



# End-of-waste and by-product hazard and risk assessment

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# 1. Introduction

## 1.1. Definition of waste

The Waste Framework Directive provides the definition for when a material is a waste, when it ceases to be waste and when it is a by-product. Defra (2012) provides guidance on the legal definition of waste and its application.

Article 6 of the Waste Framework Directive 2008 sets out that a material ceases to be waste when:

- the waste has been converted to a distinct and marketable product
- the waste-derived product can be used in exactly the same way as a non-waste material
- the waste-derived product can be stored and used with a 'no worse' environmental effect compared with the non-waste material it is intended to replace

Article 5 of the Waste Framework Directive 2008 sets out the criteria for a production residue to meet the by-product test:

- further use is certain
- the material can be used directly without any further processing other than normal industrial practice
- the material is produced as an integral part of the production process
- further use is lawful, that is, the material fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts

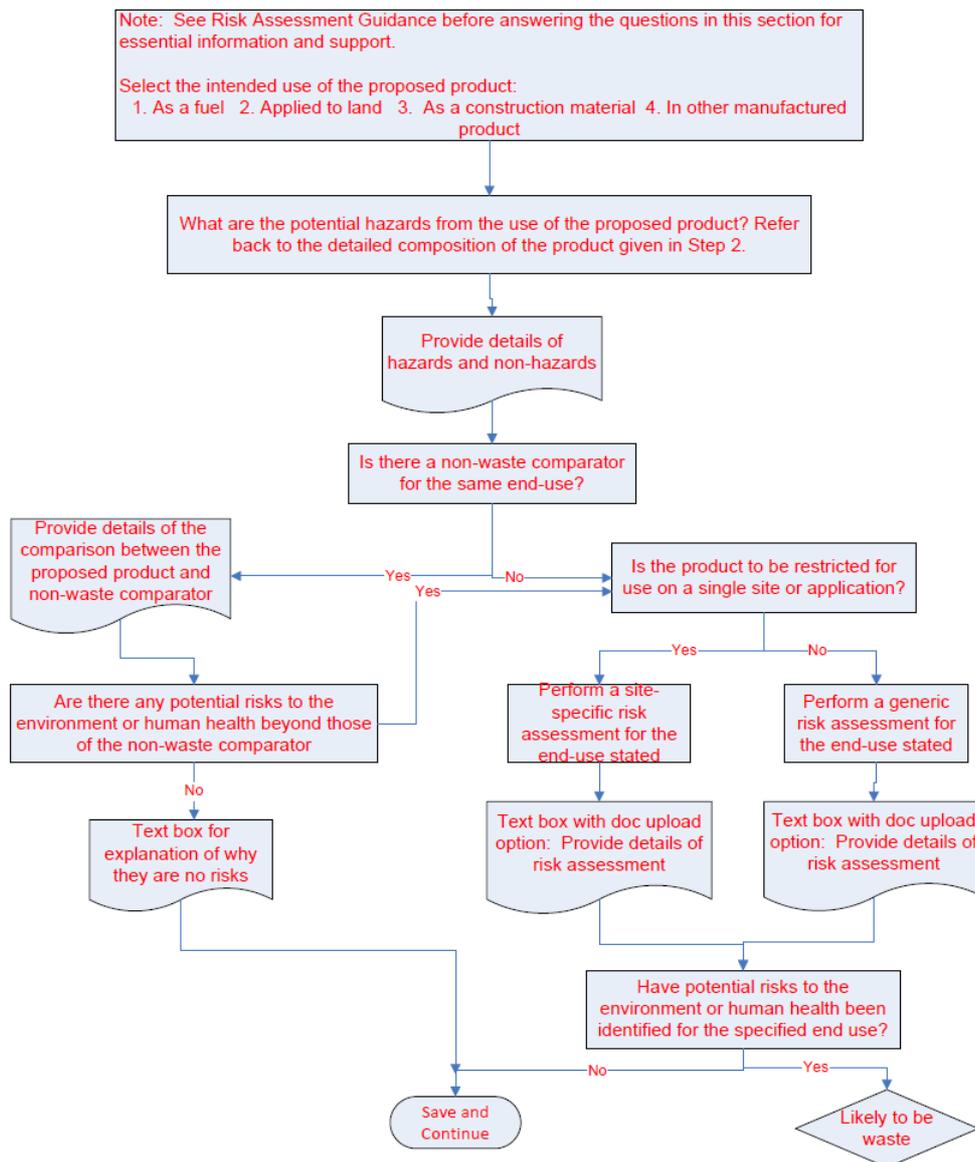
This guidance relates to the last of these two sets of criteria: how to conduct a risk assessment to demonstrate that the environmental and human health impacts are not adverse.

## 1.2. Scope of this guidance

As part of a European Union (EU) LIFE+ project called 'EQual' (Ensuring the Quality of waste-derived products to achieve resource efficiency), the Environment Agency has worked with Rijkswaterstaat from the Netherlands to develop the IsItWaste? online tool for the definition of waste. IsItWaste? is an assessment tool to help decide whether a material is a waste or not. Figure 1.1 illustrates the part of the tool that deals with environmental and human health risk assessment.

This guidance has been produced to help those making an environmental and human health impact assessment for end-of-waste decision making. It covers the principles for conducting a risk assessment for a material under specified uses to determine whether it is likely to cause an unacceptable level of harm to the environment or human health.

This guidance is not prescriptive, but it does outline good practice and gives options and examples where these are available. The considerable range of end uses for all the potential materials means that it is not possible to account for every possible permutation within this document, but the important principles described in this report can easily be extrapolated to other situations. A range of approaches may be needed to build up several lines of evidence.



**Figure 1.1 The section of the IsItWaste tool supported by this guidance**

Potential environmental and human health risks from the reuse of a material in a specific way may result from the physical, chemical and biological properties of that material. The main focus of this guidance is on chemical related risks, specifically the assessment of the potential for the use of a material to cause adverse environmental and human health.

This guidance seeks to be consistent with definitions and terminology from the Waste Framework Directive and guidance from the Department for the Environment, Food and Rural Affairs (Defra) on the legal definition of waste (Defra 2012). However, reference is also made to terminology from other regulatory sources and directives, and associated technical guidance on how to perform chemical related environmental and human health risk assessments. These include:

- guidance on the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation from the European Chemicals Agency (ECHA) such as Chapter R16 on environmental exposure estimation (ECHA 2012a)
- Water Framework Directive technical guidance such as European Commission (2010, 2011)
- Human and Veterinary Medicines Directives guidance such as CVMP (2005, 2008)

This guidance sets out the principles of risk assessment used to determine the extent of risk to human health or the environment. Potential impacts on human health, livestock, air, controlled waters, soil and crops may need to be assessed, depending on potential uses of a material. The

guidance follows principles used in the Waste Quality Protocols Project which developed national Quality Protocols to help determine when specified wastes can be considered to have been fully recovered and no longer be considered waste. Examples from these protocols are used to illustrate what may be considered good risk assessment practice.

### 1.3. Guidance structure

Section 2 provides a general outline for conducting a quantitative risk assessment based on current practice and guidance. The differences and similarities between assessments performed to assess risks to the environment and human health are summarised and how such assessments can be made at different levels of detail and effort (tiered assessments) is explained. Guidance is also given on how the information in the risk assessment should be presented to ensure the process is transparent and auditable.

Section 3 covers the characterisation of the potential hazards while Section 4 describes the development of end use scenarios. Conducting an environmental risk assessment for controlled waters and soils is discussed in Section 5 and human health risk assessment from exposure via air, diet and soil is covered in Section 6. Section 7 provides examples of the use of natural and manufactured comparators in risk assessment.

# 2. Conducting a risk assessment

## 2.1. Risk assessment principles

Risk assessment is an iterative process and can be considered as a tool to:

- target effort and resources
- clarify potential risks
- support decision making

The source–pathway–receptor approach to risk assessment is used throughout this guidance. Without all three components there is no pollutant linkage and there can be no risk.

Other overarching principles of risk assessment can be found in:

- Green Leaves III (Defra and Cranfield University 2011)
- Contaminated Land Report 11 (CLR 11) (Environment Agency 2004)

### 2.1.1. Pollutant linkages and developing the conceptual model

In the early stages of most risk assessments, conceptual models are developed to help identify pollutant linkages between the sources, pathways and receptors.

A conceptual model can be a textual or graphical representation of the relationship(s) between hazard source(s), pathway(s) and receptor(s) developed and refined during subsequent risk assessment phases or tiers. They can be expressed as a table, matrix, diagram (for example, Figure 2.2), picture or a narrative description.

A number of important components make up the process of determining the presence of a pollutant linkage (the presence of each of the source–pathway–receptor) to decide whether use of a material may pose a risk to health or the environment.

- Define the situation(s) in which a material may be used ('use scenarios').
- Identify and quantify any chemicals that may be present in the material that pose a hazard to human health and the environment ('sources').
- Identify routes by which these chemicals may move from the material in a particular use scenario ('pathways').
- Identify which environmental compartments ('receptors') are vulnerable to the chemicals, and to what extent there is a pollutant linkage.

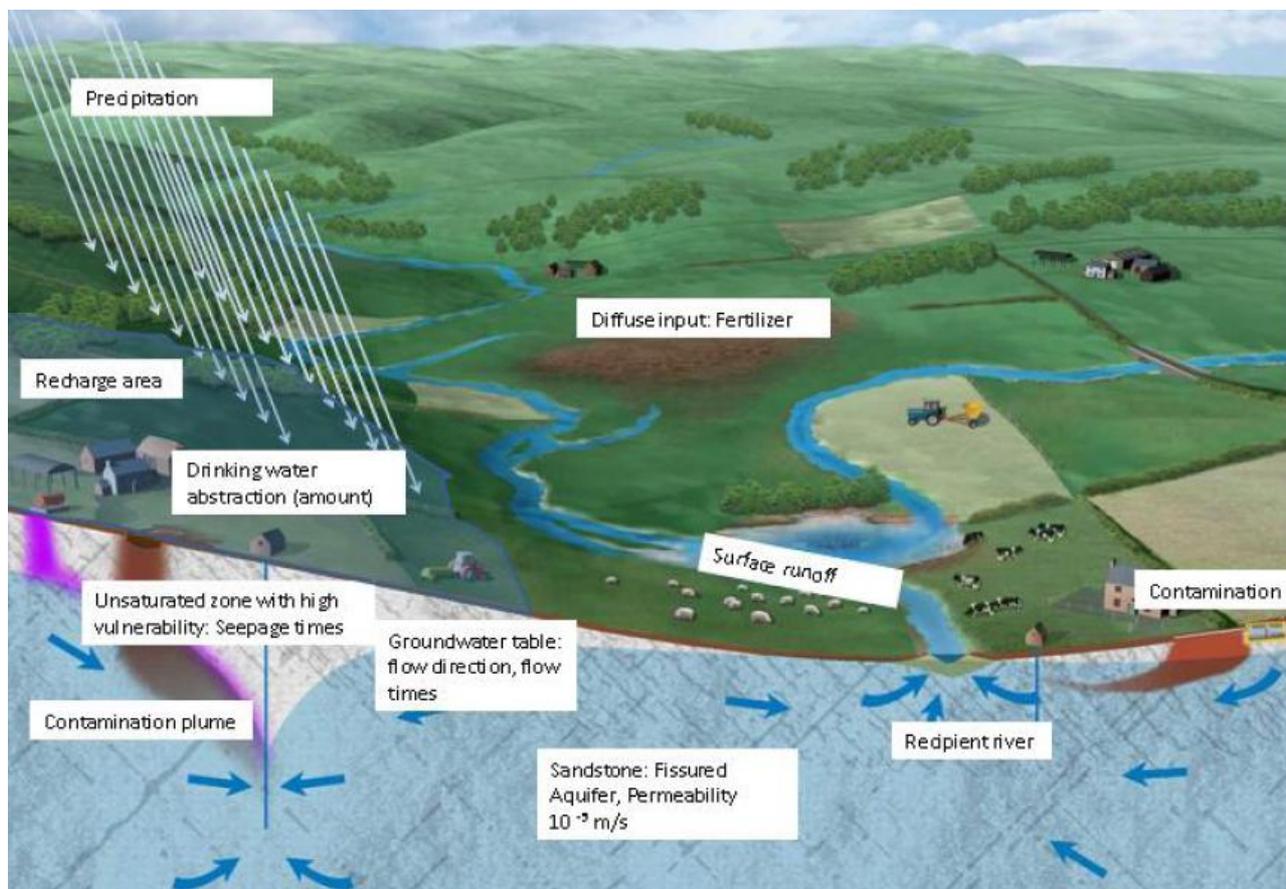
This information is then used to make an informed judgement about whether such combinations are probable.

The development of the conceptual model is central to the risk assessment process, as it defines the way in which subsequent stages of risk assessment are followed and ensures that each relevant pollutant linkage is assessed.

In assessing the risks for an end-of-waste decision for a generally applicable product, the end goal is to produce a generic conceptual model for an application or an 'end use scenario' rather than a site-specific conceptual model. As a result the generic conceptual model is often represented by realistic or reasonable worst-case conditions. If the product requires complex and site-specific risk assessment before use (other than within general risk management guidelines) then it may not be suitable for an end-of-waste decision, where the risks are intended to be broadly negligible or low under a wide range of circumstances.

