Project UKCC02

Environmental Legislation and Human Health – Guidance for Assessing Risk

August 2007

Environment & Heritage Service
www.ehsni.gov.uk
An Agency within the Department of the Environment
www.doeni.gov.uk
SEPA
Scottish Environment Protection Agency
Health Protection Scotland
SNIFFER
SCOTLAND & NORTHERN IRELAND FORUM FOR ENVIRONMENTAL RESEARCH

Dissemination status
Unrestricted

Project funders
Scotland & Northern Ireland Forum for Environmental Research (SNIFFER)

Whilst this document is considered to represent the best available scientific information and expert opinion available at the stage of completion of the report, it does not necessarily represent the final or policy positions of the project funders.

Research contractor
This document was produced by:

Land Quality Management Ltd
Unit 8, The Business Park
Technology Drive, Beeston
NOTTINGHAM NG9 2ND
UK

SNIFFER's project manager
SNIFFER's project manager for this contract is:

Chinny Iroegbu, Scottish Environment Protection Agency (SEPA)

SNIFFER's project steering group members are:

Paula Charleson, Scottish Environment Protection Agency (SEPA)
Theresa Kearney, Environment and Heritage Service (EHS)
Liz Smyth, Environment and Heritage Service (EHS)
Colin Ramsay, Health Protection Scotland (HPS)
Gina Martin, Scotland & Northern Ireland Forum for Environmental Research (SNIFFER)

SNIFFER
First Floor, Greenside House
25 Greenside Place
EDINBURGH EH1 3AA
Scotland
UK

Company No: SC149513
Scottish Charity: SCO22375

www.sniffer.org.uk

GLOSSARY

Hazard	A property or situation that in particular circumstances could lead to harm.
Conceptual Model	A representation of the characteristics of the situation that shows possible relationships between sources, pathways and receptors.
Detailed Quantitative Risk Assessment (DQRA)	Risk assessment carried out using detailed site specific information to estimate risk or to develop site specific assessment criteria.
Generic Assessment Criteria (GAC)	Criteria derived using generic assumptions about the characteristics and behaviour of sources, pathways and receptors. These assumptions will be protective in a range of defined conditions.
Generic Quantitative Risk Assessment (GQRA)	Risk assessment carried out using generic assumptions to estimate risk or to develop generic assessment criteria.
Harm	Adverse effects on the health of a living organism.
Hazard Assessment	A conceptual stage of risk assessment concerned with assessing the degree of hazard associated with the circumstances under consideration.
Hazard Identification	A conceptual stage of risk assessment concerned with identifying and characterising the hazards that may be associated with the circumstances under consideration.
Health Criteria Value (HCV)	Benchmark criteria that represent an assessment of levels of exposure that do not pose a risk to human health.
Pathway	The means by which a hazardous substance comes in contact with a receptor.
Receptor	The entity which is vulnerable to the adverse effect of a hazardous substance (e.g. human health).
Risk	A combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence.
Risk Assessment	The formal process of identifying, assessing and evaluating the health and environmental risks that may be associated with a hazard.
Risk Estimation	A conceptual stage of risk assessment concerned with estimating the likelihood that an adverse effect will result from exposure of the receptor to the hazardous substance.

Risk Evaluation	A conceptual stage of risk assessment concerned with evaluating the acceptability of estimated risk taking into account the nature and scale of risk estimates, any uncertainties associated with the estimate and the broad costs and benefits of taking action to mitigate the risk.
Risk Management	The process whereby decisions are made to accept a known or assessed risk and/or the implementation of action to reduce the consequences or probabilities of occurrence.
Site Specific Assessment Criteria (SSAC)	Values for concentrations of contaminants that have been derived using detailed site specific information on the characteristics and behaviour of sources, pathways and receptors and that correspond to relevant criteria in relation to harm or pollution for deciding whether there is an unacceptable risk.
Source	A hazardous substance that is capable of causing harm.
Uncertainty	A lack of knowledge about specific factors in a risk assessment including parameter uncertainty, model uncertainty and scenario uncertainty.

ACRONYMS

ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
AQS	Air Quality Standard
BAT	Best Available Technique
COSHH	Control of Substances Hazardous to Health
DQRA	Detailed Quantitative Risk Assessment
DWS	Drinking Water Standard
EAL	Environmental Assessment Level
EQS	Environmental Quality Standard
GAC	Generic Assessment Criteria
GQRA	Generic Quantitative Risk Assessment
GV	Guideline Value
HCV	Health Criteria Value
HPS	Health Protection Scotland
RSGV	Radioactivity in Soil Guideline Value
SGV	Soil Guideline Value
SSAC	Site Specific Assessment Criteria
WHO	World Health Organisation

TABLE OF CONTENTS

List of Tables

List of Figures

APPENDICES

1 PURPOSE OF THIS GUIDANCE

This guidance aims to raise the awareness of the need to protect human health and presents a simple risk assessment methodology that could be applied to address some of the specific gaps in the current guidance documents identified in the initial stages of this project as reported in SNIFFER (2007)[1].

It also seeks to provide some clarity with respect to the regulatory criteria for the protection of human health as the lack of transparency on the origins of regulatory criteria leading to doubt as to whether human health is adequately protected was identified as a gap.

This document does not seek to address identified gaps in the guidance relating to the wider regulatory frameworks of sustainable development and human rights or on risk communication but will signpost the user to existing guidance. It is likely the agencies will need to develop further guidance on these issues.

1.1 How to use this guidance

This guidance forms a generic technical framework and may be adapted for application within the specific environmental legislative regimes. It is not intended that this guidance will replace existing good practice guidance for the protection of human health where available under the specific regimes, e.g. contaminated land.

In applying this guidance it is imperative the user takes account of the particular legislative context within which the work is being carried out.

1.2 Structure of this guidance

Section 1 outlines the purpose of this guidance. Section 2 provides an overview of the risk assessment process. Section 3 presents a tiered methodology for assessing risks to human health and signposts users to existing information and guidance that may be of relevance. Details of other health-based organisations that may be able to provide some assistance and/or expertise are given in Section 4.

1.3 What does this guidance do?

The environment agencies recognise the explicit consideration of human health impacts is a relatively new area of work to some of their staff and there may be skills gaps that need to be addressed to enable robust, transparent and consistent regulation.

This document outlines a tiered methodology for assessing risks to human health and signposts currently available information that may assist decision-making.

Assessing risks to, or impacts on, human health is technically complex and requires the consideration of many influencing factors on a site specific basis. It can also be an emotive area of work influenced by risk perception and involving risk communication. This guidance assumes that users will have access to other resources e.g. in-house human health experts or external advisory bodies to assist in drawing conclusions on a site specific basis.

[1] Assessment of Environmental Legislative and Associated Guidance Requirements for the Protection of Human Health. SNIFFER Project Reference UKCC02 (SNIFFER, 2007)

It is likely agency staff already consider the potential risks to human health in their regulatory functions although the assessment may not be undertaken in a formal manner. Information relevant to the assessment of human health risks will have been supplied to the agencies in many forms e.g. as part of the PPC application process and this guidance directs the user to these readily available sources of information. This guidance seeks to provide a framework to enable the extraction and use of relevant data in a logical and transparent way enabling robust decision making.

1.4 Legislative Context

The legislative context can vary across the different administrative regions and SNIFFER (2007) reports on the identification of the requirements for the various environmental frameworks across the regions.

This guidance is intended to be applicable across all regions although as part of the risk assessment process the user must check the legislative context for the region in which they are working.

Throughout this guidance the user is signposted to other documents that may be helpful in assessing potential risks to human health and available at the time of publication of this document. It is the responsibility of the user to ensure they are using the most up-to-date guidance and standards. The references provided here are not intended to represent an exhaustive list.

