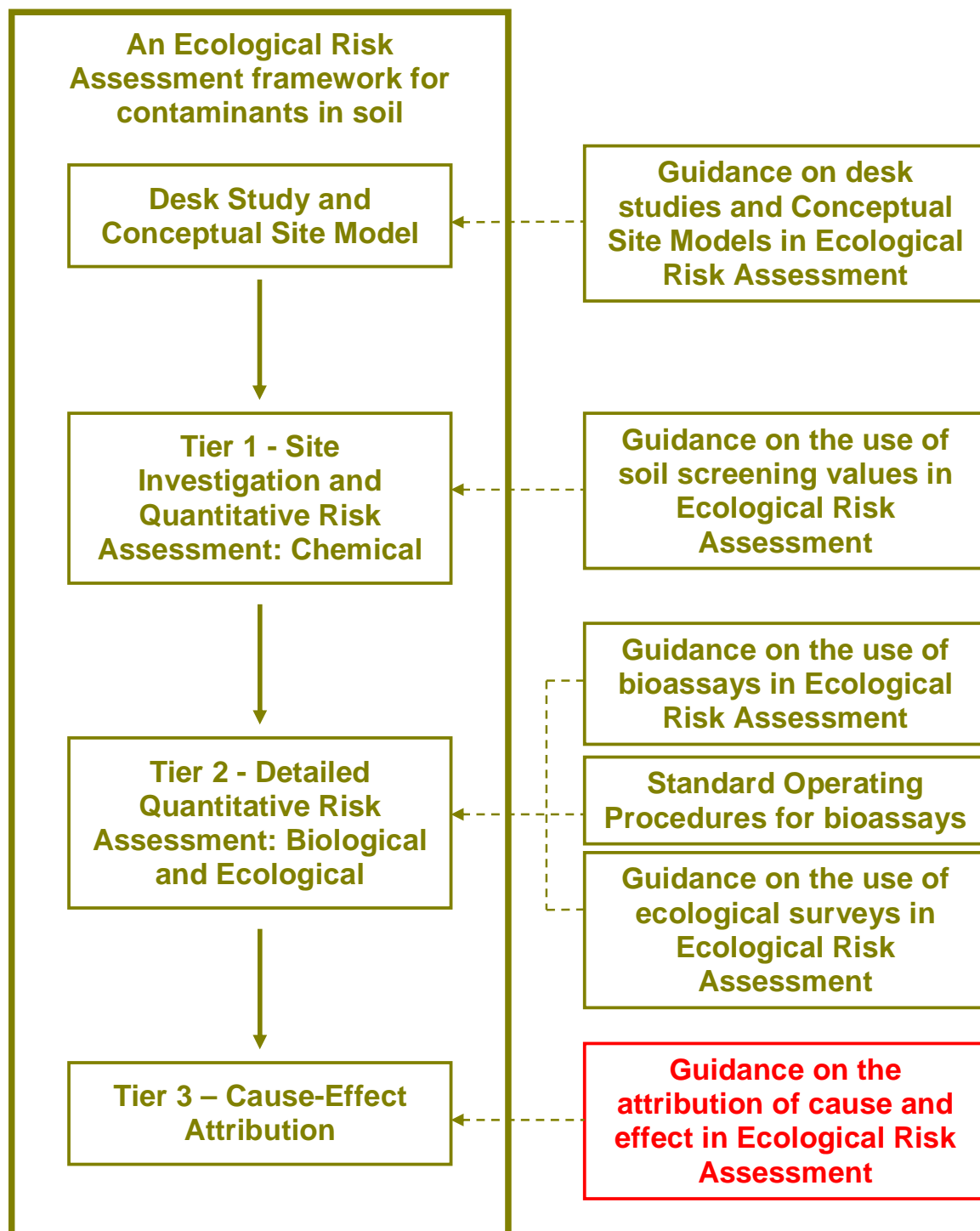
This document is one of six guidance documents that support the ERA framework.

The purpose of this guidance is to support activities in Tier 3 of the ERA – known as ‘Cause-Effect Attribution’.

The position of this document (shown in red) within the overall ERA framework is summarised in the flow chart shown in Figure 1.1.