Realistic worst case (RWC) is a widely used term in many forms of risk assessment and may be considered as being the worst manifestation of the wider generic exposures and effects that are still credible and relatively plausible. An example of such an approach would be the use of a relatively high percentile (90–95th) of a frequency distribution of concentrations of a chemical in a material as a summary statistic for environmental exposure calculations.

It may be useful to develop the conceptual model through the use of simple tables that identify end uses, pathways and receptors as shown in an example for the applications of steel slags in Table 5.1. These types of information can provide a qualitative assessment of likelihood of risk that can ensure effort is focused on the appropriate uses and receptors.



**Figure 2.2 Example of a conceptual model for groundwater**

Notes: From European Commission (2010)

## 2.2. A tiered approach to assessing risk

For the purpose of this guidance, there are three main levels or tiers of risk assessment:

- **Tier 1: Risk screening.** This is concerned with the development of an outline conceptual model and establishing whether there is any potential for unacceptable risks and a need for further assessment based on the presence of chemicals that are hazardous to health or the environment.
- **Tier 2: Generic quantitative risk assessment (GQRA).** This tier uses the conceptual model and generic assessment criteria applicable to a range of scenarios, if available, to identify potentially unacceptable risks.
- **Tier 3: Detailed quantitative risk assessment (DQRA).** This tier involves risk assessment focused on a specific scenario and material being considered. Tier 3 generally requires more

complex risk modelling tools and the generation of more detailed data to characterise the scenario, material and receptors under consideration.

For most end-of-waste assessments, a screening or generic risk assessment is likely to be sufficient. One of the crucial paradigms of a risk assessment is that the intensity of effort in performing the assessment is commensurate with the complexity and likelihood of the identification of risks. As outlined in Green Leaves III (Defra and Cranfield University 2011), an iterative approach is recommended, which generally means that the assessment is tiered or staged.

In the early stages of an assessment, simple RWC comparisons may be made between exposures of chemicals and assessment criteria, such as Environmental Quality Standards (EQS) or limit values. Importantly, these comparisons need to be precautionary in any assumptions made.

Early tiers of risk assessment are usually structured in such a way as to avoid the possibility of screening out risks as negligible or low when they are actually significant (known as Type II errors or false negatives). Although these early tiers of assessment will also screen out the more obvious low risk scenarios, it is generally accepted that some low risks will not be correctly screened out (Type I errors, or false positives) until after they are investigated further in later tiers.

The results of the early tiers of an assessment provide an opportunity to prioritise resources to specific hazards that present the highest potential risks. This may be in the form of collating or generating better data on source characterisation, better scoping and design of the end use scenario, and the methods used to predict or estimate exposures. The aim, through the iteration in the tiers, is to improve confidence in the assessment of potential risks by reducing uncertainty.

## 2.3. Environmental and human health risk assessment

When assessing chemical risks to environmental and human health there are some important commonalities but also differences in the approaches taken. It is important to note these differences as they will mean that data will be treated differently.

Both approaches utilise the source–pathway–receptor concept (the pollutant linkage), follow a similar tiered approach and require data (modelled or measured) for calculating exposure. Effects-based information to characterise hazard are also required for both approaches. For environmental receptors these ‘ecotoxicological’ data are often in the form of concentrations in a matrix (for example, µg/l for chemicals in waters) and for human health the data are often as intakes of a chemical per mass bodyweight (bw) per time period (for example, mg/kg bw/day).

Some regulatory guidelines to assess risk or control human exposure may also be presented as chemical concentrations in a particular medium; examples include air quality guidelines, drinking water standards and maximum permissible concentrations in foodstuffs. Some environmental receptors such as domestic animals and livestock may also use intakes to assess risk but this is rare.

### 2.3.1. Assessment criteria

In both environmental risk assessment (ERA) and human health risk assessment (HHRA), an estimate of exposure, intake or media concentration is compared with an assessment criterion. Assessment criteria include:

- effects based intakes such as a predicted no effect concentration (PNEC) for environmental flora and fauna
- a health criteria value (HCV) for human health
- derived environmental and health guidelines based on the chemical concentration in a specified medium (for example, air, soil or water)

The ratio of predicted exposure or media concentration to the assessment criteria is called the risk quotient. As a guide, if this value is equal to or greater than unity then there is a potential risk from that chemical in that matrix.

### **2.3.2. Environmental risk assessment**

ERA is fundamentally different from HHRA in that it must take into account the complexity of ecosystems and seek to offer protection to the majority of organisms living in specific environmental compartments (for example, water, sediment or soil). PNECs used in environmental risk assessment can be derived from effects data from a number of different organisms covering a number of trophic levels and the nature of testing integrates all possible routes of exposure. In assessing the environmental risks, chemical concentrations in a matrix such as soil, surface water or sediment (that is, the media concentration) are compared directly with the relevant effects concentration.

A brief environmental example for the assessment of chemical risks to surface waters could be an initial comparison of the source term, or estimated exposure concentration of the chemical in the surface water resulting from the RWC conditions (probably no dilution) of the specified use with 10% of the EQS concentration for the specific chemical. The 10% value is recommended in the Environment Agency's risk assessment guidance where background concentrations of a chemical and low watercourse flow conditions are not taken into account. By using such a fraction of the EQS, the method accounts for the possibility of other local, unknown pollution sources being present that would affect available dilution. This comparison would represent the first tier of a surface waters risk assessment and an exceedance of 10% of the EQS would prompt progression to the next level of the assessment. This would include greater estimates of realism in exposure, such as accounting for dilution.

Further detail on how to conduct an environmental risk assessment is provided in Section 5.

### **2.3.3. Human health risk assessment**

HHRA is only concerned with one type of animal species (us). However, within the human population it is possible to identify a range of sub-groups that may be affected by or exposed to contaminants quite differently. Common sub-populations include children and those sensitive to specific health effects, and also direct users and consumers of a product versus those that might be indirectly exposed.

There are often a number of different exposure pathways requiring assessment so as to accurately determine overall exposure; that is, exposure to a contaminant may arise from inhalation of dusts and vapours, ingestion of foodstuffs, dusts and soils, and direct skin contact with products.

Effects data are generally derived from toxicological studies on laboratory animals or from epidemiological data derived from studies of workers or the general population. It is important to note that the hazard posed by a chemical to human health may vary according to the exposure pathway and often HCVs are derived separately for the oral and inhalation routes.

HHRA is usually precautionary and exposure pathways are considered with a relatively high degree of conservatism, especially for early tier generic quantitative risk assessments. HHRA also considers the different modes of action by which chemicals can exert health effects, and toxicants with threshold or non-threshold effects are considered differently.

Further detail on how to conduct a human health risk assessment is provided in Section 6.

## 2.4. Presenting the assessment

The general principles of presenting a risk assessment should be very familiar to most practitioners. However, it is also necessary to ensure that the style and format of the writing is clear and takes account of the fact that the reader, while technical, may not be an expert in this specific area.

The process followed, assumptions made, caveats, justifications and uncertainties all need to be clearly presented and well referenced. If the assessment were to be performed again in the future, perhaps with a new set of data, the method should be set out in such a way that this could be easily done.

The conclusions drawn and characterisation of the risks must be supported by the evidence. If during the assessment more data are collected, as one of the iterations or refinements, then this needs to be referred to and developed in the text.

A report template is not provided in this guidance. However, the risk assessments that support the Quality Protocols provide a useful indication of:

- the types of information needed for the generic assessment
- the technical depth that may be needed to support that assessment

## 3. Source characterisation

This section presents guiding principles for performing desk-based screening for hazards in the material, sampling the material and collating data, and calculating the concentrations of chemicals in those materials.

The quality of the data can dramatically influence the certainty associated with the results of a risk assessment. Furthermore, poor or limited data will mean that the process the assessor must follow has greater levels of inherent precaution. Poor quality data will mean high levels of uncertainty.

### 3.1. Screening for potential hazards

This step in performing an assessment is often overlooked or conducted with limited attention to detail. It involves searching for data or information about the chemical composition, hazard profile and physicochemical properties of the material under consideration, with secondary reference to the likely reuse. Considerable information can also be obtained from manufacturers and producers of waste including an upstream understanding of the raw materials, products and processes including material safety data sheets.

Generally the search strategy for screening for potential hazards starts broadly, that is, a wide-ranging literature search using open literature sources such as:

- TOXLINE (via TOXNET)
- search engines
- regulatory sites in the UK, Europe and across the developed world such as the US Environmental Protection Agency's ECOTOX database (<http://cfpub.epa.gov/ecotox/>).

It is essential to detail the search strings used for the search as this forms part of the audit trail and an important information source if iteration is required in the assessment. Depending on the availability of literature, time and resources, the assessor may follow the principles of an evidence review to ensure a comprehensive, systematic and objective process (Collins *et al.* 2014).

To assist in the task of identifying potential hazards in materials, the Environment Agency recently completed a project to develop a method for the rapid evidence assessment of the physical, biological and chemical hazards associated with waste types that may be spread to agricultural land (Environment Agency, in press a). While spreading to agricultural land is just one, albeit common, end use scenario, there are aspects of the approach that can be applied to other end uses, including the need to prioritise the hazards and to flag data gaps and uncertainties.

Open literature searches generally return a large number of 'hits'. It is therefore important to have already developed a conceptual model of the assessment to be performed beforehand. This will then enable those performing the screening to develop criteria by which to include or dismiss references.

As a note of caution, a chemical present in the material may not have been previously identified in the literature or measured widely in the specific uses being considered. However, this does not mean it is not a potential hazard (for example, benzothiazole in tyre-based materials). This is one of the reasons for undertaking such a broad ranging search at the start of the screening exercise. Generally, components that are relatively easy to analyse and determine chemically in a material are often what are measured (such as trace elements) although this is not always a strong criterion for potential hazard identification.

The outputs from the hazard screening exercise could be presented in the form of a table identifying the chemical and the potential hazards it presents in reference to a specific use, along with full references. Again, this is part of the technical foundation on which decisions throughout the risk assessment will be built and so these outputs need to be recorded.

It is important to recognise that, for some chemicals, it may be considered that no safe level exists for which it may be reintroduced into the environment in any form. These chemicals are often identified as persistent, bioaccumulative and toxic (PBT). Their production and use may be banned under international conventions such as the Stockholm Convention<sup>1</sup> or scheduled for phase out in the near future under existing European directives such as the chemicals identified as priority hazardous substances under the Water Framework Directive.

The screening exercise for potential hazards of a material, chemical composition, hazard profile and the physicochemical properties will also indicate the chemical analysis requirements after any sampling.

## 3.2. Sampling and collating data

### 3.2.1. Sampling

When considering sampling a material that is currently a waste but for which the intention is some form of reuse or declaration of end-of-waste, it is important to thoroughly understand the input materials to the processes and the process controls that may affect the material quality (for example, the co-burning of different materials to produce an ash). This understanding is important in relation to identifying the hazards; refining the risk assessment and understanding the material heterogeneity (see, for example, Environment Agency 2010a).

Physical sampling can be performed on the inputs and output material from a process but should always follow a specific sampling plan. Guidance is available that provides the principles and practical steps needed to undertake sampling of solid and liquid materials in heaps, piles or tanks, off conveyor belts, and so on. It includes:

- BS EN 14899:2005 Characterization of waste. Sampling of waste materials. Framework for the preparation and application of a sampling plan (BSI 2005)
- Resource Conservation and Recovery Act Waste Sampling Draft Technical Guidance (USEPA 2002)
- advice on sampling slurries and solid manures (Chambers et al. 2001)

For example, USEPA (2002) provides excellent guidance on:

- developing sampling strategies
- controlling variability and bias in sampling
- determining the appropriate number of samples to estimate a percentile or a mean value for the sample population

Estimating the appropriate number of samples to deliver an acceptable level of statistical confidence may also be important, especially if early data from the literature indicate relatively high levels of variability. Sampling programmes can be designed and structured to achieve levels of statistical confidence. This understanding is important in estimating the likely analytical costs of a sampling programme.

Information on some material properties may be required to conduct any subsequent risk assessment in addition to measuring chemical levels or to provide product specifications. The risk assessments supporting the Quality Protocols programme indicate some of the supporting parameters that are important in the risk assessment. These supporting parameters are needed to characterise the material. They are also inputs to some of the commonly used tools available to refine exposure and effects concentration in the risk assessment. Supporting parameters could include:

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<sup>1</sup> <http://chm.pops.int/Implementation/NewPOPs/DecisionsRecommendations/tabid/671/Default.aspx>

- bulk density or specific gravity
- moisture content
- pH – in water or calcium chloride
- particle size distribution
- total organic carbon content
- dustiness
- calcium carbonate content

### 3.2.2. Collating and analysing data

In addition to sampling, data may already be available from a range of published or internal sources which could be utilised in an assessment of potential chemical risks. These data, perhaps on input or output physicochemical characteristics, may have been collected for other reasons or for the fulfilment of other regulatory drivers. When using such data consideration should be made for the original sample type, batch, feedstock, process descriptions and so on. It is important that all these types of information are available to provide context to any physicochemical determinands measured. Indeed, without an appropriate audit trail, including sample and analytical chemistry performance data (methods, limits of detection and so on), historic data may be of limited value in the risk assessment. Furthermore, it is the raw, unprocessed data and not meta or summary data that are often of greatest use. A list of considerations when collating monitoring data to estimate exposure concentrations of chemicals from various uses is given in ECHA (2012a). They include:

- quality of the sampling and analytical techniques (for example, in accordance with the Environment Agency's Monitoring Certification Scheme)
- selection of representative data for the process and environmental compartment of concern
- identification and treatment of outliers (for example, ISO 2008)
- treatment of values below the limit of quantification; highly variable or censored datasets require particular treatment to provide a reliable exposure concentration (see, for example, Environment Agency in press b)
- data comparability within the dataset and with other similar data

As well as solid and liquid sampling data that may be available (or may need to be generated) are leachate data from solid materials. Leaching tests are conducted to examine mass transfer from a solid to a liquid. Depending on the characteristics of the material, its end use scenario and the surrounding environment, the infiltrating liquid (leachant) may flow through the material, maximising contact between the leachant and solid, and mobilise contaminants. It is important to note these are not the data from general Waste Acceptance Criteria testing.