This guidance is concerned only with the environment agencies roles and responsibilities for protection of human health and therefore does not cover workplace health and safety or occupational exposure.

1.5 Target Audience

This guidance is aimed primarily at the staff of the environment agencies who need to be familiar with how to meet the requirements for the protection of human health under the relevant environmental legislative regimes. It will also be of use to other stakeholders including the regulated community e.g. applicants and other bodies that the agencies are required to consult with when fulfilling their roles and responsibilities. These may include the health boards, the NI health and social services boards and local authorities amongst others.

It is intended that this guidance will be of benefit to users who undertake and/or review human health risk assessments.

2 THE RISK ASSESSMENT APPROACH

2.1 The UK approach to risk assessment

The UK has adopted a risk-based approach to preventing or minimising environment damage or loss including the protection of human health. This generic approach to environmental management is emphasised in the guidance document "Guidelines for Environmental Risk Assessment and Management[2]" (DETR, 2000). The document – commonly referred to as Greenleaves II - provides a framework for the development of functional technical risk assessment guidance by the regulators, which will inevitably be geared towards specific sectors such as waste management, major accident hazards, contaminated land etc. Much existing guidance consistent with the approach in DETR (2000) adopts a tiered approach to risk assessment and recognises that risk assessment, management and communication are essential tools in the decision-making processes relevant to environmental management.

In all risk assessment there will be a degree of uncertainty and this must be taken into account in the decision-making process. It may also be necessary to undertake a cost benefit analysis as part of the risk assessment process.

> Hazard is a property or situation that in particular circumstances could lead to harm.
>
> Risk is a combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence.
>
> Guidelines for Environmental Risk Assessment and Management (DETR, 2000)

Human health risk assessment considers the magnitude of a hazard and the vulnerability of human health. The consequences would be in terms of the response to a given dose and could include sickness, disease, increased cancer incidence or death.

> If there is no hazard or no consequence there is by definition no risk. So for example if exposure to a particular chemical is not possible then there is no risk.

A prerequisite for any risk assessment is what level of risk any given legislative regime deems to be unacceptable and therefore requires risk mitigation measures to be taken.

> The risk assessment approach is intended to be
>
> - practical,
> - cost effective,
> - proportionate i.e. the effort expended in assessing the potential risk should be proportionate to its seriousness, and
> - iterative

To assist the approach, it is broken down into a series of 'tiers' – preliminary, generic and detailed quantitative (site specific) risk assessment. The preliminary tier identifies the potential sources (e.g. emissions, concentrations in soil etc), the potential receptors who

[2] Guidelines for Environmental Risk Assessment and Management (DETR, 2000)

may be affected and the potential pathways through which exposure may occur (e.g. inhalation of dusts etc). The generic tier uses appropriate generic guidelines or standards to determine whether the level of the substance in the environmental media is acceptable.

The guideline or standard must of course be protective of human health. Where the generic tier indicates there is no unacceptable level of risk it is not necessary to undertake any further assessment. Where the generic tier indicates the level of risk may be unacceptable or there is no appropriate guideline/standard available for assessing risks to human health it may be necessary to progress to detailed risk assessment. This tier will take even greater account of individual site circumstances and may demonstrate an acceptable standard for use at this particular site or determine whether the existing concentration in environmental media is acceptable.

The risk assessment process is explored in detail in Section 3.

2.1.1 Specific Guidance for Assessing Risks to Human Health

Guidance available under specific regimes for assessing impacts on human health and the environment generally utilises a risk-based approach. Guidance relevant to PPC, waste management and the contaminated land regime all make specific reference to the principles contained in DETR (2000).

As reported in SNIFFER (2007) the currently available guidance for assessing risk to human health is more effective under some of the specific environmental legislative regimes than others. For example under the contaminated land regime there is specific guidance on assessing risks to human health from contaminants in soils whereas under some of the other regimes the requirement to protect human health is less obvious with the emphasis on complying with environmental standards or guidelines which may or may not be health based. This lack of explicit consideration of human health resulted in the guidance user questioning whether human health was adequately or even overly protected. Appendix II contains details of human health related guidance available under the specific regimes.

Table 1 below provides an overview of some of the existing standards applied across the regimes together with an indication of the basis of the standard.

Table 1 : Summary of existing regulatory standards with reference to the protection of human health

Legislative Context	Standards Applied	Basis of the standards
*PPC/IPC/COMAH	Environmental Quality Standards for air and surface water	EQS for air usually based on World Health Organisation (WHO) air quality guidelines – which are developed to protect human health
	Environmental Assessment Levels for air and surface water	EALs for air based on modified occupational exposure limits, air quality standards or WHO air quality guidelines EQS and EAL for surface water based on aquatic organisms and ecotoxicity
	Drinking Water Standards	Usually based on WHO guidelines for drinking water quality - a guideline value that represents the concentration of constituent that does not result in any significant risk to the consumer over a lifetime of exposure
	Emission Limit Values	Usually based on BAT which may although not always relate specifically to the protection of human health.
	National Air Quality Objectives Expert Panel on Air Quality Standards	Usually human health based - some are based on occupational exposures
	Thresholds for bacterial endotoxins	Usually based on human toxicological data
	Noise Guidelines	Some consideration of human health, may also be set relative to background exposure
Radioactive Substances	Legal dose limits and defined dose constraints	Human health based
	RSGVs (draft) for radioactivity in soil	Also requirement to keep exposure as low as reasonably achievable - ALARA

Contaminated Land	UK Soil Guideline Values Generic assessment criteria produced by others e.g. LQM/CIEH Site specific assessment criteria	Derivation of human toxicological benchmarks for contaminants of concern combined with a consideration of receptor exposure
Waste Management	Emission limits (landfill surface and engine emissions) e.g. lateral emissions and odour	Some are achievable standards with no direct link to human health; others are based on human health
	Classifications: Waste Acceptance Criteria Approved Supply List European Waste Catalogue Wastes that may possess one or more hazardous properties	Take account of potential human health impacts e.g. explosive, oxidising, flammable, toxic, harmful, irritant, corrosive, carcinogenic, mutagenic, toxic for reproduction, infectious, produces toxic gases
Water Environment	UK Drinking Water Standards	Usually based on human toxicological data
	WHO Drinking Water Standards	Usually based on World Health Organisation guidelines for drinking water quality
	Imperative & Guide Standards (bathing, surface and shellfish waters	Usually applicable to surface waters – concentration of specific substance that is protective of aquatic life
	Environmental Quality Standards (water)	Usually based on a consideration of vulnerable ecosystems

* SNIFFER project UKCC01 covers the derivation of health based environmental quality threshold criteria for PPC licensing in more detail: Development of a Methodology for use by Staff Assessing Impacts on Human Health Associated with PPC Licensing. SNIFFER Project Ref: UKCC01 (SNIFFER, 2006a)

2.1.2 The development of regulatory standards

Regulatory standards are generally set to either control emissions to environmental media and/or protect a vulnerable receptor e.g. human beings, water environment or ecosystems. As indicated in Table 1 existing standards may be health based or environmental. Not all substance specific standards have the same basis as the impact on human health and/or the environment will vary as will the availability of information relevant to each substance.

Standards are usually a combination of science and policy. The science considers the substance i.e. its properties and behaviour in the environment and the receptor i.e. how exposure occurs and its likely impact. Whereas policy influences will include a consideration of society's attitude to risk, achievability, costs and benefits to the environment and society, economic growth and wider issues such as sustainability.

Some regulatory standards are encased in primary legislation and are therefore mandatory i.e. there is a legal requirement to meet the standard and failure to do so is an offence. Others are issued in the form of guidance to demonstrate compliance with a legislative requirement and achieving this type of standard may be good practice but it is not mandatory and non compliance alone would not constitute an offence.