This report and the guidance documents in the series refer to each other in the following manner (full details can also be found in the reference list):

- This report is referred to as ERA 2e (Guidance on the attribution of cause and effect).
- The overarching Ecological risk assessment framework for contaminants in soil is referred to as ERA 1 (Framework document).
- The Guidance on desk studies and Conceptual Site Models in Ecological Risk Assessment is referred to as ERA 2a (Guidance on desk studies and CSM).
- The Guidance on the use of Soil Screening Values in Ecological Risk Assessment is referred to as ERA 2b (Guidance on the use of SSVs).
- The Guidance on the use of Bioassays in Ecological Risk Assessment is referred to as ERA 2c (Guidance on the use of bioassays).
- The Guidance on the use of Ecological Surveys in Ecological Risk Assessment is referred to as ERA 2d (Guidance on the use of ecological surveys).
- The Standard Operating Procedures for Bioassays is referred to as ERA 3 (SOPs for bioassays).



**Figure 1.1** Position of this document within the overall ERA framework

## 1.3 Potential regulatory drivers for Ecological Risk Assessment

The primary driver is Part 2A of the Environmental Protection Act 1990. Other potential regulatory drivers include the Habitats Directive and the planning regime.

### 1.3.1 Part 2A of the Environmental Protection Act

Section 57 of Part 2A of the Environmental Protection Act 1990 (EPA 1990) introduced a new statutory regime for the identification and control of contaminated land in England and Wales (DEFRA 2006, WAG 2006 and Scottish Executive 2006). The Act states that:

*‘Contaminated land’ is any land which appears to the local authority in whose area it is situated to be in such a condition, by reason of substances in, on or under the land, that –*

*significant harm is being caused or there is a significant possibility of such harm being caused; or pollution of controlled waters is being, or is likely to be, caused...*

where ‘harm’ is defined as:

*harm to the health of living organisms or other interference with the ecological systems of which they form a part, and in the case of man includes harm to his property.*

‘Ecological harm’ within Part 2A is confined to specified receptors as set out in Table A of the Statutory Guidance (DEFRA 2006, WAG 2006 and SE 2006). In summary, these are:

- any ecological system, or living organism forming part of such a system, within a location which is:
  - a site of special scientific interest (SSSI) notified under section 28 of the Wildlife and Countryside Act 1981;
  - a national nature reserve (declared under section 35 of the above act);
  - a marine nature reserve (designated under section 36 of the above act);
  - an area of special protection for birds (under section 3 of the above act);
  - any habitat or site afforded policy protection under paragraph 6 of Planning Policy Statement (PPS 9) on nature conservation;
  - any nature reserve established under section 21 of the National Parks and Access to the Countryside Act 1949;
  - any European site within the meaning of regulation 10 of the Conservation (Natural habitats etc) Regulations 1994;
  - any candidate Special Areas of Conservation or potential Special Areas of Conservation given equivalent protection.

### 1.3.2 Habitats Directive

Regulation 3 of the Conservation Regulations 1994 (commonly known as the Habitats Regulations) implements the requirements of the European Habitats Directive 92/43/EEC in Great Britain. It also secures the protection of areas classified under the Wild Birds Directive 79/409/EEC.



The Environment Agency is the competent authority (in England and Wales) for these regulations. As such, it applies the regulations when considering all applications for authorisations, permissions, permits, consents and environmental licences and for all relevant Environment Agency policy and operational activities.

A risk assessment process is initiated in situations where an application under the UK system of land use planning or a review of permits, licences, etc. is likely to impact on sites protected under the regulations. There are four stages to the risk assessment:

- identifying relevance;
- likely significant effect;
- identifying adverse impacts;
- implementing any changes.

The ERA framework will be a useful aid in this process.

### 1.3.3 Planning

Planning Policy Statement (PPS) 23: *Planning and Pollution Control* states that:

*Land contamination, or the possibility of it, is a material planning consideration in the preparation of development plan documents and in taking decisions on individual planning applications (ODPM 2004).*

The remediation of contaminated land through the planning process should secure the removal of unacceptable risk and make the site suitable for its new use. Following redevelopment, the land should not be capable, as a minimum, of being determined as contaminated land under Part 2A of the Environmental Protection Act 1990.