There are several standardised test methods for conducting routine leaching tests, which are applicable to original wastes, and bound and unbound products. Leach test standards are variable and the suitability of the test carried out has to be related to the end use scenario and any regulatory or good practice requirements. The most useful data in previous risk assessments supporting the Quality Protocols programme were generated from up flow percolation tests (for example, DD CEN/TS 14405:2004 and prEN 14405:2002) and batch leaching tests (BS EN 12457).

A number of variables can influence the concentration of a chemical in the eluate and should be recorded with the dataset. They include:

- site of origin
- production process
- particle size distribution (grading)

- extent of weathering
- test liquid to solid (LS) ratio

If leachate data are being generated then direct reference should be made to the earlier hazard screening. The concentration for the particular LS ratio that is used depends on the chemical and also the stage in the risk assessment. Generally, an approach is adopted that may be considered a reasonable balance between worst case and most likely behaviour, with an emphasis on lower LS ratio concentrations. Previous risk assessments supporting the Quality Protocols programme showed that, in addition to determining specific chemical concentrations, speciation of inorganic determinands can be very useful in ascribing risks, especially for trace elements such chromium and arsenic if these are relevant.

### 3.3. Calculating concentrations of chemicals in materials

Once the chemical and hazard data have been collected and collated, the next step is to derive a summary statistic of these data and a measure of the variance. The particular summary statistic for the physicochemical determinand chosen may be used to inform the exposure assessment or to model the behaviour and fate in environmental systems.

The choice of the summary statistic is an important factor in determining the level of precaution in a risk assessment. Progress through the tiers of an assessment may justify a different summary statistic, but this will be on an individual case or chemical basis, and narrative would need to be provided to explain this.

In the risk assessments supporting the Quality Protocols programme a range of summary statistics were used to represent physicochemical data in the assessments to establish RWC source terms and to assess average exposures. The general trend in environmental chemical assessments is to summarise chemical data for the source term using a high percentile from the frequency distribution of the data (such as a 90th or 95th percentile) or a maximum value. Guidance in Chapter R16 of the REACH guidance (ECHA 2012a) suggests that the frequency distribution can give a relevant single summary statistic of a material chemical concentration, such as a median or 90th percentile if the distribution function has only one mode. The REACH guidance also suggests that, if this approach is used, data should not be taken from different populations, obtained with different sampling frequencies (or analytical methods) or used without appropriate consideration of the number of data available from each site.

Occasionally, if only metadata are available or if the dataset is relatively small, only maximum concentrations might be reported. However, this may not always represent the maximum value encountered in the waste stream (only the highest value measured so far). There may be some circumstances where these could perhaps be considered as a worst case assumption, providing they do not correspond to an accident or spillage. However, there is going to be little certainty associated with any assessment performed using these types of data without other forms of corroboration (perhaps a weight of evidence developed from relevant published literature).

In deriving summary statistics of data for use in exposure assessments for humans, the inherent precaution at stages in the process can justify a range of statistics. This is the case for the Environment Agency's consideration of soil concentrations as there are competing factors of enrichment versus intake; ambient background data (such as for soils and waters) are often log-normally distributed and therefore a median value is a less biased measure of central tendency. For waste material data, when considering long-term exposure scenarios, the USEPA and others recommend the 95th upper confidence limit (UCL95) which can be estimated from a range of distributions (normal, log normal and non-parametric methods) (see, for example, USEPA 2002).

It is important to fit the summary statistic to the data and the circumstance under which it is being considered in the risk assessment. The summary statistic of the chemical determinands is then used in the calculations of the exposure concentrations for the respective use scenarios of the material, as outlined in Sections 3 and 4.

# 4. Use scenarios

## 4.1. Uses and potential uses of a material

One of the legal criteria defined in the Waste Framework Directive in relation to establishing end-of-waste for a material is that there must be a specific end use for that material. The risk assessment assesses the potential risks associated with those end uses. If other end uses are identified through the assessment process then these too must be considered.

The end uses of the material are also termed 'end use scenarios'. Effectively, these are the principal industrial or consumer applications of a product and take into account existing regulatory and good practice guidance on the use of similar materials (for example, the use of recycled aggregates for construction must comply with existing standards and codes of practice). In most cases, the reused materials are intended to compete with existing products in the marketplace and therefore the end use scenario may be based on how these products are typically used. More rarely, the product is proposed to be used in a novel market, making it more difficult to define the end use scenario. In this case it may be necessary to take into account the much broader requirements of legislative consumer and worker safety, and environmental protection.

While the end use scenarios may be relatively specific (for example, application to agricultural land as a manufactured fertiliser replacement), the characteristics of each end use should be defined in a way that adheres to the principles of the tiered assessment, in that they would be generic but reasonable worst case.

Once an end use scenario is identified it should then be possible to assess the likelihood of potential risks for the chemical hazards identified by the screening process described in Section 3.1. For example, a chemical might have been identified as presenting a potential hazard in the material, but if the chemical is readily degradable under the conditions of the end use scenario, then the source to the receptor pathway may not be present. In addition, the conceptual model can be refined once the end use scenario has been fully described. This will often lead to a reduced number of chemicals for which data may be required, resulting in a more focused set of priorities.

In an ideal situation, measured data would be present from the end use scenario with the material under consideration. For example, data might be available from the application of material to agricultural land as a replacement of manufactured fertilisers to demonstrate its potential for soil accumulation or transfer through the agricultural food chain. However, these data often do not exist for many combinations of products and end use scenarios and therefore the fate and transport of these chemical contaminants and the quantification of environmental or health exposures will need to be modelled to conduct an appropriate assessment. This modelling is described in Sections 5 and 6.

It is reasonable to assume that good practice for the use of the material in the end use scenarios is followed. The two examples below of common end use scenarios illustrate some of the important considerations when developing an end use scenario for a material.

### 4.1.1. Example: application to agricultural land

The chemical concentration in soil resulting from use of soil improvers depends on a number of basic factors including:

- ambient soil level
- amount of material added to soil
- frequency of application

- extent of the mixing of existing soil and added material

The generic risk assessment supporting the Quality Protocol for poultry litter ash (PLA) gives a range of assumptions that form the basis for the estimation of exposure concentrations modelled for the application of PLA to agricultural land (RPS 2010). These assumptions are in line with good practice such as the Code of Good Agricultural Practice for Farmers, Growers and Land Managers (Defra 2009) and the Fertiliser Manual, RB209 (Defra 2010).

**Table 4.1 Assumptions used in the development of the end use scenario for the application of poultry litter ash to agricultural land**

Assumption	Primary assumption (conservative)	Secondary assumption (realistic)
Mixing depth (grassland)	0.05 m	0.10 m
Mixing depth (arable)	0.20 m	0.25 m

Source: RPS (2010)

The selection of these mixing depths for arable and grassland use of PLA is justified in the risk assessment report in the context of how the material is to be used. The application rate of PLA is based on macronutrient content and linked to RWC crop requirements as given in RB209 and calculated to be 1000 kg/ha and applied once a year for a period of 10 years. Incorporation depths for materials applied to land as a surface dressing or ploughed in are typically 5–10 cm and 20–30 cm respectively.

Frequency of application for modelling purposes is often given as once per year for fertilisers but may be less frequent for other materials such as liming agents. An important factor in the long-term risk from soil improvers is the potential for chemicals to build up in soil over time with repeated applications (Defra 2006). Therefore, the potential for accumulation and increased risk should be considered after multiple applications – typically at least 10 applications over a 10–30 year period.

#### 4.1.2. Example: construction end uses

Numerous materials have the potential for construction end uses. Indeed, some of these materials may be widely in use already (for example, recycled aggregates). For these types of material there are standards and specifications, beyond chemical characteristics, that need to be met for particular uses of unbound aggregates in construction. These standards and specifications may include:

- *BS EN 13242:2002 Aggregates for unbound and hydraulically bound materials for use in civil engineering work and road construction*
- *BS EN 13285:2003 Unbound mixtures. Specifications*
- *BS EN 13043:2002 Aggregates for bituminous mixtures and surface treatments for roads, airfields and other trafficked areas*
- *BS EN 14227-1:2004 Unbound and hydraulically bound mixtures. Specifications. Cement bound granular mixtures*
- *Manual of Contract Documents for Highway Works Volume 1 Specification for Highways Works Series 500 Drainage and Service Ducts*
- *Manual of Contract Documents for Highway Works Volume 1 Specification for Highways Works Series 600 Earthworks*
- *Manual of Contract Documents for Highway Works Volume 1 Specification for Highways Works Series 800 Road Pavements, Unbound, Cement and Other Hydraulically Bound Mixtures*

The generic risk assessment that supported the steel slag Quality Protocol (Environment Agency 2013a) included end use scenarios for:

- embankments
- road sub-base/capping scenario
- pipe bedding scenario
- surface dressing

These scenarios were developed from the standards and specifications given above, with dimensions for each of the scenarios shown in Table 4.2. The table also shows the summary statistic used for the estimation of the exposure concentrations generated from the chemical composition of leachate formed as a function of the LS ratio from an up flow column test. The infiltration is calculated as rainfall infiltration taken as an average over the entire surface area of the scenario. For this final figure RWC are generally always assumed and a narrative in the assessment explains this further.

**Table 4.2 Dimensions of the use scenarios for steel slags**

End use scenario	Dimensions (m)			LS (years) <sup>1</sup>	Infiltration (mm/year)
	Length	Width	Depth		
Road embankment	500	20	3	LS 0.1	165
Road sub-base or capping layer	1000	20	0.5	LS 0.1 LS 0.5	100 50
Pipe bedding	1000	1.5	0.3	LS 0.5	500
Surface dressing	1000	20	0.005	LS 10	100

Notes: <sup>1</sup> Pore water concentration estimate (90th percentile) for declining source behaviour

Source: Environment Agency (2013a)

# 5. Environmental risk assessment

An environmental risk assessment (ERA) is necessary if the conceptual model has identified that an environmental receptor may potentially be at risk from a specified use of the material under consideration. All environmental matrices may be of relevance:

- soils
- sediments
- marine and fresh surface waters
- groundwater
- crops and livestock
- wildlife

Air is primarily considered from the perspective of human health (see Section 6).

This section provides an outline of some of the principles that should be considered when planning and conducting an ERA including:

- the estimation of environmental exposure concentrations
- the identification and use of environmental assessment criteria for different receptors

The following sections refer specifically to trace elements. This is because trace elements present some unique regulatory challenges that mean they require specific treatment to make a scientifically sound assessment of potential risks. These challenges include the following issues.

- Trace elements occur naturally and so are ubiquitous in all environmental matrices at concentrations that vary due to a range of geogenic and anthropogenic factors – typically less than 1000 mg/kg dry weight (DW).
- Trace elements can change form or species in response to environmental conditions, which can subsequently affect potential bioavailability and ecotoxicity. Although this has been understood for many decades, the scientific understanding has only recently become available to fully take these changes into account and to link them to toxicity. It is generally the case that the ionic form of the metal represents the most ecotoxicologically relevant species or form. Therefore, this is often the selected form in a risk assessment as it provides reasonable worst case conditions of exposure and effects. Total measures of trace elements (such as aqua regia digests or whole water samples) in soils, waters and sediments are generally poor predictors of potential environmental risks.
- Some trace elements are also biologically essential and the amount required to fulfil the essential requirements varies greatly between types of organism.

Organic micro pollutants present a different set of regulatory challenges with properties such as:

- low or limited environmental degradability
- production of hazardous metabolites
- potential to accumulate through food chains

## 5.1. Estimation of environmental concentrations

The starting point for estimating environmental chemical concentrations is a clear understanding of chemical levels in the material (see Section 3) and the end use scenario (see Section 4). Unless there is published evidence of the outcome of the application of these materials in a relevant end use scenario, the emission of chemicals into the environment and the resulting chemical concentrations in different environmental media will need to be estimated or modelled. These predictions can be relatively straightforward in the early stages of the risk assessment but get

progressively more complex as the need arises (for example, where a potential risk identified at an early stage is subject to further investigation and assessment).

Section 2 emphasised the importance of the conceptual model to the risk assessment process. Such a model can be used to develop a **decision table**, which shows where the attention should be focused in terms of the risk assessment and gives an insight into the thinking behind each decision. An example is given in Table 5.1 for use of steel slags in unbound applications for construction and the potential pathways to a surface water receptor. The table refers to the different end use scenarios for steel slags and shows that understanding them is critical to developing an approach to estimating chemical emissions and environmental concentrations.