It is also important to understand the purpose of the standard – some are screening criteria i.e. below this level there is no unacceptable level of risk and no further action is required and others are action levels i.e. above this level there is an unacceptable level of risk and risk management measures need to be instigated.

2.1.3 Toxicological Data

Where environmental standards for the protection of human health are available they are usually underpinned by toxicological data. "Toxicology is the study of the adverse effects of chemical, physical or biological agents on living organisms and the ecosystem, including the prevention and amelioration of such adverse effects" (http://www.toxicology.org/).

"Toxicology is the science of disease induced by chemicals present in the diet, medicines, the environment and the workplace" (The British Toxicology Society: http://www.thebts.org)

Assessing the potential human health impacts of a substance or group of substances requires an understanding of the toxicological properties of that substance or group of substances.

The availability and reliability of toxicological data varies between substances and for some there is no reliable data at all. Human toxicological data can be derived from a number of sources with laboratory studies on bred-for-purpose animals and human epidemiological studies as the most likely. The various sources have advantages and disadvantages that must be taken into account when determining the suitability of the data for use in a risk assessment.

It is important to recognise the complexities of deriving toxicological data inputs for use in human health risk assessment. Substances may have different adverse effects depending on the route of entry into the body (oral, inhalation and dermal). They may cause threshold effects (there is an acceptable level of exposure) e.g. trichloroethene via the

inhalation route, or non-threshold effects (there is no acceptable level of exposure) e.g. benzene via the inhalation route of entry, or both – and the assessment and evaluation of risk needs to reflect these behaviours. For some substances the effects on the body are fairly well understood and documented whereas for others less is known e.g. the impact may be known but the mode of action poorly defined.

In deriving appropriate toxicological inputs the risk assessment community often relies on the opinions of authoritative bodies such as the Department of Health, the Health Protection Agencies (associated committees), relevant EU Scientific Committees and the World Health Organisation among others. It may not always be possible to source an opinion of an authoritative body thus necessitating a consideration of the study data e.g. the dose-response results of the animal study combined with a consideration of uncertainty (and the resulting application of uncertainty or safety factors) for the derivation of toxicological data inputs for human health. This requires a thorough understanding of the principles of toxicology and it is recommended in this instance the user seeks specialist advice from a suitably experienced toxicologist or human health risk assessor.

It is usually the case that people may be exposed to more than one substance but knowledge of the toxicity of groups of substances is rarely available. Toxicological benchmarks have been set for some groups of substances which are usually found as mixtures (e.g. dioxins or petroleum hydrocarbons). In general where substances displaying threshold effects are believed to affect the same target organ via the same toxicological pathway it may be necessary to consider additive effects. This is particularly the case where the exposure approaches the health criteria values of individual substances. Where substances display non-threshold effects (Defra and Environment Agency (2002a) guidance states a consideration of combined effects is a matter for expert judgement.

One of the series of technical guidance documents developed to support the contaminated land regime CLR 9 provides a framework for deriving toxicological data and intake values for humans (Defra and Environment Agency, 2002a) for use in derivation of soil contaminant intakes that are protective of human health (e.g. the Defra/Environment Agency Soil Guideline Values (Defra and Environment Agency 2002-2004) or LQM/CIEH Generic Assessment Criteria (Nathanail *et al*, 2007)). Although developed to support the contaminated land regime the principles could be applied in other regimes. The document provides a hierarchy of information sources for the derivation of toxicological data prioritising UK sources of information where available. As part of the CLR series of reports, Defra and Environment Agency have published toxicological (TOX) reports for twenty-four substances including metals, chlorinated solvents and hydrocarbons for use in assessing risks to human health from land contamination. The list of currently available TOX reports is provided in Appendix I.

It should be noted that issues surrounding the derivation of toxicological data inputs and the determination of acceptable levels of risk for different types of substances in the contaminated land context are currently under discussion. The Defra 'Way Forward' discussion paper (Defra, 2006) outlined emerging conclusions and the consultation period for this paper ended in February 2007. It is anticipated that the outcome of the consultation and any required changes to existing policy will be made available on the Defra website (http://www.defra.gov.uk) in due course.

Even where toxicological information for a substance is well defined it may be difficult to

prove a causal link with a potential source as other contributory factors may be present e.g. smoking, occupational exposure, genetics etc. It will be necessary to seek specialist advice. Section 4 provides an overview of some health-based organisations that may be of assistance.

2.1.4 Epidemiology

Epidemiology is the science of studying populations and their characteristics in relation to distribution patterns of disease and their potential causes. Descriptive epidemiology is conventionally used to "describe" the pattern of ill health within a defined population and to describe the distribution of "risk" factors (e.g. exposure to an environmental agent), which might explain the distribution of that particular disease. Epidemiological studies may provide evidence that certain patterns of illness are related to exposure to certain levels of a specific environmental agent.

Ideally when considering the human health risks associated with exposure to chemicals, physical or biological agents, a risk assessment would be based on robust toxicological information relating to that specific agent. However, human toxicological data is often very limited and may rely on the extrapolation of animal toxicology data, incorporating relevant uncertainty (safety) factors, in order to derive tolerable human exposure thresholds. Epidemiological data may be available to supplement limited toxicological data or may be the only form of objective data upon which to base a risk assessment.

However, epidemiological data may also be very limited or may have to be interpreted with great caution, especially where the data is derived from studies of populations, which are not directly comparable to the identified "receptors" in a local case.

Epidemiological data is inherently limited in that it cannot categorically define a "cause" and "effect" relationship between an illness and an agent (e.g. a chemical). The most that epidemiological data can show is the relative strength of association between exposure to an environmental agent and the probability of having a particular illness or health status.

The strength of association between exposure to a possible risk factor and having a health effect, varies depending of the type of study carried out. The strongest type of evidence is derived from a "cohort" type study where a defined population is studied over a period of time to find out who develops an illness. This allows an "incidence rate" to be calculated (e.g. the number of new cases per thousand). Comparing the incidence in people who were exposed to an agent (e.g. tobacco smoke) with those who were not gives the "relative risk" of developing the illness if exposed to that agent. A relative risk of greater than one implies that exposure to that agent carries an increased risk of developing the illness. The higher above one the relative risk is, the stronger is the evidence that the risk of illness is associated to exposure to the agent in question. However, it is highly unlikely that a cohort study has been or will be carried out in the local population of concern to discover the local relative risk. Published studies therefore generally have to be used as proxies.

The next best type of epidemiological evidence is derived from a "case/control" study. In this scenario "cases" of a particular illness are identified and their exposure to a particular agent is investigated. The frequency with which cases report exposure to the agent (the risk factor) is then compared to the frequency in a group of well people (the controls) to calculate the "odds ratio", i.e. the ratio of the probability of having the disease if a person was exposed to the agent compared to the probability of illness if a person was not exposed to the agent. An odds ratio of greater than one implies an increased risk of illness among those exposed to the agent. The higher above one the odds ratio is the more the

risk is increased. Again it is highly unlikely that a specific case/control study will have been carried out in a local population, hence published data may be all that is available.