Development plans and decisions on individual planning applications should take into account the potential sensitivity of the area to adverse effects from pollution, including nature conservation interests such as:

- SSSIs;
- National Parks;
- Areas of Outstanding Natural Beauty (AONBs);
- Special Areas of Conservation (SACs);
- Special Protection Areas (SPAs);
- wetlands of international importance (RAMSAR sites).

Where appropriate, soil screening values and the wider ERA framework can be used to assess the possible risks to nature conservation interests when potentially polluting activities are proposed. Where necessary, they can also be applied to the assessment and remediation of historic contamination.

## 1.4 Report Structure

Section 2 gives the approaches that can be used to assess, measure or strengthen the association between the observed effects and the contaminants of concern.

Section 3 outlines Hill's Causal Criteria, which is the recommended framework for considering and making decisions as to whether the observed effects can be attributed to the contaminants of concern and the source of contamination.

# 2 Attributing impacts to chemical contaminants

## 2.1 General approach

The question posed at the end of the Ecological Risk Assessment (ERA) process is whether it is possible to attribute the impacts seen to specific stressors. It is necessary to understand the link between stressors and impacts to ensure that any subsequent measures to reduce risk focus on the main stressors. Under Part 2A of the Environmental Protection Act 1990, the stressors under risk assessment are chemical contaminants.

It is important to be realistic about the level of proof that can be gathered about the role of a contaminant or group of contaminants in causing environmental impact. The current state of the science does not yet permit a mechanistic approach such as that developed for identifying toxicants responsible for whole effluent toxicity in discharges to receiving waters (US EPA 1991, 1993a, 1993b). Instead, the Environment Agency advocates the use of a checklist based on Hill's causal criteria (Hill 1965) for:

- assessing the available evidence;
- identifying key gaps;
- informing decisions about whether or not chemical contaminants can reasonably be held responsible for impacts.

In future, the development of Toxicity Identification Evaluation (TIE) approaches and diagnostic assays similar to those that have been used in the aquatic environment may be an area for development. As such, they are briefly described in this document for additional information (see section 2.3).

## 2.2 A framework for addressing cause and effect

Hill's causal criteria are used in epidemiological studies. They offer an approach for establishing the strength of causal relationships between environmental stressors (in this case chemical contaminants) and biological responses (based on ecological survey and/or bioassays).

Essentially, Hill's causal criteria set out a series of questions that the risk assessor should consider.

- If a large proportion of the more heavily weighted criteria are satisfied, the assessor can be reasonably confident there is sufficient association between the stressor(s) and biological impact.
- If there is contra-evidence (e.g. there is an inverse association between chemical contamination and biological impact) then it is unlikely that such a link will be established and attention should shift toward other possible causes.
- If evidence is equivocal (e.g. some lines of evidence point to a link between contamination and biological impacts while others do not), further work may be needed to fill critical data gaps.

This guidance sets out Hill's Causal Criteria for use at Tier 3 of an ERA. It also suggests:

- how much weight might be applied to different criteria for the purposes of ERA;
- the type of analysis a risk assessor could undertake;
- the outcome expected if the criterion is met.

It is only intended to give the decision-making process a structure. It should not be used as a formal scoring scheme or as a replacement for proper review and judgement by all the stakeholders (including the enforcing authority, the relevant conservation organisation and the site owner).

The starting point for a decision should be the data generated during the earlier tiers of the ERA. The decision-making process up to this point should have involved all the stakeholders who should therefore be familiar with both the data and the any gaps and uncertainties still outstanding. The aim is to reach consensus, based on the available evidence, as to the overall likelihood that the observed effects are being caused by the contaminants.

Additional work should only be proposed where:

- it will help address specific outstanding questions;
- the evidence is so equivocal that a defensible decision cannot be reached.

## 2.3 Diagnostic tools

### 2.3.1 Toxicity Identification Evaluations (TIEs)

TIEs have been used extensively in North America to support the introduction of whole effluent toxicity (WET) testing as a means of regulating point source discharges to water (US EPA, 1991, 1993a, 1993b) or to diagnose unexplained impacts. The WET approach bases control measures on assessments of effluent toxicity and TIEs are used to identify the components responsible for toxicity so that appropriate steps can be taken to reduce the risk.