**Table 5.1 Potential pathways between leachate from steel slags and surface waters**

Pathway	Present	Comments
Surface run-off	Possible	Run-off may be expected from the surface dressing scenario. Likely to be intercepted by edge drains. Other scenarios where steel slag would be exposed at the surface are restricted to stockpiles and exposed layers during construction.
Flooding	Possible	It is possible that a road may be temporarily flooded during intense rainfall. Run-off may be expected from surface dressing and infiltration through the sub-base or bulk fill may occur, either through degraded pavement surface or from flooded drains, and add to base flow.
Direct deposition	Very unlikely	It is highly unlikely that any slag would be deposited directly into a watercourse during any legitimate construction activity.
Base flow	Possible	Infiltration of rainfall through the slag then migration through shallow layers to surface water. Likely to be intercepted by edge drains.

Source: Environment Agency (2013a)

A predicted environmental concentration (PEC) needs to be estimated for each environmental medium to which chemicals may be emitted through the material end use. In some cases, a medium can be both a pathway and a receptor. For example, use of a soil improver on agricultural land may mean emissions directly to the soil receptor, which is also a pathway for contamination to reach other receptors such as controlled waters.

Many of the principles associated with model development can be found in the technical reports that support the Quality Protocols programme (for example, those for PLA, steel slags, recycled aggregates and biomethane). These represent a good starting point for assessing similar end use scenarios.

An example of how the concentrations of a chemical in a material can be used to estimate the exposure concentrations in an environmental receptor is given in Table 5.2 for PLA use as a replacement for manufactured fertilisers. The table provides an outline of how exposure concentrations can be estimated for soils for several use scenarios (grassland and arable), with indicative parameters that might be used in the calculation.

**Table 5.2 Parameters used to estimate chemical exposures to soil from use of PLA**

Parameter	Unit	Value	Source
Application rate (AR)	kg/ha	1,000 <sup>1</sup>	Informed by the Technical Advisory Group
Application area (AA)	m <sup>2</sup>	10,000	1 hectare
Number of applications (NA)	–	1–10	Random incremental increase
PLA mixing depth (MD)	m	0.05 0.20	EUSES 2.1 Background Report, Table III-198 <sup>2</sup>
Soil density (SD)	kg/m <sup>3</sup>	1,700	European Commission's Technical Guidance Document on Risk Assessment Part II (JRC 2003, p. 44)
Application area soil mass (AASM)	kg	850,000	AA × MD × SD
PLA dry conversion factor (CF)	fraction	0.9	Informed by the Technical Advisory Group

Notes: <sup>1</sup> Based on RB209 requirements for phosphorus (Defra 2010)

<sup>2</sup> The European Union System for the Evaluation of Substances (EUSES) is a mathematical model for calculation of PECs used in the fulfilment of several European chemical regulations such as REACH. EUSES documentation, including 'Chapter 3 'Model Calculations' containing Table III-198, is available to download from the EUSES web page ([http://ihcp.jrc.ec.europa.eu/our\\_activities/public-health/risk\\_assessment\\_of\\_Biocides/euses/euses](http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/euses/euses))

Source: RPS (2010)

Equation 5.1 was used (populated by parameter values defined in Table 5.2) in the PLA risk assessment to calculate the exposure concentration of a chemical in a generic soil receiving applications of PLA, as a substitute for manufactured fertilisers.

$$C_{RES} = \frac{(C_{PLA} \times CF \times AR \times NA) + (C_{BG} \times AASM \times AA)}{AASM} \quad (5.1)$$

where:

$C_{RES}$  = concentration in receiving medium

$C_{PLA}$  = concentration in PLA

$C_{BG}$  = concentration deemed as representing background.

The exposure concentrations of those chemicals identified as potential hazards for a specific use scenario may again be represented by a summary statistic, such as a median or a 90th percentile of the frequency distribution, as the input from the source term.

For chemicals that are likely to accumulate in the environment over time it is important to account for the temporal aspect of exposures. As mentioned previously, the Environment Agency regularly considers this to be up to 30 years. However, the actual time used will depend on factors linked to the use scenario such as the design life of the structure (for example, motorway ramp, road capping) which could feasibly be over 100 years (Environment Agency 2013a).

### 5.1.1. Soils

The potential environmental receptors in the terrestrial environment include:

- microbial populations
- invertebrates and vertebrates living in the soil
- plants and crops
- wildlife affected by secondary poisoning (that is, organisms higher up the food chain)

Soil itself may also be adversely impacted by waste materials (for example, use of sodium-rich materials can cause structural collapse). There is also a potential pathway from soils to groundwater following surface applications of materials, but this depends on the amounts of material applied and the solubility of the chemicals.

Examples are given above of possible methods of calculating concentrations of chemicals in soils receiving surface applied material. Four factors must normally be considered:

- rate of application – along with the chemical concentration in the applied material, this governs the emission of chemicals to soil
- frequency of application – many chemicals build up in soil over time
- application method – the degree to which materials are mixed with soil will affect the depth profile and the impact of emissions on soil enrichment
- existing soil levels – many of these chemicals already occur in soils as a result of natural processes and manmade emissions

In developing an end use scenario for land application of a material, it is imperative that the rate of application is justified on the basis of the benefit it is providing. If that benefit is as a fertiliser or a liming agent, then guidance such as the Fertiliser Manual (Defra 2006) should be used.

In the early tiers of the risk assessment, the generic calculation of soil concentration may be as simple as that shown in Table 5.1. If risks are identified then the calculations might be further refined, if this is justifiable, through consideration of the parameters used. Other factors such as potential chemical losses through leaching, degradation, off-take and volatilisation may be introduced.

If a product or material requires detailed site-specific risk assessment then it may not be a suitable candidate for an end-of-waste decision unless the user can be clear it will only be used at that site.

This type of analysis might provide an indication of where better data would reduce the use of precautionary assumptions; see, for example, RPS (2010). If the chemical identified as a potential risk is naturally occurring, then context to that risk could be gained through a comparison of the exposure concentration with the chemical's ambient background concentration in soils.

For site-specific assessments, the refinement steps are perhaps easier to identify in relation to calculation of soil concentrations if the starting point was a generic soil. For example, the site soil characteristics could be considered directly in the development of the end use scenario.

#### *Trace elements in soils*

Ambient background concentrations (ABCs) for trace elements are available from several UK sources including the Forum of European Geological Surveys (FOREGS), the UK Soil and Herbage Survey (UKSHS) and the National Soil Inventory (NSI). Methods are also available for ABC estimation from soil physicochemical parameters (Environment Agency 2006a).

When considering ABCs in a risk assessment context the starting point (that is, in earlier tiers of the assessment) is generally the use of low percentiles of the dataset such as the 5th or 10th percentile concentration (see, for example, Environment Agency in press b). This relatively precautionary approach acknowledges that many monitoring data sets for soil, water and sediment

for trace elements do not represent natural background concentrations and will be affected to some degree by anthropogenic pressures. Furthermore, if the assessment is generic it is important that the RWC conditions are accounted for. Methods of identifying outliers in these datasets are readily available and can be easily used in this context (Environment Agency 2006a).

### 5.1.2. Groundwater

The conceptual model many identify groundwater as a potential receptor. Modelling chemical concentrations in groundwater can be undertaken using the Environment Agency's 'P20 worksheet for determining remedial targets'<sup>2</sup> for contaminated soil and groundwater (Environment Agency 2006b). The tool can be used to undertake screening assessments and further refinements if potential risks are identified.<sup>3</sup>

Important considerations in estimating the concentration of chemicals in groundwater are the definition of source area, infiltration rate and aquifer properties to establish the critical dilution and attenuation required between source and receptor to nullify any potential risk. The potential release and transport of substances from a material to groundwater is a function of interactions between the material and infiltrating water.

Soluble and even sparingly soluble chemicals can leach from materials and be transported into groundwater through the sub-surface that includes soil, made ground, rock and other construction materials. Other properties such as cover soil thickness, drainage and topography (slope or gradient) also control the infiltration rate and emissions of leachate.

The chemical concentration in groundwater can be estimated at different locations (see Figure 5.1) which take into account to varying degrees the fate and transport processes such as attenuation, degradation, dilution and dispersion. Generally speaking, the chemical concentration in groundwater decreases as the distance from the source area increases. The compliance point is defined as the location of the predicted groundwater contamination that is relevant to the assessment criteria for groundwater and appropriate to the uncertainty at each assessment tier. The compliance points used in the P20 worksheet are shown in Figure 5.1; each corresponds to a different location where there may be a concern about groundwater quality. The P20 model provides a comparison of the remedial target (the assessment criterion) with the estimated chemical concentration at that location.

For each chemical, the P20 model typically requires a range of chemical data such as:

- background concentrations of chemicals for a given end use scenario
- partition coefficients from solid to liquid
- a relevant dilution and dispersion factor depending on the distance from the source area to the compliance point

Standard groundwater risk assessment such as that adopted by the P20 worksheet uses a tiered approach that is broadly similar to that defined in Section 2.2 (the three levels shown in Figure 5.1 can be treated as the equivalent tiers).

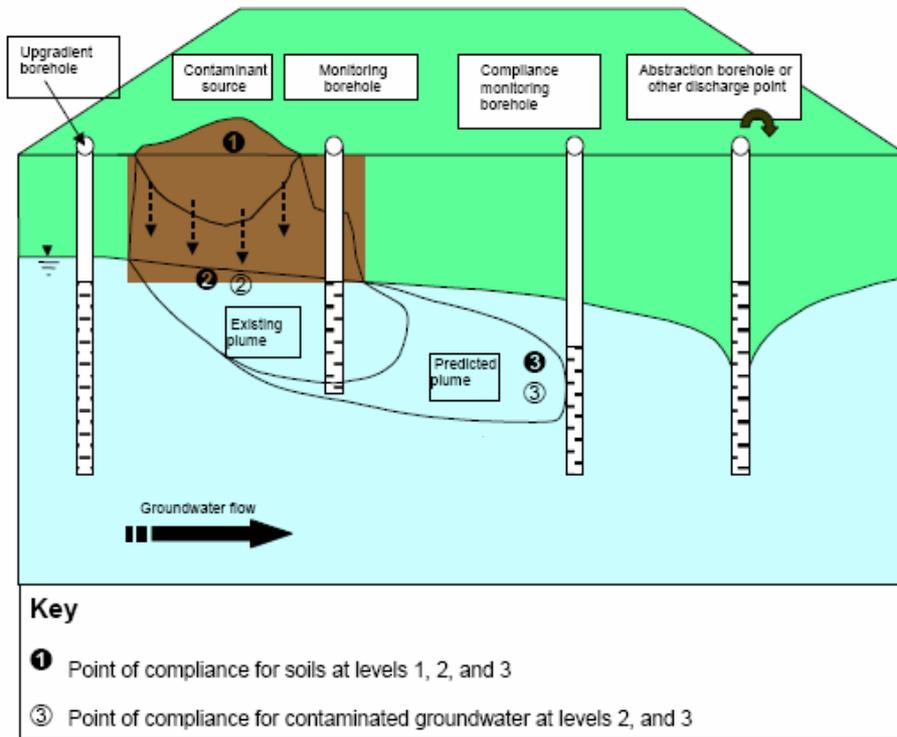
At level one (Tier 1), chemical concentrations in the pore water within the source area are compared directly with the assessment criterion. Pore water concentrations can be determined in either the material alone or, in the case of fertilisers or soil improvers, within the amended soil. Pore water concentrations may be predicted from a standard leach test (where usually the 90th percentile at a LS ratio of 0.1 or 0.2 is used) or by using measured or theoretical partition

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<sup>2</sup> A remedial target is the necessary concentration of a contaminant required in the source material to ensure that an environmental standard is met in the receptor at one of the three levels of the model.

<sup>3</sup> The ConSim model has also been used widely for further refinements in groundwater assessments to take account of: attenuation in the unsaturated zone, especially important for (interim) hazardous substances; and parameter variability and uncertainty in the final level of assessment.

coefficients between the solid medium and water. This latter approach tends to involve considerable uncertainties and it is important to select an appropriate RWC partition coefficient (USEPA 2005).



**Figure 5.1 The three compliance points used in P20**

Source: Environment Agency (2006b)

Level two (Tier 2) refers to a compliance point in the aquifer that lies immediately beneath the source area (Figure 5.1). It assumes that water percolates through the source area and the unsaturated zone to reach the water table where it mixes with groundwater immediately beneath the source. The dilution effect is calculated using the equation:

$$DF = \frac{1 + [K \times l \times Mz]}{L \times Inf} \quad (5.2)$$

where:

DF = dilution factor

K = hydraulic conductivity (m/day)

l = hydraulic gradient

Mz = mixing zone thickness (m)

L = length of contaminant source in direction of groundwater flow (m)

Inf = infiltration rate (m/day)

Some parameters in the calculation of the dilution factor such as the length of the source area and the water infiltration rate are highly dependent on the material and the end use scenario. Other factors such as mixing zone thickness are typically generic. Each end use scenario is likely generate a different dilution factor.

An example from the risk assessment that supports the steel slag Quality Protocol is shown in Table 5.3 for calculation of exposure concentrations for the use of steels slags as pipe bedding. The table also provides an example of the type of justification required in the selection of the input parameters.