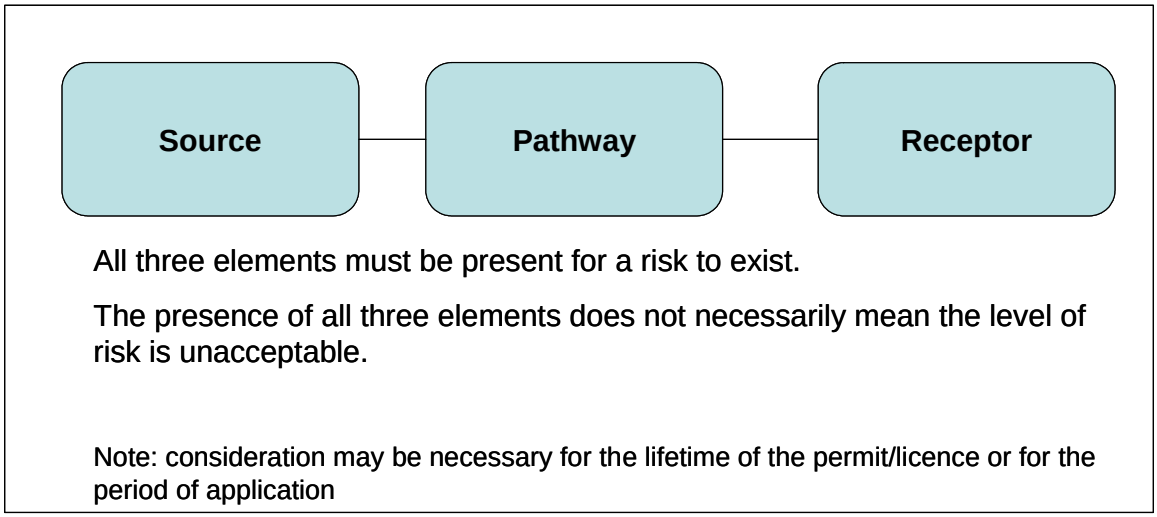
Other types of epidemiological study produce much weaker evidence which should be interpreted very cautiously, especially a “case series” where a number of cases of the same illness have been identified in a locality or over a time period, possibly forming an alleged “cluster”. It is generally not possible to derive meaningful inferences on the effect of exposure to a particular chemical or other agent from such case series. The most that can usually be attempted is to try to calculate an incidence rate for that locality using routinely available health data and compare that to a standard population (e.g. the incidence rate for all of Scotland) to see if there is a statistically significant difference.

Using epidemiological data is therefore problematic and requires careful evaluation. Expert guidance should normally be sought to assist its interpretation.

2.2 Assessing risks to human health

For an environmental risk to exist there must be a source of contamination, a receptor and a pathway(s) linking the two i.e. the pollutant linkage.

Figure 1 : Source-pathway-receptor paradigm



As an example Table 1 below outlines some source, pathway and receptor considerations for an emission to air. The relevant considerations need to be defined on a site specific basis.

It is important to recognise the risk assessment process may not always provide a definitive answer. For example it is possible that scientific knowledge for a particular circumstance may be limited and any decisions are based on the best available information. Decisions may have to be made on the basis of the information currently available and revised in light of new findings. Some legal regimes explicitly recognise this and impose restrictions on the minimum amount of certainty required for a decision to be taken. For example the contaminated land regime requires a contaminated land determination to be made if the Local Authority considers a significant pollutant linkage is present ‘on the balance of probabilities’ (Scottish Executive, 2006).

Table 2: Source-pathway-receptor considerations for an emission to air

Source	Pathway	Receptor
What is (are) the substance(s) of concern? What are the substance(s) properties e.g. physical and chemical state and toxicity? How is it likely to behave in the environment (persistent, mobile, volatile, bioaccumulate etc)? Where is it coming from e.g. a chimney at *x*m above ground Are there any abatement measures in place?	What is the direction of the emission relative to the receptor? Are there any barriers to transfer? What is the predominant wind direction? What is the likely wind speed? Are there seasonal effects?	Who is likely to be affected - there may be more than one receptor or group of receptors? Who is likely to be the most critical – there may be more vulnerable groups e.g. children Are there any other possible sources e.g. industrial, natural, lifestyle sources that may need to be taken into account?

2.2.1 The Conceptual Model

The conceptual model represents the characteristics of the site in diagrammatic and/or written form. It should show the possible relationships between the sources, pathways and receptors i.e. the pollutant linkages. The conceptual model can be presented in a variety of ways usually a combination of pictorial representation, simple network diagrams illustrating the potential pollutant linkages and accompanying text.

Risk assessment guidance (Environment Agency, 2004a) and some British Standards emphasise the need to develop a conceptual model detailing the pollutant linkages and the associated uncertainties at all stages of the assessment.

The initial conceptual model will be refined during the subsequent stages as more information becomes available.

2.2.2 Objectives

It will also be necessary to clearly define the objective of the risk assessment. Having a clearly defined objective will allow logical, transparent, resource-efficient and focussed decision-making. Table 3 outlines some objectives under the specific regimes.

Table 3 : Objectives under the specific environmental legislative frameworks

Legislative Context	Objectives
PPC/IPPC/COMAH	What is the likely risk to the nearby population from a release to environmental media? What is the likelihood of an accident?
Radioactive Substances	Does the effective dose exceed the regulatory criteria?
Contaminated Land	Does the concentration of contaminant in soil pose an unacceptable level of risk to the defined receptor?
Waste Management	Is there a risk to the nearby residents from waste management operations at this site?
Water Environment	Is there a risk to the recreational users of this surface water body? Is the surface/ground water body used for drinking water abstraction – is there a risk to the end-user?

3 GUIDANCE FOR ASSESSING RISKS TO HUMAN HEALTH

3.1 Types of Risk Assessment

The risk assessment approach can either be ***qualitative*** or ***quantitative***.

In the assessment of risks to human health it is more common to use quantitative techniques usually involving the use of a risk assessment tool to model generic assumptions and produce generic assessment criteria or to model the site-specific characteristics of the situation and provide an estimate of the likely risk to the receptor. It may not always be appropriate or indeed possible to quantify aspects of the pollutant linkage and it may be necessary to rely on qualitative techniques to examine the relationships between the three elements of the risk assessment and inform a decision on the likelihood of an occurrence. For example when assessing the likelihood of accidents or major incidents qualitative techniques involving an assessment of the probability of occurrence and magnitude of the consequences are normally undertaken.

Risk assessment comprises three tiers – preliminary, generic and detailed quantitative risk assessment.

Tier 1 – **Preliminary Risk Assessment** – identification of the potential sources, the potential receptors and the potential pathways linking the two, including development of the initial conceptual model.

The preliminary risk assessment tier is generally a qualitative assessment of the available information to enable the development of the initial conceptual model and identification of the associated uncertainties and/or information gaps.

Tier 2 – **Generic Quantitative Risk Assessment** - generally involves comparison of site-specific data e.g. emissions data, soil concentrations, concentrations in water with a guideline value or standard (generic assessment criteria).

Generic assessment criteria (GAC) are based on generic assumptions regarding the source, pathway and receptor and are usually conservative by nature and can be applied across a range of sites.

Tier 3 – **Detailed Quantitative Risk Assessment** - usually involves the development of site-specific assessment criteria taking account of the circumstances of a particular site.

There are a number of reasons why it may be necessary to undertake this more detailed assessment including lack of appropriate generic assessment criteria or an exceedance of a generic assessment criterion.

The following sections outline the four stages in the risk assessment process. Further consideration of generic and detailed quantitative risk assessment under the specific regimes is provided in Sections 3.10 & 3.11.

3.2 The Four Stages of Risk Assessment

The assessment of risk in each tier – generic and detailed - can be broken down into four stages (DETR, 2000) as indicated in Figure 2a. The four stages are:

- Hazard identification – what is (are) the substance(s) of concern?
- Hazard assessment – what is context e.g. proximity to sensitive receptors etc and what are the properties of the hazardous substance(s)?
- Risk estimation – how much reaches the receptor? How does that exposure (numerically) compare with relevant health criteria values?
- Risk evaluation - does the exposure pose an unacceptable level of risk under the specific legal regime or decision making context?