In principle, the TIE approach involves:

- manipulation of an environmental sample to remove specific contaminants (e.g. sequestration of metals, purging of volatile solvents);
- use of bioassays to compare toxicity in the treated sample to that seen in the original sample.

A reduction in toxicity is taken to indicate a role for the substance in question (more usually, class of substances) in the original toxicity.

Most experience of TIEs has been with aquatic media, but recently published guidance from the US Environmental Protection Agency (US EPA) outlines current understanding and TIE methods for interstitial waters and whole sediment (US EPA 2007).

Using the TIE approach for soil would present new challenges. It would require modification of existing procedures and development of new ones. However, examples of sediment TIE might be helpful in developing methods for soils. Some examples are given below.

- Kosian et al. (1998) adapted existing TIE methods for fractionated extracts of sediment pore water to identify the compounds responsible for photo-induced toxicity in sediment samples.
- Carr et al. (2001) used TIE methods on pore waters extracted from marine

sediments suspected of contamination with munitions.

- Araújo et al. (2006) used pore water and elutriate TIE methods to help identify the cause of toxicity in highly contaminated sediment from a water reservoir in Brazil.
- Amweg and Weston (2007) tested the addition of piperonyl butoxide as a TIE tool for identifying pyrethroid insecticide in whole sediment testing.

If a TIE approach is considered for use in an ERA, the bioassay chosen must:

- be sensitive to the toxicants present;
- give a positive response in the unaltered sample.

However, it is not necessary for the bioassay chosen to use a species or endpoint that is closely related to the assessment endpoints identified in the desk study and Conceptual Site Model because the purpose of the tests performed within a TIE are simply as a comparison made before and after manipulation and as such need not relate to the ecology at the site under investigation.

### 2.3.2 Diagnostic assays

There has recently been much interest in the development of bioassays to assess the hazards posed by contaminants in water and soil. Most of these bioassays have been developed as 'broad spectrum' assays that respond to chemicals with a wide range of modes of action and physico-chemical properties. However, some biomarker or genomic assays may have applications in a more diagnostic role when they respond to a narrow range of contaminants (e.g. a class of substances with a particular mode of action). Such assays have been used to diagnose *exposure* in soil (e.g. metallothionein induction in response to metal exposure).

The Environment Agency is not aware of diagnostic assays being used in this way for diagnosing *impacts* in soil but, in principle, they could be. This is an area warranting further investigation.

### 3 The use of Hill's causal criteria within ERA

| Criterion                      | What does this mean?   | Suggested 'weight' in decision-making | Suggested analyses   | What to look for  |
|--------------------------------|--|---------------------------------------|--|---|
| (a) Strength of association    | There should be a strong relationship between the presence of a stressor and a biological change, e.g. in the structure of an assemblage, change in population size or decline in favourable status. | +++                                   | Techniques such as regression applied to plots of effect versus contaminant levels allow measured levels of contaminants to be related to the magnitude of biological response.<br>Principle Components Analysis (PCA) can help identify factors that are more strongly associated with adverse impacts. | Positive correlation in regression. Complete elimination of sensitive taxa or large shifts from sensitive to tolerant taxa. In PCA, contaminants exceeding soil screening values (SSVs) are highlighted as principle components associated with biological differences. |
| (b) Consistency of association | The biological response to a stressor should be consistent across sites and between investigations.  | ++                                    | Evidence from other locations which are subject to the same contaminants as those found here.  | The presence of this stressor gives rise to similar impacts at other sites and there is agreement between different investigators. Mitigation at such sites restores biological quality.  |
| (c) Specificity                | Does <b>only</b> the potential cause lead to the effect?<br>Does the potential cause lead <b>only</b> to the effect?   | +                                     | Association of chemical and biological data.<br>PCA may help identify other factors contributing to impacts.   | Many contaminants are likely to lead to similar effects so this may not be a useful criterion. However, if particular concentrations of a contaminant always cause a particular effect (e.g. elimination of a sensitive species) this may be useful evidence.           |
| (d) Temporality                | Does the cause precede the effect?   | +                                     | Comparisons of biological impacts over time, especially if the survey includes the period prior to the contamination.  | This may be difficult to demonstrate during routine field monitoring, but may be possible when spatial (e.g. upstream/downstream) analyses can be performed or where there is evidence of biological status <b>before</b> contamination occurred.                       |