**Table 5.3 Input parameters for calculation of exposure concentrations of chemicals at level 2 for the pipe bedding end use scenario for steel slags**

Input parameter	Value	Unit	Justification
Infiltration	0.00137	m/day	Based on water balance assuming 100% infiltration. Pore water estimate based on 90th percentile at LS 0.5.
Length (in direction of groundwater flow)	1,000 1.5	m	Length of structure – agreed with Technical Advisory Group  Width of structure – agreed with Technical Advisory Group
Mixing zone thickness	10	m	Standard value assumed for a shallow aquifer
Aquifer hydraulic conductivity	0.432	m/day	Equivalent to fine sand – relatively low value for an aquifer (considered to be moderately conservative)
Hydraulic gradient	0.01	Dimensionless	Relatively low gradient (moderately conservative)

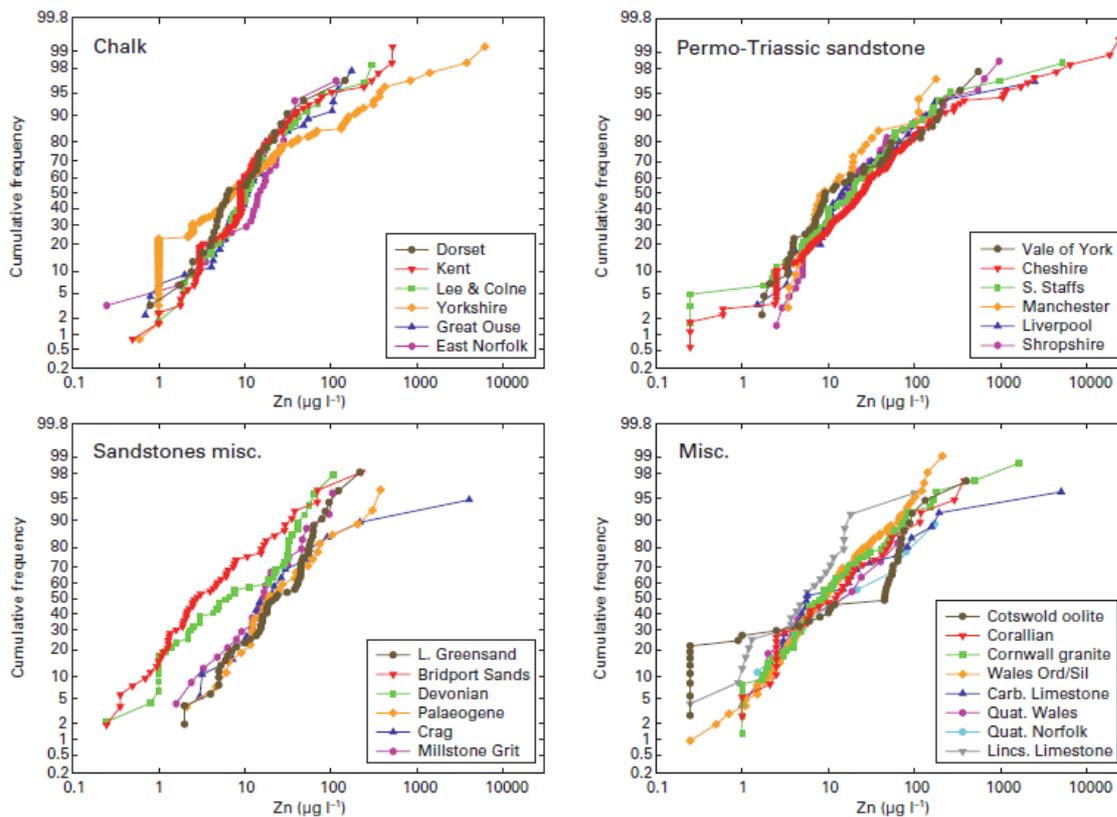
Source: Environment Agency (2013a)

Level three (Tier 3) considers a compliance point in the saturated zone at a specified distance from the contaminant source. As the contaminated groundwater plume travels through the aquifer and away from the source area, the chemical concentration will decrease. The complexity, and therefore the cost in terms of time and resource, at this level is considerably greater than at previous tiers. It is at level three that other models such as ConSim may be more applicable than the P20 worksheet. The ConSim model can also be used to assess multi parameter variability using probabilistic simulation. Examples of the ConSim model inputs and interpretation of the outputs can be found in the risk assessment supporting the Quality Protocol for steel slags (Environment Agency 2013a).

### *Trace elements in groundwater*

At levels two and three, the AMCs of trace elements should be considered. An excellent source of data is the work undertaken by Shand et al. (2007) on the trace element composition of groundwater in England and Wales. Figure 5.2 shows the frequency distributions of zinc concentrations in different aquifers in England and Wales.

During the generic risk assessment stage, the summary statistic chosen to provide a context for the exposure data or use in the predictive tools should be representative of RWC.



**Figure 5.2 Frequency distributions of zinc concentrations in groundwater in England and Wales**

Notes: From Shand et al. (2007)

### 5.1.3. Surface waters

Predicting the emission of chemicals to surface waters and the subsequent chemical concentration in surface water depends on a number of factors including:

- source area
- infiltration rate
- water chemistry
- distance to the watercourse
- volume flow within the receiving waters

The effective area of the source will vary significantly depending on the nature and characteristics of the end use scenario and its orientation in relation to the receiving watercourse (Environment Agency 2013a). The conceptual model for the end use scenario should, where available, take into account good practice in drainage and water management.

This type of risk assessment commonly considers only the leachable chemicals in a material and the potential for them to reach a nearby watercourse or wetland either as surface run-off or by shallow lateral migration within the unsaturated zone.<sup>4</sup> Chemicals may enter run-off or percolated water after it has passed through material in an emplaced structure. The circumstances where this exposure pathway may occur would be where infiltration through the structure is high and the in situ geology of low hydraulic conductivity promotes a high proportion of surface or base flow to an adjacent watercourse.

<sup>4</sup> In some circumstances, the emission of chemicals (for example, phosphates) to water may depend on particulate emissions such as from wind-blown dust or run-off erosion rather than the dissolved phase.

The plausibility of any pollutant linkage within a conceptual model should always be considered carefully as without a source–pathway–receptor there can be no risk. In the case of surface waters, civil engineering structures will usually be designed to minimise infiltration and, with edge drainage, to shift both run-off and leachate away from the structure.

Nevertheless there may, under some circumstances, be a potential exposure pathway to surface waters from chemicals leaching from material in a specific end use scenario. A Tier 1 assessment could simply be a comparison of the results from a standard leach test (for example, the 90th percentile LS 0.1 or 0.2) with the respective assessment criterion. At Tier 2, for those chemicals that show an exceedance at the first tier, the same leach test results could be adjusted for RWC dilution in the receiving watercourse. Equation 5.3 can be used to provide a generic level of dilution to estimate the final exposure concentrations in the receiving water.

$$DF = \frac{([Inf.A] + Q_u).C_c}{([Inf.A].C_c) + (Q_u.C_u)} \quad (5.3)$$

where:

- DF = dilution factor
- Inf = infiltration rate (m/day)
- A = surface area of stockpile or structure (m<sup>2</sup>)
- Q<sub>u</sub> = river flow rate (m<sup>3</sup>/day)
- C<sub>c</sub> = leachate concentration (µg/L)
- C<sub>u</sub> = background concentration (µg/L)

As noted above for the groundwater receptor, some parameters in the calculation of the dilution factor such as surface area of the stockpile or structure and the water infiltration rate are highly dependent on the material and the end use scenario. Other factors such as the river flow rate are typically generic. Each end use scenario is likely to generate a different dilution factor.

A ‘target’ concentration for leachate is calculated by multiplying the watercourse environmental standard, CT, by the dilution factor. The ‘target’ concentration is then normalised by dividing by the leachate concentration, C<sub>c</sub>, giving acceptable dilutions above unity and unacceptable dilutions below unity. This is equivalent to a Level 2 groundwater risk assessment (see Environment Agency 2013a).

Previous risk assessments supporting Quality Protocols have used the median river flow rates for England and Wales shown in Table 5.4. However, the low flows may be considered as representing the RWC.

**Table 5.4 Median surface water flows in England and Wales**

Region	Low flow (m <sup>3</sup> /s)	Medium flow (m <sup>3</sup> /s)	High flow (m <sup>3</sup> /s)
Anglian	0.054	0.241	0.884
Midlands	0.2523	1.026	9.57
Northeast	0.212	0.929	7.689
Northwest	0.592	1.904	7.310
Southern	0.0630	0.280	1.401
Southwest	0.347	0.854	3.249
Thames	0.069	0.436	2.040
Wales	0.399	1.565	6.164

Notes: From RPS (2008)

Section R.16.6.6.2 of the REACH guidance (ECHA 2012a) also suggests that low flows, as derived by 10% of surface water flow, could also be used to provide RWC conditions.

### *Trace elements in waters*

As for soils and groundwater, ABCs may be used to contextualise the predicted trace element concentrations estimated in surface waters, as for example, in a report prepared by Defra and the Environment Agency for the WFD UK Technical Advisory Group (Peters et al. 2009). It is also important to note that some assessment criteria for surface waters require that ABCs are taken into account.

#### **5.1.4. Other compartments**

Other environmental matrices that may be of relevance to specific end use scenarios but not considered here in detail include:

- air
- plants and crops
- livestock and other animals
- sediments
- marine waters

The principles outlined above are relevant for these compartments and can be applied. Air as a pathway is considered further in Section 6 in relation to the assessment of potential chemical risks to human health.

## **5.2. Effects in the environment**

A key source of assessment criteria for chemicals is the Hazard Matrix (Environment Agency, unpublished). This spreadsheet provides benchmark values for assessing the risks to soils and waters for a range of commonly encountered chemicals. An accompanying 'Explainer' document (Environment Agency, unpublished) provides background reasoning behind the selection of the values and what can be done if a value is not in the matrix for a substance or a receptor that should be considered.

### **5.2.1. Soils**

There are relatively few chemicals for which legal standards or advisory guidelines exist for soils. The Sewage Sludge Regulations 1989 provide some limits for commonly encountered trace elements that vary with soil pH for agricultural land. Additional guidance was published by the then Department of Environment in 1996 for use of sewage sludge which included additional advisory limits for soil for some potentially toxic elements.

In addition, there are guidelines for ecological protection (soil screening values) which the Environment Agency has derived and tested that make use of the improvements in understanding of trace element, behaviour and fate to allow soil-specific limits accounting for soil texture, pH, organic carbon and so on (Environment Agency 2008a).

## 5.2.2. Groundwater

Under European legislation, the UK is required to implement measures necessary to prevent hazardous substances from entering groundwater and to limit inputs of non-hazardous chemicals into groundwater. Whether a chemical is defined as hazardous or non-hazardous depends on its persistence, bioaccumulation potential, and toxicity to health and the aquatic environment.

Where a chemical is defined as hazardous, the assessment criterion used is the minimum reporting value (MRV). This has been developed to prevent, as far as possible, further deterioration of groundwater quality.

Where a chemical is non-hazardous, the assessment criterion depends on the potential receptor for contaminated groundwater which includes surface waters, groundwater dependent terrestrial ecosystems (such as wetlands), human health and amenities. Note that non-hazardous chemicals are still capable of causing pollution, that is, they may still cause harmful effects on a receptor.

Example assessment criteria include Drinking Water Standards (DWS) to protect human health and Environmental Quality Standards (EQS) to protect surface water quality. Further information on these criteria can be found in the Hazard Matrix (Environment Agency, unpublished) and the Environment Agency's Chemical Standards Database ([www.gov.uk/chemical-standards-database](http://www.gov.uk/chemical-standards-database)).

The Groundwater Daughter Directive requires groundwater to be protected as a receptor in itself rather than just as a pathway.

## 5.2.3. Surface waters

Under the Water Framework Directive, the UK is required to:

- implement measures to prevent the deterioration of the status of all surface water bodies
- protect, enhance and restore all surface water bodies with the aim of achieving good surface water status

The directive requires specific measures against pollution of water by individual or groups of chemical pollutants which present a significant risk to or via the aquatic environment including risks to human health from drinking water abstraction.

The most important assessment criteria for these risks are the EQS for fresh and marine waters, and the DWS to protect human health. The Hazard Matrix (Environment Agency, unpublished) and the Chemical Standards Database are useful sources of EQS and DWS values.

Some of the EQS for trace elements are given in the Hazard Matrix as EQS<sub>bioavailable</sub> or may vary with water hardness. To perform a robust and RWC generic risk assessment with these EQS it is important to select surface water conditions that represent sensitive waters. In risk assessments that support published Quality Protocols, this has generally meant the use of a low percentile of physicochemical conditions of waters from the Environment Agency's North West Region (see Table 5.5). Importantly, the sensitivity of a water body to trace element levels is **not** the same for all trace elements, although conditions of low dissolved organic carbon (DOC) and hardness (or calcium) tend to be sensitive for most.

The Environment Agency's M-BAT tool can be used to predict site-specific PNECs for copper, nickel, manganese and zinc (see, for example, Peters et al. 2009). There is also an availability correction tool for lead with DOC.