There will be a degree of uncertainty associated with the process and it is important to define this uncertainty – where has it arisen from and what is the likely impact on the overall outcome. Uncertainty is discussed in more detail in Section 3.12.

Where the risk assessment process indicates an unacceptable level of risk to the defined receptor it will be necessary to manage the risk. This could involve the removal/treatment of the source, the protection/removal of the receptor or breaking the pathway.

Figure 2b provides a more detailed breakdown of the process.

Figure 2a: An outline of the risk assessment process

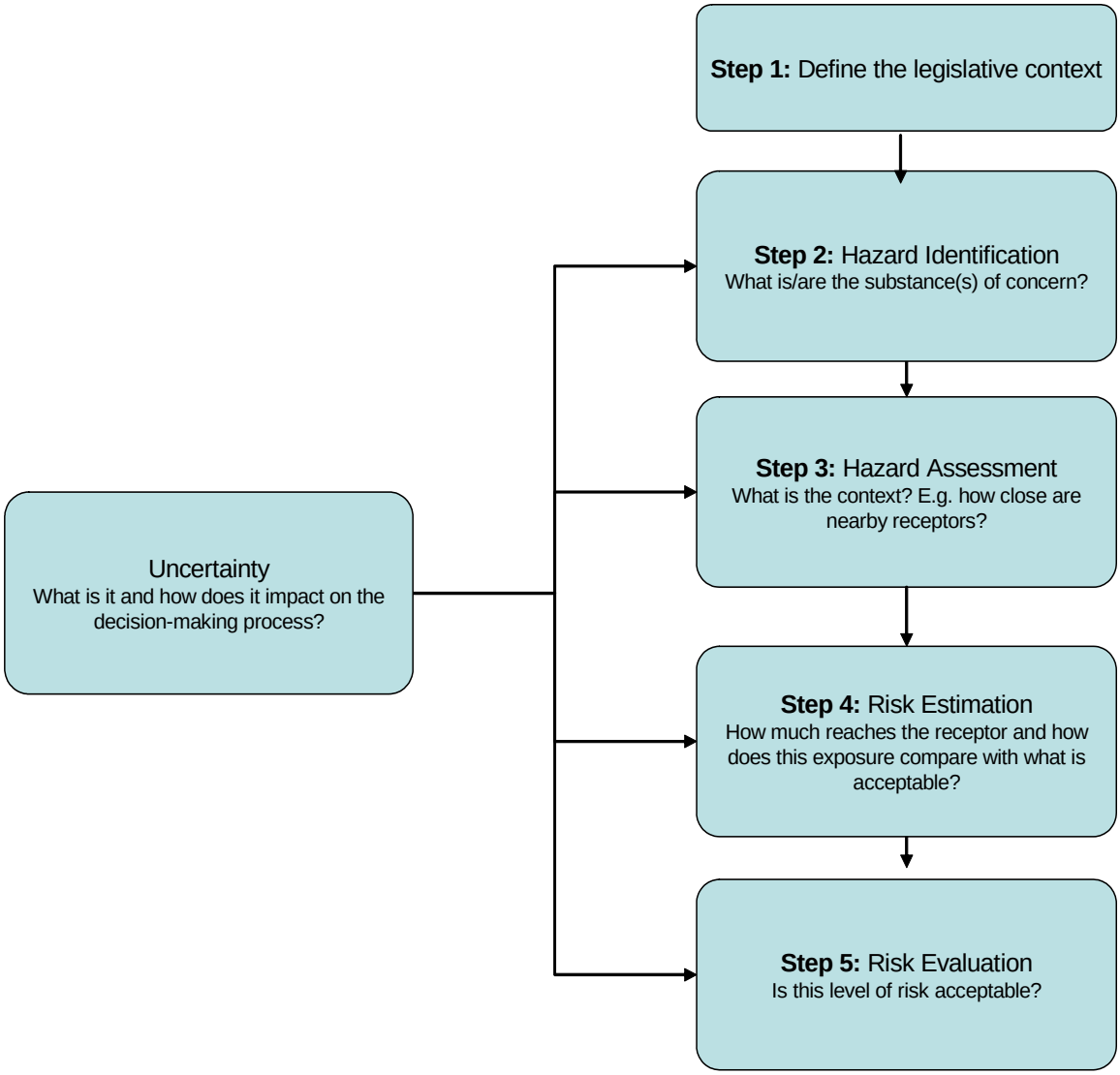
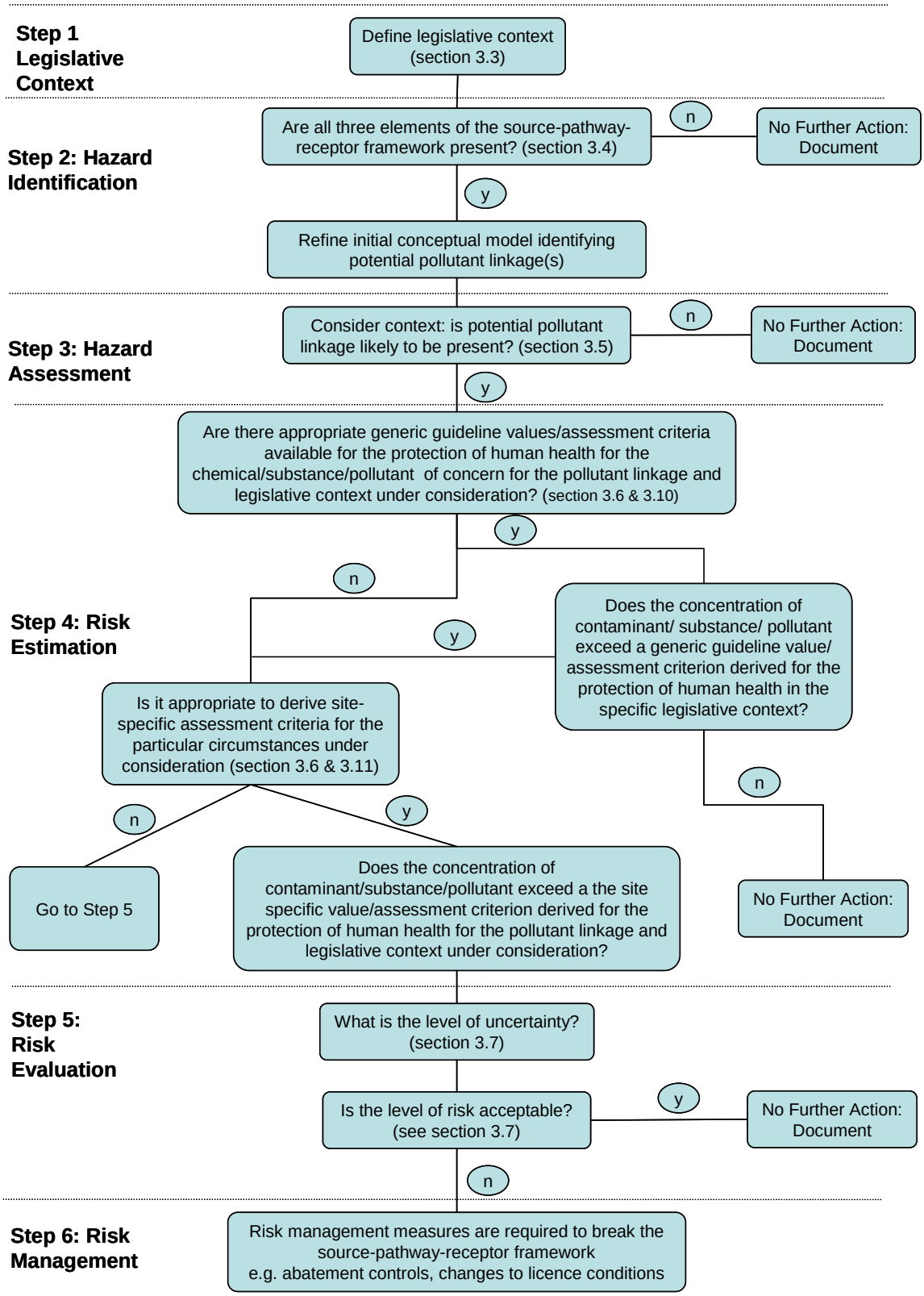


Figure 2b Detailed breakdown of the risk assessment process



3.3 Step 1 - Define the Legislative Context

The first step in assessing risks to human health is to establish the legislative context which will determine the constraints under which the work will be undertaken. It will also define the standard to be achieved.