| Criterion        | What does this mean?  | Suggested 'weight' in decision-making | Suggested analyses  | What to look for  |
|------------------|---|---------------------------------------|---|---|
| (e) Plausibility | There should be a credible mechanistic explanation for observed responses.  | ++                                    | <ol style="list-style-type: none"> <li>1. Scientific literature</li> <li>2. Credible effects</li> <li>3. Identity of missing species</li> <li>4. Diagnostic assays</li> <li>5. TIE</li> </ol> | <ol style="list-style-type: none"> <li>1. There should be a strong scientific basis to link the observed effects with the contaminants</li> <li>2. The effects and the range of species affected should be consistent with what is known of the contaminant(s) present. For example, some herbicides give rise to characteristic symptoms in sensitive plant species.</li> <li>3. Some species are particularly sensitive to certain contaminants, e.g. insects to insecticides, and therefore their absence is notable.</li> <li>4. Certain assays respond only to certain classes of toxicant, e.g. metallothionein induction in response to metal exposure.</li> <li>5. Manipulation of environmental samples to remove or sequester specific groups of contaminants eliminates or reduces toxicity implicating these contaminants in the observed impacts.</li> </ol> |
| (f) Coherence    | Biological responses should agree with current knowledge about the effects of contaminants on particular species. | ++                                    | See (e) and (i)   | Reinforces inferences about cause and effect relationship.  |
| (g) Analogy      | Contaminants with similar structures and mechanisms of effect should produce the                                  | +                                     | Evidence from other locations subject to similar contaminants (same chemical classes with   | Similar effects have been seen elsewhere following exposure to related substances. For example, if the  |

| Criterion               | What does this mean?   | Suggested 'weight' in decision-making | Suggested analyses  | What to look for   |
|-------------------------|--|---------------------------------------|---|--|
|                         | same types of effects on assemblages.  |                                       | comparable modes of action) as those found here.  | range of species affected is consistent with organophosphorus insecticide exposure. Reinforces inferences about cause and effect relationship.   |
| (h) Ecological gradient | A concentration–response gradient in which decreasing concentrations of a contaminant are associated with a decreasing level of effect.  | ++                                    | Regression<br>Spatial mapping   | Lower levels of contaminants lead to reduced biological impact or, at least, impact diminishes with increasing distance from contaminant source. Reinforces inferences about cause and effect relationship.                        |
| (i) Experimentation     | Direct experimental evidence of the causal relationship between the stressor and the observed effect on an assemblage gained from ecosystem manipulation, or microcosm and mesocosm studies. | ++                                    | Dose–response experiments using species relevant to the assessment endpoints identified in the desk study and CSM.<br><br>TIE | Strengthens belief in associations observed during Tier 2, especially if reliance was placed on an ecological survey.<br><br>Demonstrates a reduction in the observed effect when the contaminant is removed by TIE manipulations. |

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# List of abbreviations

|        |  |
|--------|--|
| AONB   | Area of Outstanding Natural Beauty                 |
| CSM    | Conceptual Site Model                              |
| DEFRA  | Department for Environment, Food and Rural Affairs |
| EPA    | Environmental Protection Act [1990]                |
| ERA    | Ecological Risk Assessment                         |
| MNR    | Marine Nature Reserve                              |
| NNR    | National Nature Reserve                            |
| PCA    | Principle Component Analysis                       |
| SAC    | Special Area of Conservation                       |
| SE     | Scottish Executive                                 |
| SPA    | Special Protection Area                            |
| SSSI   | Site of Special Scientific Interest                |
| SSV    | Soil Screening Value                               |
| TIE    | Toxicity Identification and Evaluation             |
| US EPA | US Environmental Protection Agency                 |
| WAG    | Welsh Assembly Government                          |
| WET    | Whole Effluent Toxicity                            |