Where background concentrations and low watercourse flow conditions have not been taken into account, comparison of calculated surface water concentrations to 10% of the EQS value is recommended by Environment Agency risk assessment guidance. This generally occurs at an early stage of a risk assessment such as the screening level. Furthermore, by using such a fraction

of the EQS, the method accounts for the possibility of other local, unknown pollution sources being present that could affect available dilution. For the trace elements where an EQS<sub>bioavailable</sub> is given, however, this almost always means that the PEC will be exceeded.

**Table 5.5 Median and mean percentiles of important physicochemical parameters of freshwaters in the North West Region as derived from routine monitoring data**

Percentile	Median DOC (mg/L)	Mean calcium (mg/L)	Mean pH
5th	0.52	1.60	6.29
10th	0.68	1.84	6.45
15th	0.74	2.11	6.55
25th	1.15	2.75	6.98
50th	2.63	7.06	7.31
75th	5.91	39.49	7.72
90th	9.00	52.34	8.02
95th	10.28	60.58	8.20

#### 5.2.4. What if assessment criteria are not available?

If an assessment criterion is not available for a combination of a chemical and a receptor, it is potentially possible to derive an informal value for the specific assessment. There are three issues to consider.

- An absence of an assessment criterion may indicate that a pathway is unlikely or that the hazard to a specific receptor is low. For example, aquatic guidelines may not be established for chemicals insoluble in water.
- Underlying data on the toxicity of a chemical and its effect on a receptor may not be available on which to base an assessment criterion.
- Developing an assessment criterion often requires expert knowledge and to do so may prove costly in terms of time and resources.

Environment Agency (2010a) sets out a method for doing this in an assessment of the potential environmental risks following the agricultural use of mechanical–biological treatment compost-like output. The methodology follows closely that performed under the REACH regulations (R10<sup>5</sup>), with examples for soil limits derived for perfluorooctane sulfonate (PFOS) and dibutyl phthalates. These examples demonstrate the intensity and complexity of effort needed to perform these derivations.

### 5.3. Estimating potential risks

For ERA, the risk is estimated by comparing the PEC for the chemical under consideration for the specific end use scenario with the assessment criterion (for example, EQS). This ratio is called the risk characterisation ratio (RCR) or risk quotient. If the value is  $\geq 1$ , this triggers progression to the next tier and further iteration.

<sup>5</sup> [http://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r10\\_en.pdf](http://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf)

## 6. Human health risk assessment

Human health risk assessment (HHRA) is conducted to establish whether or not use of waste material and any resulting exposure poses an unacceptable risk to human health. Potential impacts on human health should be assessed using recommended UK methods and current guidance. Links to appropriate guidance and references to relevant technical reports are included in this section and these sources should be referred to for detailed guidance on specific aspects of HHRA.

The UK Risk Assessment Framework as presented in Green Leaves III (Defra and Cranfield University 2011) should be applied when considering HHRA of waste materials. The framework is based on a tiered approach, where the level of complexity increases with each tier as conservatism and uncertainty decrease.

A quantitative risk assessment (Tier 2 or 3) should be able to predict the likely magnitudes of associated risks to human health with an acceptable degree of confidence based on the use of robust exposure data and health criteria values (HCVs), which characterise the levels of exposure at which health effects are expected to be minimal. Exposure modelling parameter values should be taken from authoritative sources. Where necessary, the assumptions used in exposure modelling for HHRA can be examined in further detail by probabilistic modelling or sensitivity analysis in the final stages of risk characterisation.

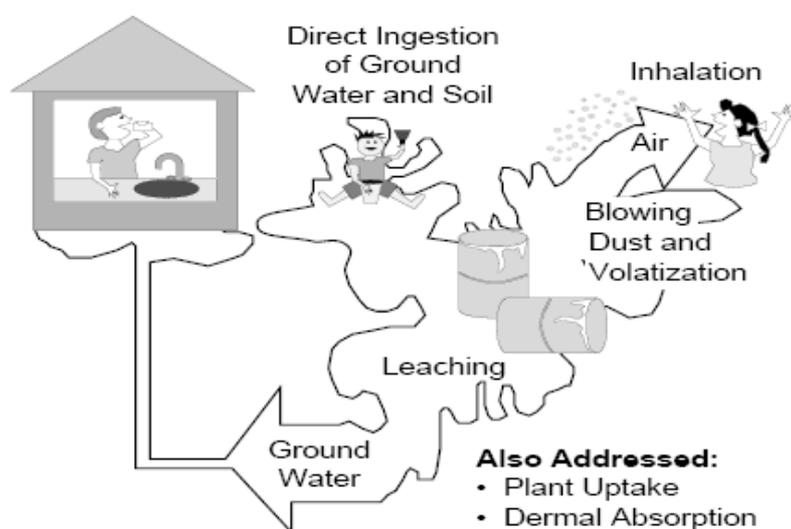
The HHRA process utilises the source–pathway–receptor concept in the development of a conceptual model (see Section 2). It identifies sources of potential contaminants, receptors that could be at risk, and the contaminant transport and exposure pathways that might result in the receptors being directly or indirectly exposed.

Therefore, the initial step in the HHRA process is to develop a sound conceptual model for each end use scenario. This should highlight all potential exposure pathways and the likely exposed populations, which might include:

- indirect exposure following application of material to land and subsequent uptake into the agricultural food chain
- direct consumer exposure from use of the product (for example, exposure to a toy or to buildings constructed from reused materials)
- direct occupational exposure to workers handling the material during the manufacturing process or use of the material in a workplace (for example, workers using the material in the factory to manufacture a final product or where the material is used on-site during construction activities)
- direct bystander exposure following dispersal of material during use (for example, inhalation exposure following use of material containing dust or dust generated during handling and use)

This section generally deals with direct exposures to human health based on the end use scenario (the notable exception being dietary exposure). Indirect exposures to human health, for example via controlled waters, are generally considered under environmental risk assessment (see Section 5).

Figure 6.1 illustrates possible exposure pathways when considering HHRA. Table 6.1 details exposure parameters that require quantification following identification of relevant pollutant linkages.



**Figure 6.1 Potential human health exposure pathways**

**Table 6.1 Summary of exposure scenarios for HHRA with examples of relevant exposure parameters**

Receptor characteristic	Value
Gender	Male or female
Age group	Child or adult
Exposure duration	Number of years
Averaging time	Number of years (usually same as exposure duration)
Inhalation rate	15.7 m <sup>3</sup> /day (mean value for adult) <sup>1</sup> 8.8 m <sup>3</sup> /day (average of mean values for child aged 0–6 years) <sup>1</sup>
Bodyweight	70 kg adult (arithmetic mean for adult UK female) <sup>2</sup> 13.3 kg (average of mean values for female UK child aged 0–6 years) <sup>2</sup>
Soil ingestion rate	100 mg/day for child <sup>3</sup> 50 mg/day for adult <sup>3</sup>
Exposure frequency (all pathways)	Days per year – with justification for selected value
Soil to skin adherence factor outdoors	Units: mg/cm <sup>2</sup> <sup>4</sup>
Time spent indoors or outdoors	Hours per day – with justification for selected value
Default soil	Sand or loam and so on <sup>5</sup>
Annual air dispersion factor	Units: g/m <sup>2</sup> /s per kg/m <sup>3</sup> <sup>6</sup>
Relevant exposure pathways	Select from: <ul style="list-style-type: none"> <li>• oral</li> <li>• direct soil and dust ingestion</li> <li>• dermal</li> <li>• inhalation</li> <li>• outdoor dust</li> </ul>

Notes: <sup>1</sup> USEPA (2011)

<sup>2</sup> Environment Agency (2008c)

<sup>3</sup> Typical values used for risk assessment of contaminated land from Environment Agency (2009c).

<sup>4</sup> See Environment Agency (2009c) for default values for adult and child receptors in the risk assessment of contaminated land.

<sup>5</sup> See Environment Agency (2009e) for default soil types and properties.

<sup>6</sup> See Environment Agency (2009e) for values relevant to different exposure scenarios.

## 6.1. Existing guidance

The subsections below provide signposts to useful reference materials on the general principals of HHRA including exposure assessment. This detailed technical guidance should be used to guide quantitative risk assessment and to establish whether there is an acceptable level of risk to human health from all exposure pathways.

### 6.1.1. Principles of toxicology for human health risk assessment

Any waste material may contain a number of chemicals that have the potential to be hazardous to health; many of these will be naturally occurring – see the discussion on trace elements in Section 5.

Each constituent identified as hazardous to health should be considered in HHRA. For chemicals that should be screened for refer to:

- Department of Environment (DoE) land contamination industry profiles ([www.gov.uk/government/publications/department-of-environment-industry-profiles](http://www.gov.uk/government/publications/department-of-environment-industry-profiles))
- material safety data sheets (MSDSs)
- Public Health England's compendium of chemical hazards ([www.gov.uk/health-protection/chemical-hazards](http://www.gov.uk/health-protection/chemical-hazards))
- EH40 Manual (HSE 2011)

The nature of the health effect(s) resulting from exposure to a chemical and the dose at which this occurs are defined by the discipline of toxicology. The principles of toxicology for HHRA in the context of contaminated soils are outlined in the Environment Agency guidance, *Human Health Toxicological Assessment of Contaminants in Soil* (Environment Agency 2009a) and are broadly applicable to other environmental health assessments. Public Health England (PHE) also provides general guidance on HHRA<sup>6</sup> as well as useful information on specific chemicals.

### 6.1.2. Dietary exposure assessment

An important hazard posed by soil improvers is the potential transmission of chemicals through the agricultural food chain via uptake by crops and livestock – either from crop-derived animal feed such as grass and silage or directly by incidental soil ingestion.

The Food Standards Agency (FSA) is the leading UK authority on dietary risk assessment. Assessors are recommended to consult its reports on various food and dietary surveys for the UK

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<http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/ProductsServices/ChemicalsPoisons/ChemicalRiskAssessment/RiskAssessment/>

covering various trace elements and organic contaminants.<sup>7 8</sup> The European Food Safety Authority (EFSA) also provides extensive and authoritative guidance on dietary exposure assessment; see EFSA (2011) for a summary of this guidance.

The FSA and EFSA documents detail the assessment of potential health effects arising from the presence of contaminants in food. It is also necessary to consider the uptake of contaminants in foodstuffs and this aspect of exposure assessment is considered in Section 6.2.

### 6.1.3. Occupational exposure assessment

It may be necessary to consider a workplace exposure scenario where workers can be exposed during the handling and use of end-of-waste materials in either the production process or during product end-use. Health and safety requirements and hazards that may arise from exposure to the substance will be detailed in the MSDS accompanying the material during transport and on receipt by the end user.

It is also necessary to ensure that airborne concentrations of contaminants comply with occupational exposure levels (OELs). OELs are maximum allowable concentrations of substances in air and they are generally expressed as an eight-hour time weighted average (8h TWA) or a 15-minute short-term exposure limit (STEL). Guidance on occupational exposure assessment and workplace exposure limits (WELs) and STELs used in the UK is provided in the EH40 Manual (HSE 2011).

Exposure to airborne particulates is usually the most important exposure pathway when handling waste materials and the eight -hour TWA for dust is 10 mg/m<sup>3</sup> for the inhalable fraction (the fraction of a dust cloud that can be breathed into the nose or mouth) and 4 mg/m<sup>3</sup> for the respirable particulate fraction (the fraction of inhaled airborne particles that can penetrate beyond the terminal bronchioles into the gas exchange region of the lungs). The concentrations of contaminants present in the material within the air can be calculated on the basis that the dust is composed entirely of the material, which represents a worst case scenario.

Guidance on workplace exposure is also provided by the British Occupational Hygiene Society (<http://www.bohs.org/library/>) and in the technical guidance for the REACH Directive (ECHA 2012b). The Institute of Air Quality Management (IAQM) has published guidance on the assessment of dust from demolition and construction (IAQM 2014).

A number of modelling tools are available for estimating occupational exposure in the absence of measured data. These include:

- Advanced Research Tool (ART) ([www.advancedreachtool.com](http://www.advancedreachtool.com))
- EASE – development of this modelling tool is discussed by Tickner et al. (2005).

### 6.1.4. Consumer exposure assessment

It may also be necessary to consider consumer exposure for an end-use scenario of waste material. Chapter 14 of the REACH guidance contains comprehensive information on consumer exposure assessment (ECHA 2012b). Modelling of consumer exposure can be performed using the ConsExpo model (RIVM 2001, Delmaar et al. 2005).<sup>9</sup>

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<sup>7</sup> <http://www.food.gov.uk/science/research/surveillance/food-surveys>

<sup>8</sup> <http://tna.europarchive.org/20120530191353/http://www.food.gov.uk/science/surveillance/>

<sup>9</sup> ConsExpo can be downloaded from:

[www.rivm.nl/en/Documents\\_and\\_publications/Scientific/Models/Download\\_page\\_for\\_ConsExpo\\_software](http://www.rivm.nl/en/Documents_and_publications/Scientific/Models/Download_page_for_ConsExpo_software)

### 6.1.5. Exposure assessment of general population

Where use of a material generates fugitive dusts, gases or vapours, it may be possible for these to be dispersed and result in exposure to the general public living or working in proximity to the location of use. Assessment of this pathway is generally undertaken for the respirable fraction of dust (that is, dust with a particle size of less than 10 µm, referred to as PM10) or the vapour concentration in air. The HHRA for exposure to airborne dust is achieved by comparison of calculated concentrations of individual chemicals in the dust to air quality standards and long-term Environmental Assessment Levels (EALs).