Establish the legislative context and define the objective(s) of the work.

What are the legislative constraints?

What are the standards to be achieved?

For example, the contaminated land regime refers to and defines the "significant possibility of significant harm (to human beings)" whereas the PPC regime makes reference to but does not define "no significant pollution".

Some of the specific regimes require consideration of guiding principles for the protection of human health and the environment including Best Available Techniques (BAT) under the PPC regime, As Low As Reasonably Practicable (ALARP) used in the contaminated land regime for certain types of substance and As Low As Reasonably Achievable (ALARA) used when dealing with radioactive substances. The status of the guiding principle needs to be made clear e.g. adherence to an environmental standard may indicate the achievement of the guiding principles; or adherence may indicate the minimum standard and demonstration of further steps towards achieving the guiding principle is required.

3.4 Step 2 - Hazard Identification

This initial stage focuses on identifying the potential hazards:

- what are the substances/pollutants/contaminants of concern (i.e. the source(s))?
- the hazard could be natural or anthropogenic (man-made); some legal regimes make no differentiation while others only consider man-made contamination;
- what are the particular circumstances under consideration e.g. an emission, leachate, in soil?
- who may be impacted (i.e. the receptor(s))?
- how may they be impacted via inhalation (of dusts, gases, vapours), ingestion (of contaminated soils, homegrown produce, water), and/or dermal contact (with contaminated soils, water, dusts) (i.e. the pathways)?

Information relevant to the identification of hazards may be readily available. Table 4 identifies some of the potential sources of information under the specific regimes.

Table 4 : Potential sources of information for the identification of hazards

Legislative Context	Potential source of Information
PPC/IPC/COMAH	Information provided as part of a PPC application including Manufacture Safety Data Sheets; COSHH assessments, emissions and monitoring data, environmental impact assessment, accident management plans, site closure plans
Radioactive Substances	Information provided with the application for authorisation
Contaminated Land	Desk study reports; Site investigation information
Waste Management	Information provided with the application for a waste management licence or exemption (e.g. the working plan); routine monitoring data e.g. leachates and emissions
Water Environment	Monitoring data, emission inventory for releases to surface, ground or coastal water

It should be noted that information on the manufacturer safety data sheets is generally restricted to raw and pure materials. The hazard identification will also need to include substances that may be formed as intermediary or by-products including gases and vapours. This type of assessment will be required under Control of Substances Hazardous to Health (COSHH) and should be provided by the operator.

There may be other information available on a site specific basis e.g. information from baseline surveys or monitoring data held by the environment agencies.

In addition to identifying potential hazards it is also necessary to identify the likely sensitive receptors e.g. local residents, schools children, hospital patients, office workers, users of parks, playing fields and open spaces. Again this information is usually provided in the sources of information identified in Table 4 e.g. the application process for a permit or licence under the specific regimes will require the operator to have regard to nearby receptors.

3.5 Step 3 - Hazard Assessment

This stage looks more closely at the conceptual model seeking to establish the likelihood of the existence of the potential pollutant linkages. This could include

- the consideration of existing abatement measures for the prevention or reduction of emissions to the environment;
- the substance properties e.g. the physical and chemical state, toxicity
- is exposure intermittent or continuous?
- what is the spatial scale e.g. is it a localised effect or more widespread?
- what is the likely duration?
- fate and transport of the substance in the environment e.g. potential for aerial deposition, release to the water environment, behaviour in the soil etc.
- behaviour of the receptor e.g. how often are they likely to be exposed?

Many factors will influence the assessment of potential hazards and the decision relating

to the possibility of the existence of a pollutant linkage. In undertaking the assessment it is important to consider all three elements i.e. the source, the pathway and the receptor.

Table 5 outlines potential sources of information which may be of assistance in hazard assessment.

The decision making process must be robust, transparent and well documented. It will also need to take account of any uncertainties.

There will be uncertainties and these need to be considered e.g. lack of information. Some of the uncertainty may be addressed in the next stages of the assessment. It is important not to be overly cautious in the consideration of uncertainty as this will result in creeping conservatism in the overall assessment. It is usual to consider a reasonable worst case scenario e.g. under the contaminated land regime but it also important to take account of the legislative context.

Table 5 : Potential sources of information to assist hazard assessment

Legislative Context	Potential sources of Information
PPC/IPC/COMAH	Information provided as part of a PPC application demonstrating the application of BAT including Manufacture Safety Data Sheets; COSHH assessments, emissions and monitoring data, environmental impact assessment. Assessment may have been undertaken in accordance with the guidance contained in the Horizontal Guidance Notes Impact assessment of releases e.g. using the Horizontal Guidance Note 1 software tool to screen out insignificant releases – allows quantification of impacts of emissions to air and water, impact of noise, odour and accidents.
Radioactive Substances	Information provided as part of an authorisation application.
Contaminated Land	Desk study reports; Site investigation information e.g. presence of geological barriers preventing transfer of contamination. Toxicological properties – further information can be found in the Defra and Environment Agency TOX series (see Appendix I). Review of the Fate and Transport of Selected Contaminants in the Soil Environment (Environment Agency, 2003).
Waste Management	Information provided with the application for a waste management licence or exemption (e.g. the working plan) ; routine monitoring data. Properties of the waste constituents may be found in the European Waste Catalogue.
Water Environment	Monitoring data.

3.6 Step 4 - Risk Estimation

This stage addresses the potential risk to the receptor via each of the pollutant linkages usually by comparing the effective dose to the receptor (via the exposure pathways) with acceptable or minimal level criteria. Risk estimation can be undertaken via a number of means and a tiered approach is usually incorporated to ensure the efficient use of resources.

The risk estimation stage generally comprises the quantification of exposure i.e. how much of the substance(s) reaches the receptor via each of the exposure pathway?

Table 6 : Some considerations at the risk estimation stage

Issues for consideration	Notes
Data inputs used to generate risk estimates	Where have they come from? How relevant are they to the specific circumstances under consideration? Is it necessary to undertake a sensitivity analysis on some of the inputs? What degree of conservatism has been used – e.g. worst case scenario, reasonable worst case?
Generic quantitative risk assessment: how well does the scenario under consideration reflect the site specific circumstances?	Is it adequate to justify the use of the generic assumptions?
Detailed quantitative risk assessment: How reliable are the modelling techniques?	Is an established UK policy compliant tool used to develop the site specific assessment criteria? What is the justification for its use? Does it model all of the relevant linkages? If not, how have the others been accounted for?

Generic and detailed quantitative risk assessment is discussed in more detail in Sections 3.10 and 3.11.

3.7 Step 5 - Risk Evaluation

The purpose of risk evaluation is to consider the outcome of the previous stages and determine if there is a need for risk management action. The risk evaluation will need to be undertaken on a site-specific basis and consider all of the pollutant linkages. For any given estimate of the risk, remedial action may or may not be warranted depending on the legal regime under which the assessment is being carried out.