# Glossary

|                                  |  |
|----------------------------------|--|
| Adverse effect                   | An impairment of biological functions or description of ecological processes that results in unfavourable changes in an ecological system.   |
| Assessment Endpoint              | An explicit expression of the environmental resource that is to be protected. It is defined operationally in structural terms (e.g. a population of a particular species) or functionality (e.g. supporting processes that are typical of a particular habitat).   |
| Bioassay                         | A test to measure the toxicity of a contaminant or environmental sample by exposing a specific organism and measuring a life-cycle parameter (e.g. survival, reproduction, development, growth).   |
| Conceptual Site Model (CSM)      | A representation of the characteristics of the site in a diagrammatic or written form that shows the possible relationships between contaminants, pathways and receptors.  |
| Contaminant                      | In general terms, a substance that is in, on or under the land and that has the potential to cause harm or to cause pollution of controlled waters. Within ecological risk assessment the specific emphasis will be on contaminants that have the potential to cause harm to ecological receptors.                                     |
| Contaminant of Potential Concern | A contaminant identified as being present or likely to be present at the study site, included in the CSM and agreed to be of concern by all the stakeholders.  |
| Desk Study                       | Interpretation of historical, archival and current information to establish where previous activities were located, and where areas or zones that contain distinct or different types of contamination are expected to occur, and to understand the environmental setting of the site in terms of pathways and receptors.              |
| Ecological Receptor              | In general terms, [a receptor is] something that could be adversely affected by a contaminant, such as people, an ecological system, property or a water body. Within Ecological Risk Assessment, an ecological receptor will be an organism, population, or community that might be affected by exposure to a contaminant of concern. |
| Ecological risk assessment       | Evaluation of the likelihood of adverse effects on organisms, populations and communities from chemicals present in the environment.   |
| Ecological Survey                | Surveys of habitats and species; a method of gathering spatial and/or temporal ecological data on a site.  |
| Ecosystem                        | An ecological community of plants and animals together with its physical environment or habitat, regarded as a unit.   |
| Effect                           | A change in the state of an organism or other ecological component, resulting from exposure to a chemical or other stressor.   |

|                               |   |
|-------------------------------|---|
| Endpoint                      | The biological or ecological entity or variable being measured or assessed (see measurement endpoint and assessment endpoint).  |
| Exposure                      | The amount of chemical available for intake by a target population at a particular site. Exposure is quantified as the concentration of the chemical in the medium (e.g. air, water, food) integrated over the duration of the exposure. It is expressed in terms of mass of substance per kg of soil, unit volume of air or litre of water (e.g. mg/kg, mg/m <sup>-3</sup> or mg/l). |
| Habitat                       | A place in which a particular plant or animal lives. Often used in the wider sense referring to major assemblages of plants and animals found together.   |
| Hazard                        | The intrinsic danger of a substance or process.   |
| Measurement end-point         | Quantifiable indicators that relate directly to assessment end-points, for example, viable offspring per female bird.   |
| Organism                      | An individual plant or animal.  |
| Pathway                       | A route or means by which a receptor could be, or is exposed to, or affected by a contaminant.  |
| Pollutant linkage             | The relationship between a contaminant, pathway and receptor.   |
| Population                    | A group of individuals of the same species interacting within a given habitat.  |
| Protected location            | A location protected by a nature conservation designation of a type listed in Table A of the Statutory Guidance on Contaminated Land.   |
| Receptor of Potential Concern | An ecological receptor identified as present or likely to be present at the study site, included in the CSM and agreed to be of concern by all the stakeholders.  |
| Remediation                   | Action taken to prevent or minimise, or remedy or mitigate the effects of any identified unacceptable risks.  |
| Species of Special Interest   | A species within a protected location that, through discussion with relevant conservation organisations has been established as being of special interest.  |
| Stressor                      | A physical, chemical or biological agent that can induce an adverse response in organisms or other components of ecosystems.  |
| Terrestrial                   | Living or growing on land.  |
| Transport and fate            | A description of how a chemical is carried through the environment. This may include transport through biological as well as physical parts of the environment.   |
| Trophic level                 | Broad class of organisms within an ecosystem characterised by mode of food supply.  |
| Toxicity test                 | The means by which the toxicity of a chemical or other test material is determined. A toxicity test is used to measure the degree of response produced by exposure to a specific level of stimulus.   |

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