Technical guidance on environmental HHRA under the Integrated Pollution Prevention Control (IPPC) regime (Environment Agency 2010b), from which the EALs are taken, states that:

‘process contributions can be considered insignificant if:

- the long-term process contribution is <1% of the long term environmental standard; and
- the short-term process contribution is <10% of the short term environmental standard.’

For assessment of indirect exposure to the general population it may also be useful to consider the findings of the Joint Working Group on Bystander Risk Assessment (BRAWG 2012).

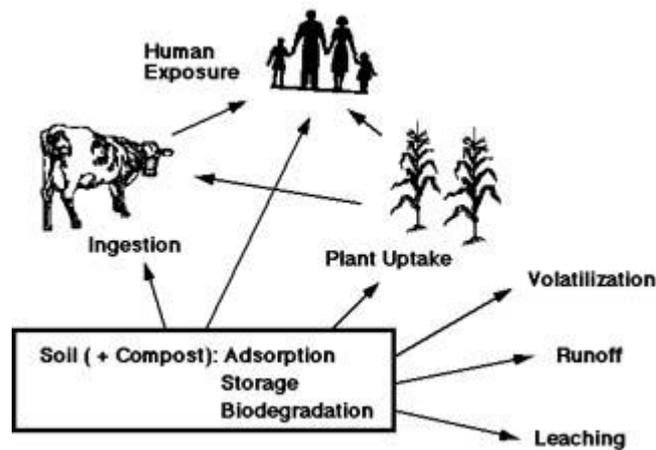
It is essential to fully characterise the conceptual model and associated emission scenario. A useful example is provided by the risk assessment for exposure to fugitive dust arising from a stockpile of steel slag detailed in the Quality Protocol for this material (Environment Agency 2013a). In this example a generic HHRA is undertaken at three tiers. Tier 1 is an initial screening step to rule out those potential chemicals of concern (PCOCs) in steel slag that pose little or no risk to public health. Tier 2 considers those PCOCs identified as still being of concern with a reasonable worst case dust emissions or dispersion based on an estimate of steel slag dust concentrations at the site boundary. Tier 3 uses the reasonable worst case model at Tier 2 but allows for effective dust control measures.

## 6.2. Land spreading and dietary exposure assessment

As explained earlier, dietary exposure assessment is considered in detail in this guidance because it is the exposure pathway that will require assessment for all materials applied to agricultural land.

For materials applied to land as a fertiliser or soil improver, the potential impact on human health through the food chain is often the most significant exposure pathway. Dietary exposure assessment for materials spread to land involves calculating the uptake of chemicals from soil into plants such as fruits, vegetables and cereals and subsequent transfer to humans through the consumption of these foods and also meats, egg and dairy products (following consumption of silage and forage crops by farm animals).

Figure 6.2 shows a conceptual model for landspreading exposure pathways.



**Figure 6.2 Conceptual model for landspreading exposure pathways**

The Environment Agency's Technical Guidance Note EPR 8.01 (Environment Agency 2013b) provides guidance to operators on the most commonly encountered benefits and potential hazards associated with various waste types permitted to be applied land and is a useful starting point for HHRA.

The first step in assessing risks from applying material to agricultural land is to calculate the concentration of various chemicals in soil (mg/kg DW). See Section 5 for further information on estimating environmental concentrations.

The transfer and accumulation of chemicals in crops, meat and dairy produce is calculated based on soil concentrations and transfer factors between soil and plants and between soil/feed and edible parts of livestock. Sources for plant uptake factors for inorganic contaminants include IAEA (2010), Baes et al. (1984) and USEPA (2005). A number of models are available for organic contaminants including Trapp and Matthies (1995), Trapp and Schwartz (2000), Trapp (2002, 2007) and Legrind and Trapp (2009).

Chemical transfer and accumulation is generally considered for, but not limited to:

- crops: cereals, fruits, green vegetables, root vegetables and forage for estimating animal feed concentrations)
- meat and dairy produce: chicken, beef, pork, edible offal (liver and kidney), milk and eggs

Accumulation in meat and dairy produce is estimated using generic biotransfer factors applied to concentrations of chemicals in representative livestock diets that include incidental soil ingestion. Livestock are more sensitive to application of waste materials as surface dressing than plant uptake as a result of this additional dietary component during grazing activities.

After calculating the chemical concentrations in food stuffs, dietary assessment will usually be conducted on a RWC basis utilising assumptions on the types and quantities of foods typically eaten by consumers and whether a national or a local diet is considered (for example, regional communities may exhibit a preference for locally sourced food). Potential assumptions for this type of assessment include the following.

- UK resident receptor will source all their food from land spread with the material. This is a very conservative assumption and it is also possible to consider a scenario where only 50% of the consumer diet is sourced from land treated with the material.
- Food intake rates were taken from UK dietary surveys (NRPB 2003) and the FSA's first National Diet and Nutrition Survey (FSA 2010). Dietary risk assessment is often made based on a high level consumer (97.5th percentile consumption rates), but it is likely to be more realistic to use the mean consumption rates if utilising conservative assumptions such as those detailed above (that is, all or half of the diet coming from a farm spreading material to land).
- Overall exposure should be calculated for adult and child receptors (see Environment Agency 2009c).

It is important to note that the farmer may be both a worker and a consumer.

### 6.3. Selection of health criteria values

Health criteria values (HCVs) are intake values considered to be protective of human health and which define the intake of a chemical that a person can be exposed to long term that poses a minimal or tolerable level of risk.

HCVs are usually expressed as intake per bodyweight (bw) per day, that is, mg/kg bw/day. HCVs are an essential component of HHRA and are compared with estimates of exposure (similarly expressed as intake) to determine whether exposure represents a potentially unacceptable level of risk.

For inhalation exposure it is possible to use an intake-based HCV or an air quality standard such as the air quality objectives recommended in UK and Europe or the reference concentration (RfC) recommended by the USEPA.

HCVs for HHRA of contaminated land are split into tolerable daily intake (TDI) for substances with a threshold critical health effects and Index Dose (ID) for substances with non-threshold health effects. TDI is defined as the estimate of the amount of a chemical, expressed on a bodyweight basis, which can be ingested daily over a lifetime without appreciable health risk.

Where an authoritative HCV is not available, it may be possible to use general expert advice on levels found in media such as food. For example, the opinions of the UK Expert Group on Vitamins and Minerals (EVM), FSA, Public Health England or the Committee of Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on the levels of contaminants found in UK diets may indicate levels unlikely to be of concern.

HCVs are generally concerned with long-term exposure to contaminants. However, it is also important to consider acute health effects arising from short-term exposure to relatively high levels of contaminants and health effects such as eye and skin irritation arising from direct contact. Consideration of skin irritation arising from dermal contact with phenol in soil is included in the relevant TOX report for risk assessment of contaminated land (Environment Agency 2009d). Assessment criteria for short-term exposure are not commonly available for the majority of contaminants, though the US Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile reports ([www.atsdr.cdc.gov/substances/indexAZ.asp](http://www.atsdr.cdc.gov/substances/indexAZ.asp)) detail oral and inhalation minimal risk levels (MRLs) for acute exposure.

Occupational or workplace exposure levels (OELs/WELs) are sometimes used as the basis for provisional HCVs. However, this approach should be treated with caution as the basis of some OELs may not be health-related and WELs are intended for protection of workers in their workplace rather than the general population.

#### 6.3.1. Threshold and non-threshold substances

Where the critical health effect of a chemical is understood to have a threshold, the oral HCVs available such as TDI, reference dose (RfD) and acceptable daily intake (ADI) are broadly comparable and generally derived by a similar approach involving application of assessment factors to toxicological points of departure (no effect or lowest effect levels in toxicological studies). The assessment factor is a reflection of the reliability of the study and certainty in the point of departure, that is, higher assessment factors reflect uncertainty in the study used as the basis for the HCV.

For chemicals for which there is not believed to be a threshold for the critical toxicological effect,<sup>10</sup> there are limitations in applying a strict hierarchical approach to sources of HCVs. This is because approaches used widely by some jurisdictions (such as quantitative extrapolation of cancer risk using data from bioassays in laboratory animals) are not supported by UK expert committees, although HCVs based on this methodology have been adopted in technical guidance produced by UK agencies.

Consequently, both the type of data on which an evaluation is based and the method used to extrapolate from these data to a negligible/minimal risk level in the general human population, need to be borne in mind and are important factors in the reliability scoring scheme detailed in the following section of this report. For instance, Environment Agency guidance on toxicological risk assessment (Environment Agency 2009a) recommends applying an uncertainty factor of 10,000 to a calculated benchmark dose level identified from animal studies (for example, BMDL10 for tumours) as a preferred approach for deriving IDs for non-threshold substances from animal studies. A very similar approach is recommended in guidance on risk characterisation methods published by the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC 2012). In addition, the policy context for the existing evaluation needs to be borne in mind, in particular whether considerations of As Low As Reasonably Practicable (ALARP) might have been applied which might not be applicable to this project.

### 6.3.2. Sources of HCVs

HCVs are available from a number of sources and so it is important to select the appropriate value. Where possible this should be the value used in a recent HHRA by UK authorities. A number of useful sources of HCVs are discussed below.

#### *Hazard Matrix*

The Environment Agency's Hazard Matrix (Environment Agency, in press c) is a compilation of HCV values and environmental quality standards developed to make it easier to achieve consistent generic assessment of potential environmental and human health risks from a chemical substance present in waste streams.

HCVs for the Hazard Matrix were selected following a broad hierarchy of preferred sources:

- recommendations of TDIs, air quality and drinking water standards, and so on by authoritative UK bodies
- recommendations made by EU scientific advisory panels and working groups
- recommendations by international authoritative organisations such as the World Health Organization (WHO) and associated working groups)
- recommendations of other national organisations such as USEPA and RIVM

The range of sources for HCV selection detailed in the Hazard Matrix (UK, European , and WHO) is a useful starting point for selecting HCVs, although it is essential to consider the following factors:

- date when values were derived (the most recent are generally the soundest and most reliable)
- method by which HCV was derived (some bodies may use techniques that not approved in the UK, for example, low dose extrapolation from animal data for genotoxic carcinogens)
- preference for HCV derived from human data compared with animal data
- recent toxicological findings on the critical health effect(s)

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<sup>10</sup> Typically genotoxic carcinogens but also including lead which is considered likely to have a non-threshold effect on neurological development.

Where HCVs are not readily available it may be necessary to derive them from toxicological data; the principles of this process are outlined in Environment Agency (2009a). It is important that the task is carried out by a suitably qualified person.

## 6.4. Alternative approaches for some chemicals

Many chemicals can be assessed on an individual basis by a direct comparison of intake to the HCV. For some classes of compound, however, they should be assessed on an aggregated basis. This is particularly relevant for some groups of organic chemicals that include a large number of structurally similar compounds. Two examples of these types of compounds are polycyclic aromatic hydrocarbons (PAHs) and the dioxins (polychlorinated dibenzodioxins and furans, and dioxin-like polychlorinated biphenyls).

### 6.4.1. Polycyclic aromatic hydrocarbons

PAHs constitute a large class of organic compounds composed of two or more fused aromatic rings.

Benzo(a)pyrene (BaP) is used as a surrogate marker compound for other genotoxic PAHs as it has been demonstrated to be present at a relatively constant ratio in relation to other genotoxic PAHs in contaminated land where the PAHs are generally derived from combustion sources (HPA 2010). Use of BaP as surrogate marker for the HHRA of PAHs is likely to be appropriate for assessment of materials derived from combustion processes and this can be confirmed by comparing the PAH profile to that detailed in HPA (2010).

EFSA (2008) recommends the assessment of eight genotoxic PAHs (PAH8) for risk assessment of PAHs in food. This approach may be most appropriate for materials with a non-standard PAH composition/profile including an absence of BaP or low levels in relation to other genotoxic PAHs.

### 6.4.2. 'Dioxins'

Polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) are an important group of environmental contaminants, which together form a structurally related group of 210 theoretical compounds. A number of polychlorinated biphenyls (PCBs) are also considered to possess dioxin-like toxicity and are known as 'dioxin-like PCBs'. Dioxins and dioxin-like compounds cause a wide range of health effects including suppression of the immune system and reproductive and developmental toxicity

The relative contribution of individual congeners to the overall toxicity of a mixture of dioxins is calculated by the use of toxicity equivalence factors (TEFs). It is generally acknowledged that the toxicity of individual dioxins is mediated by the same mechanism of action, with 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD) being the most potent and best studied congener. Hence TEFs define potency in relation to 2,3,7,8-TCDD.

The WHO European Centre for Environment and Health and the International Program on Chemical Safety together developed a set of criteria for TEF calculations for the relevant dioxin and furan congeners (Van den Berg et al. 2006). These TEFs were endorsed by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) for use in UK assessments of dioxin exposure (COT 2006). The potential dioxin-like activity contributed by each congener is determined by multiplying the concentration of the congener by its WHO designated TEF to yield the dioxin toxic equivalent (TEQ) for that congener. The net TEQ is the sum of the individual TEQs for each dioxin or dioxin-like compound.