This is often the stage the majority of stakeholders are most interested in therefore the evaluation should provide a clear and concise decision on the acceptability of the risk considering the uncertainty and its impact on the overall process. Where exceedances of assessment criteria are evident the evaluation needs to take account of the magnitude of

the exceedance in informing any opinion on the unacceptability of risk.
Any decision on acceptability must take account of the legislative regime and any criteria that may have been set therein. For example, the legal test in the contaminated land regime is “significant harm” or the “significant possibility of significant harm” and is defined in the statutory guidance underpinning the regime. Other regimes are less specific e.g. PPC states no “significant” pollution should be caused without defining what is meant by “significant”. Ironically the Scottish Executive guidance on Part IIA (Scottish Executive, 2006) does include a definition of significant pollution of controlled waters.

The risk evaluation needs to be

- transparent, and
- well documented stating the limitations of the assessment process.

As with the previous stages, limitations in scientific knowledge (e.g. toxicological data and the uncertainty inherent in the risk assessment process) mean the evaluation is likely to require application of professional judgement.

Table 7 : Some considerations at the risk evaluation stage

Issues for consideration	Notes
What does it all mean?	Message needs to be communicated in a transparent manner – without the use of scientific jargon.
Uncertainty	What is it?
	How much is there?
	What is the impact?
	Is it necessary to incorporate safety/uncertainty factors?
Acceptability of risk	Is the estimated level of risk acceptable within the legislative context?
	The decision making process needs to be robust, transparent and well documented.
	If the level of risk is deemed to be unacceptable it will be necessary to implement risk management measures.

3.8 Step 6 - Risk Management

Where an unacceptable level of risk has been identified it will be necessary to manage the risk to protect the receptor. The risk management process seeks to identify and evaluate viable options taking account of site-specific considerations including scientific and technical; social, economic and possibly political considerations. The risk communication process should continue into this stage to ensure the solutions are acceptable to the people affected.

Risk management should seek to address one or more of the elements of the pollutant linkage. This could entail removal or treatment of the source, breaking the pathway and/or protecting the receptor or a combination of these.

3.9 Decision Outputs

The risk assessment process will inform decisions on the acceptability of the risk to human health. As indicated in Figure 2b the process may indicate

- there is no pollutant linkage therefore by definition no risk and no further action is necessary;
- the level of risk is acceptable and no further action is required;
- the level of risk is unacceptable and risk management measures need to be to instigated.

The risk assessment process may also indicate that there is insufficient information to make a robust decision on the acceptability of the risk. It will be necessary to collect more information and then return to the process.

It is important the decision-making process is robust and transparent and has been comprehensively documented and justified.

3.10 Generic Quantitative Risk Assessment (GQRA)

Generic quantitative risk assessment relies on the use of guideline or standards (generic assessment criteria) to inform decisions on the acceptability of the risk. It is imperative these GAC are health-based to ensure the protection of human health. They must also be authoritative and relevant to the situation under consideration. If at this generic stage it can be demonstrated there is no unacceptable risk to human health with a degree of certainty it is not necessary to progress to the detailed stage.

It is important to understand the purpose of the generic assessment criterion as this will impact on any decision regarding acceptability. Some GAC are intended as screening values i.e. below this value or standard there is no unacceptable risk to human health. An exceedance of a screening criterion identifies the need for further assessment but does not necessarily imply an unacceptable level of risk. Other GAC are intended as action levels i.e. above this value or standard there is an unacceptable level of risk and risk management measures need to be employed. Some standards are legally mandatory e.g. Drinking Water Standards and if the risk assessment demonstrates exceedance the risk is unacceptable and measures must be put in place to reduce the risk. There may also be the possibility of prosecution under the specific regimes.

Some criteria for consideration in selecting appropriate generic assessment criteria are considered in Table 8.

Table 8 : Criteria for assessing guideline and/or standards (generic assessment criteria)

Criteria	What does it mean?	Notes
Purpose	Are the criteria legally mandatory?	An exceedance is unacceptable.
	Are the criteria intended as screening or action levels?	This will have a direct impact on any decision relating to the exceedance of a criterion.
Scientific Robustness	What is the basis of the generic assessment criterion?	e.g. the Part IIA contaminated land regime requires any guideline vales to be scientifically derived.
	Does it meet the legislative requirement?	
Authoritativeness	Who has produced the criteria?	Preferably UK criteria – if using criteria derived outside the UK check scientific and policy basis to ensure relevance in UK.
Relevance	Can they be used in the specific legislative context e.g. in soil, in air?	
Appropriateness	Do the criteria cover the substances in question?	Substances may exist in more than one form with varying physical, chemical and toxicological properties e.g. chromium can exist in soil as Cr III, Cr V and Cr VI with Cr VI being the more toxic.
		If there is uncertainty conservative assumptions must be made i.e. it is the most toxic form.
	Do the criteria take account of all the potential exposure pathways identified in the conceptual model?	If the criteria do not take account of all relevant exposure pathways the exposure of the receptor could be under estimated.
	Who/what do the criteria aim to protect?	Are all relevant receptors considered including potentially sensitive subgroups e.g. the very young and the very old?

Table 9 details some generic assessment criteria under the specific regimes.

3.11 Detailed Quantitative Risk Assessment

Risk assessment tools have been developed under some of the specific legislative regimes to enable representation of the conditions under consideration and inform the detailed quantitative risk assessment e.g. CLEA and GasSim (see Table 9). It is not always necessary or possible to use risk assessment tools and the work may require the development of a site-specific methodology to adequately represent the circumstances under consideration. This guidance does not seek to address the development of such methodologies.

A detailed quantitative risk assessment will need to be scientifically robust and well documented with all assumptions justified in the context of the circumstances under consideration. The work undertaken must also fit the legislative context. This type of risk assessment involves removal of some of the conservatism of the generic stage and it must be informed by reliable and appropriate data. The output from a detailed quantitative risk assessment will only be applicable to the individual circumstances under consideration. All risk assessment tools have limitations and constraints and these should be recognised in the use of the model and in the presentation of the findings.

Table 9 : Generic and detailed risk assessment criteria under the specific regimes

Legislative Context	
PPC/IPC/COMAH	**Generic:** Comparison with health based Environmental Quality Standards, and the Environmental Assessment Levels contained in the Horizontal Guidance Notes. Comparison with health based Environmental Assessment Levels derived as part of the UKCC01 project (A methodology for use by staff assessing impacts on human health associated with PPC licensing). This project provides health based environmental quality threshold criteria for various environmental media. This methodology involved the adaptation of environmental assessment levels for protection of non-human receptors e.g. aquatic organisms to produce health based quality threshold criteria. The methodology also provides an electronic screening tool to assist the user in the application of the threshold criteria. **Detailed:** GasSim – for permit applications for landfills (see below – waste management) Methodologies for assessing chimney stack emissions
Radioactive Substances	**Generic:** Authorisation discharge limits Radioactivity in soils – RSGVs and RCLEA (see below – contaminated land) **Detailed:** less likely to be used as requirement to meet regulatory criteria is based on measurement and monitoring.
Contaminated Land	**Generic:** Comparison of soil concentrations with Soil Guideline Values developed under the CLEA framework (Defra and Environment Agency, 2002; Environment Agency 2004b & c & 2005a & b) Comparison with other UK derived generic assessment criteria. **Detailed:** Derivation of site-specific assessment criteria which may include the use appropriate risk assessment tools including CLEA UK and the SNIFFER methodology (SNIFFER, 2003; Project Ref: LQ01). The 'CLEA UK' software allows practitioners to derive generic assessment criteria, derive site-specific assessment criteria and calculate average daily exposure/health criteria ratios using a methodology that is consistent with current government policy on contaminated land. Additionally, assessment criteria can be derived for contaminants for which no government approved toxicological benchmark or Soil Guideline Values are available. SNIFFER (2003) presents a methodology for the derivation of site specific human health assessment criteria for contaminants in soil. RSGVs – Radioactivity in Soil Guideline Values for assessing individual radionuclide concentrations in soil (Defra, 2006a). RCLEA software application (Defra, 2006b) - the radioactively contaminated land exposure assessment methodology that calculates radiation doses from radionuclides in soil. Using measured concentrations of radionuclides, RCLEA calculates potential doses for comparison with regulatory criteria. It can also be used to calculate 'Guideline Values' in terms of radionuclide concentrations if reliable