Background intake to dioxins is significant due to their persistence and bioaccumulative nature; where possible this intake is assessed using region-specific data, or by using the mean daily intake

(MDI) value specified by Environment Agency (2009e) on the assessment of dioxins in contaminated land.

## 6.5. Risk characterisation for human health

In the final step of HHRA, risk characterisation involves comparing exposure defined by estimated chemical intakes by adults and children with HCVs that define acceptable or tolerable intakes derived from toxicological studies.

For non-threshold chemicals it is general practice to only consider exposure from the source being considered in the risk assessment, though it is important to always consider the ALARP principle which states that exposure from these types of substance should be 'as low as reasonably practicable'.

For threshold chemicals the risk assessment may incorporate an estimation of exposure from other 'background' sources such as air, exposure to consumer products and diet (although it will be important to avoid double-counting in dietary exposure assessment following landspreading and background dietary exposure should be proportionate to the amount of diet that does not come from farms applying the material under consideration).

The Contaminated Land Exposure Assessment (CLEA) TOX reports are a useful source of background intake levels (defined as MDI). These type of intake values can also be derived from information provided by UK dietary surveys such as the UK Total Diet Study (COT 2009) and the annual reports of the UK Drinking Water Inspectorate (<http://dwi.defra.gov.uk/about/annual-report/>).

For each chemical found in a material that is identified as hazardous to health, the risk is often characterised as a hazard quotient (HQ):

$$\text{HQ} = \text{Intake} / \text{HCV} \quad (6.1)$$

For threshold contaminants this can become  $\text{HQ} = \text{Intake} / (\text{TDI} - \text{MDI})$ .

HQ should be  $<1$  to indicate the absence of an unacceptable level of risk to human health.

Certain classes of compound are assessed as a group. It is then also necessary to consider additivity for chemicals with a similar toxicological mode of action or target organ (for example, dioxins described earlier and volatile hydrocarbons that affect the central nervous system). In this instance a hazard index (HI) is calculated by addition of HQs, that is:

$$\text{HI} = \text{HQ}_1 + \text{HQ}_2 + \text{HQ}_3 \dots\dots + \text{HQ}_n \quad (6.2)$$

As a guide, HI should also be  $<1$  to indicate the absence of an unacceptable level of risk to human health.

For dietary exposure assessment, it is also possible to compare calculated concentrations in foodstuffs to the standards enforced by the Contaminants in Food Regulations 2013 (FSA 2013).

Tabular presentation of the results as in Table 6.2 should clearly indicate the most important parameters used to inform the exposure assessment used in risk characterisation. This provides a summary audit trail of vital data and assumptions such as:

- whether mean or 90UCL concentrations have been used for soil background and chemical concentration in the waste material
- number of applications for land spreading
- final soil concentration
- dietary exposure for specific receptors (adult or child)
- HCV and resulting HQ

Supporting calculations for exposure assessment should be included as appendices to the report setting out the results.

**Table 6.2 Example results table for HHRA: land spreading and dietary exposure assessment**

PCOC	Applied material concentration : maximum 95UCL (mg/kg)	Soil ABC concentration : 95UCL (mg/kg)	Soil concentration from 10 applications (mg/kg)	% increase	Dietary exposure (receptor and % diet from farm)	Background exposure	HCV	HQ

ABC = ambient background concentration; HCV = health criteria value; HQ = hazard quotient.



Sensitivity analysis should be carried out to:

- determine the most influential parameters in estimating exposure assessment
- assess the robustness of the assumptions used in the assessment such as parameters to assess for land spreading and dietary exposure assessment including application rate, mixing depth and consumption rate

## 6.6. Risk assessment of animal health

Application of waste materials to agricultural land may present a risk to animals via chemical uptake by plants used as animal feedstock and ingestion of treated soil by grazing livestock.

The main EU legislation governing chemicals in animal feed is made under Directive 2002/32/EC. The basic principles of the legislation are to ensure the protection of public and animal health, animal welfare and the environment while promoting agricultural productivity and sustainability. The directive is enforced in the UK by the Animal Feed Regulations 2010.<sup>11</sup> The Regulations make provisions for the composition, marketing and use of animal feedstuffs for farmed livestock as well as horses, pet food and farmed fish.

The Regulations set maximum permitted levels for a number of chemicals in animal feed, including naturally occurring chemicals such as arsenic, cadmium, lead and mercury, and chemicals which arise during the production and transport of feed including aflatoxin and dioxins. They also define prohibited substances that must never be used in animal feed.

Following the application of waste material to agricultural land, the concentration of chemicals in crops used as animal feed should be calculated as outlined in Section 6.2. These concentrations should then be compared directly with the standards in the Animal Feed Regulations. The potential for cattle to direct ingest material applied as surface dressing to grassland should also be assessed. It may also be necessary to consider additional exposure materials if waste material is proposed for alternative uses such as animal bedding.

It is also possible to conduct risk assessment of animal health in a similar way to dietary assessment for human health. This type of assessment is undertaken by the EFSA Panel on Contaminants in the Food Chain (CONTAM<sup>12</sup>). Exposure estimates for animals take into account the amount of feedstuffs consumed by the respective species, as well as the concentration of the particular contaminant in animal feed. Assessments of contaminants published by CONTAM detail assessment criteria for different animal species in the form of TDIs or no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs); these are compared with estimates of dietary intake resulting from consumption of animal feed.

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<sup>11</sup> FSA notes and guidance on animal feed legislation are available from: [http://food.gov.uk/business-industry/farmingfood/animalfeed/animalfeedlegislation/#.Uu\\_AGYKYbIU](http://food.gov.uk/business-industry/farmingfood/animalfeed/animalfeedlegislation/#.Uu_AGYKYbIU)

<sup>12</sup> Reports on various contaminants by CONTAM are available from: <http://www.efsa.europa.eu/en/contam/contamscdocs.htm>



# 7. Natural and manufactured comparators

## 7.1. What is a comparator?

The Environment Agency has collated and generated physicochemical data on a range of potential comparators that are likely to be applied to agricultural land. Data have also been sourced from existing sources.

Generated data include measures from at least 10 samples of non-waste material for physical properties, macro and trace nutrients and trace elements, and also measures from a gas chromatography–mass spectroscopy (GCMS) semi-volatile screen. The most important comparators for use in assisting in decisions in relation to end-of-waste derived materials intended to be applied to land include:

- inorganic fertilisers
- non-waste wood
- PAS100 compost
- peat
- soil improver
- straw

The Environment Agency has published a series of research reports to characterise non-waste materials as comparators for waste-derived materials ([www.gov.uk/government/publications/defining-product-comparators-to-use-when-applying-waste-derived-materials-to-land](http://www.gov.uk/government/publications/defining-product-comparators-to-use-when-applying-waste-derived-materials-to-land)).

As well as providing data, these reports give an indication of:

- what this material is a comparator for
- how data on a comparator might be collected and analysed
- which summary statistic could be used in the comparison

This information is likely to be very relevant where there is a need to collect data on the comparator where these do not already exist.

Where material is not being applied to agricultural land, such as is the case for a material used for a construction application, relevant data would need to be collected and collated. An example of this is given in Section 7.2 for recycled aggregates.

Whatever the comparator used, the comparison exercise must be supported by the data; that is, the depth of the interpretative assessment should be in proportion to the data availability and quality for the comparison.

## 7.2. Examples of using comparators

In the risk assessment that supported the recycled aggregates Quality Protocol, comparators were considered to be aggregates from natural gravel, limestone and granite. Leachate data for these aggregates were obtained from NEN 7371 (NEN 2004) and a joint report by INTRON and RIVM (de Wijs and Cleven 2008) in the Netherlands.

When using comparators, it is important to provide an appropriate context for these data. Table 7.1 shows the results from a comparison of a range of recycled aggregates with the same test procedure results from testing natural aggregates.

**Table 7.1 Comparison of chromium leached from natural aggregates and recycled aggregates from construction waste using NEN 7371:2004**

Material	CrVI <sup>+</sup> concentration in eluate 1 (µg/l)	Total Cr in solids measured by XRFS (mg/kg)	Calculated emission (mg/m <sup>2</sup> )	
			d = 0.1 m	d = 1 m
Brick-based recycled aggregate (coarse)	2.406	242	59.73	597.3
	1.324	173	32.4	324
	0.986	nd	25.57	255.7
	2.169	283	59.62	596.2
Brick-based recycled aggregate (fine)	2.023	220	46.96	469.6
	1.25	271	27.14	271.4
	1.427	147	33.7	337
	0.906	208	23.81	238.1
Asphalt-based recycled aggregate	0.985	80.8	20.94	209.4
	1.056	217	22.23	222.3
Concrete-based recycled aggregate (gravel)	1.601	203	40.47	404.7
Concrete-based recycled aggregate (limestone)	0.75	nd	19.37	193.7
Natural gravel	1.33	186	34.75	347.5
Limestone	2.021	nd	55.86	558.6
Granite	0.569	nd	15.15	151.5

Notes: nd = not detected; XRFS = X-ray fluorescence spectroscopy.

Source: Environment Agency (2013a)

Comparing the results for hexavalent chromium (the most hazardous chromium species to human health) from these tests for recycled and natural aggregates provides a line of evidence to assist in the determination of no worse environmental effect. These data suggest that releases of chromium from recycled aggregates are in a similar range to those from non-waste aggregates with the 90th percentile of values for recycled aggregates being 2.15 µg/l, which is close to the value for non-waste limestone aggregates.

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## 9. List of abbreviations

ABC	ambient background concentration
ALARP	As Low As Reasonably Practicable
BaP	benzo(a)pyrene
bw	bodyweight
DQRA	detailed quantitative risk assessment
DOC	dissolved organic carbon
DW	dry weight
DWS	Drinking Water Standards
EALs	Environmental Assessment Level
EQS	Environmental Quality Standards
ERA	environmental risk assessment
FSA	Food Standards Agency
GQRA	generic quantitative risk assessment
HCV	Health Criteria Value
HHRA	human health risk assessment
HI	hazard index
HQ	hazard quotient
ID	Index Dose
LS	liquid to solid [ratio]
MDI	mean daily intake
MRV	minimum reporting value
MSDS	material safety data sheet
OEL	occupational exposure level

PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
PCOC	potential chemical of concern
PEC	predicted environmental concentration
PLA	poultry litter ash
PNEC	predicted no effect concentration
RWC	reasonable worst case
RCR	risk characterisation ratio
STEL	short-term exposure limit
TDI	tolerable daily intake
TEF	toxicity equivalence factor
TWA	time-weighted average
UCL	upper confidence limit
WEL	workplace exposure limit
WHO	World Health Organization

# 10. Glossary

Ambient background concentration (ABC)	This refers to trace elements and can be considered a concentration in environmental matrices that is representative of relatively low levels of anthropogenic pressure.
Bioaccumulation	The increase in concentration of a substance in an organism over time.
Bioavailability	For environmental considerations it can mean a combination of the physicochemical factors governing chemical behaviour (the abiotic part) and the biological receptor, that is, its specific pathophysiological characteristics such as route of entry, and duration and frequency of exposure.
Conceptual model	This can be a textual or graphical representation of the relationship(s) between hazard source(s), pathway(s) and receptor(s) developed on the basis of problem formulation and refined during subsequent risk assessment phases.
Contaminants/chemicals	Legal documents and directives may refer to substances or contaminants, but in the majority of cases these are chemicals. The term 'chemical' is used throughout this document in line with much of the European chemicals regulatory risk assessment guidance.
Effects	Effects is a term used for the environmental or ecological effects of a chemical, usually derived from laboratory ecotoxicity data and a method of extrapolation to give a limit value for an environmental receptor.
Environmental Quality Standards (EQS)	These are thresholds which, if exceeded, could result in adverse effects on ecosystems and human health from chemical and biological agents in surface waters.
Exposure	The nature and level of a situation or biological, chemical or physical agent that any component (landscape, water body, animal and so on) may be subjected to intentionally or non-intentionally. In human health assessments, it is quantified as the amount of a chemical or biological agent that is available for intake by a target receptor or population.
Hazard	A situation or biological, chemical or physical agent that may lead to harm or cause adverse effects.
Health Criteria Value (HCV)	This is a generic term used to describe a benchmark level of exposure to a chemical derived from available toxicity data for the purposes of safeguarding human health (for example, a tolerable daily intake).
Predicted environmental concentration (PEC)	Often used as an estimate of exposure concentrations.

Predicted no effect concentration (PNEC)	This concentration is derived from ecotoxicological data and an extrapolation step.
Reasonable worst case (RWC)	A realistic situation, scenario or set of circumstances that represents relatively precautionary conditions and for which the balance of risks favours the receptor.
Risk	The consequence(s) of a hazard(s) being realised and their likelihoods or probabilities.
Risk assessment	The formal process of evaluating the consequence(s) of a hazard(s) being realised and their likelihoods/probabilities.
Risk characterisation ratio (RCR)	Also sometimes called the risk quotient. This is calculated by dividing the PEC by the PNEC. Values $\geq 1$ present a potential risk.
Source term	This is the concentration of a chemical, generated or estimated from the leachate test that is used to calculate exposure concentrations to ground and surface waters.
Trophic level	Position occupied in the food chain
Waste	'...any substance or object which the holder discards or intends or is required to discard'  Source: Directive 2008/98/EC