Legislative Context	
	measurements are not yet available. R&D publication 20 –see below (water environment)
Waste Management	**Generic:** Comparison with health based Environmental Quality Standards, Emission Limits and waste acceptance criteria **Detailed:** Estimation of potential risk using risk assessment tools such as LandSim and GasSim. GasSim simulates the fate of landfill gas arising from managed or unmanaged landfill sites. The model uses information on waste composition and quantity, landfill engineering, and landfill gas management techniques to enable assessment of the best combination of control measures for a particular design and rate of filling. Model outputs include the following: ▪ estimates of the quantity of landfill gas generated; ▪ combustion emissions from flares and gas engines; ▪ fugitive emissions through the cap and lateral liner; ▪ short-term and long-term air quality impacts using the atmospheric dispersion module; ▪ lateral terrestrial migration; ▪ greenhouse gas impact; ▪ human exposure to trace constituents. GasSim was developed for the Environment Agency in 2002 – current version is GasSim 2 (see www.GasSim.co.uk)
Water Environment	**Generic:** Comparison with drinking water standards. **Detailed:** Environment Agency (2006) is a methodology to derive the level of remediation required to protect groundwater and surface water. It can be used to evaluate health and environmental risk from contaminated soil and groundwater represent ConSim is designed to provide those concerned with the management of contaminated land with a means of assessing the risk which is posed to groundwater by leaching contaminants (see www.consim.co.uk) LandSim: This model was developed for the Environment Agency and essentially tracks leachate production, chemistry, migration and leakage through engineered an non-engineered structures, followed by leachate migration through the unsaturated zone to assess the ultimate impact on the aquifer (see www.landsim.co.uk)

3.12 Dealing with Uncertainty

Uncertainty is inherent in the risk assessment process and can arise from a number of sources. It is necessary to take account of the source and magnitude of uncertainty in the decision-making process.

DETR (2000) presents the following five categories of uncertainty

Table 10 : Sources of uncertainty in risk assessment

Source of uncertainty	
Model	The extent to which the particular model chosen represents the circumstances at the site
Sample	The degree to which any sample can represent a much larger volume of ground and the degree to which the sample integrity can be preserved between sampling and analysis
Data	Analytical methods can only achieve certain reporting levels
Knowledge	The limits of present scientific understanding.
Environmental	The environmental context in which the site is located; this would now include possible changes due to climate change.

The consideration of uncertainty must be undertaken on a site specific basis and reported in a transparent manner. The degree of uncertainty will have an impact on the acceptability of the risk. The acceptability of uncertainty may vary among the stakeholders.

3.13 Other Considerations

3.13.1 Costs and Benefits

Decisions must take account of a wide range of costs and benefits, including those that cannot easily be valued in money terms as often is the case with environmental issues. It is necessary to take into account public values, the timing of costs, benefits, risks and uncertainties. A cost benefit analysis will involve the expression of as many costs and benefits as possible in terms of monetary or other value, placed on them by society and deriving the net benefits. Usually the best option is one that allows the greatest excess of benefits over costs. In pursuing any single objective, disproportionate costs should not be imposed elsewhere.

Some regimes allow for a cost benefit analysis to be taken either as part of the risk assessment or – e.g. in the case of contaminated land – in deciding whether or not the removal of unacceptable risk can be justified.

A consideration of costs and benefits may have been undertaken in the development of environmental quality standards, limits and thresholds e.g. land fill gas flare emission limits. The PPC regime takes account of costs and benefits in the selection of BAT – the IPPC Horizontal Guidance Note H1 software allows the comparison of costs and benefits of potential techniques.

3.13.2 Communicating Risk

Effectively communicating risk is of fundamental importance in making and implementing acceptable decisions in the various regulatory and policy-making contexts.

Communication must be

- undertaken in a logical and transparent manner with all relevant stakeholders, and
- a two-way process taking account of the views of all stakeholders.

A communication plan should identify

- when to communicate (as early as possible is best and as often as necessary),
- who to communicate with (identify stakeholders),
- what to communicate (the key messages in an accessible format i.e. use of non technical terms), and
- how to communicate (different formats may be necessary for different stakeholders).

How stakeholders perceive any potential risk will have an impact on the communication process.

Perception is the reality and the perception of the potentially affected community may be different to that of the regulator, indeed perception may not reflect the actual risk.

In addition to potential health concerns stakeholders may also be concerned with environmental, social, economic impacts and visual intrusiveness. It is also important to recognise perception may differ among the community due issues that may be beyond the control of the regulator including knowledge, personal experiences and familiarity. In every assessment the limitations and uncertainties must be made clear to the stakeholders in a meaningful way i.e. not using scientific jargon.

The following publications may assist in ensuring effective communication of potential risk to human health[3,4,5,6,7].

[3] Communicating Understanding of Contaminated Land Risks (Project Ref: SR97 (11)F (SNIFFER, 1999)
[4] Risk Communication – A Guide to Regulatory Practice sets out some key principles and good practice for risk communication in the regulatory context.(HSE, 1998)
[5] Communicating about Risks to Public Health: Pointers to Good Practice (Department of Health,1997)
[6] Public participation methods: evolving and operationalising an evaluation framework - developing and testing a toolkit for evaluating the success of public participation exercises summary project report (Department of Health, 2001)
[7] Risk literacy and the public - MMR, air pollution and mobile phones Department of Health (2003)

3.14 Wider Regulatory Requirements

The agencies have roles and responsibilities to protect human health under wider regulatory frameworks including sustainable development and human rights. The consultation exercise indicated most staff had an awareness of these requirements but were unlikely to give them much consideration on a site specific basis. They instead rely on the agencies to incorporate high level policies into technical guidance for use by staff. It is often the case that consideration of the requirements under these wider regulatory frameworks is inherent in the existing guidance although this is often not transparent to the user.

3.14.1 Precautionary Principle

The environment agencies in their decision-making processes with respect to the assessment of potential risks to human health under the various environmental legislative frameworks need to consider on a site-specific basis if the precautionary principle applies. SNIFFER[8] (2006b) provides practical guidance on the application of the precautionary principle. The guidance adopts the definition of precautionary principle set out by the Rio Declaration "where there are threats of serious or irreversible damage, lack of scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation" and suggests the same principle should apply concerning potential impacts on human health.

In some cases society may decide that a particular risk is so serious it is not worth living with whereas in other cases society may be prepared to live with a risk because of the other benefits it will bring. Other situations may arise where there may be reason to believe there may be a significant risk but the evidence for its existence is inconclusive or lacking. In these cases it will be necessary to revise any decisions as more information becomes available.

3.14.2 Sustainable Development

Under the specific environmental regimes much of the existing guidance assists the user in the quantification and estimation of risk and the assessment of costs and benefits. It often falls short on providing definitive guidance on taking account of the potential socio-economic impacts of for example, an installation which may have an impact on licence or permit conditions.

The environment agencies have duties pertinent to sustainable development and any environmental risk assessment must have due regard to the principles of sustainable development and take into account the likely social and economic impacts[9,10,11].

3.14.3 Human Rights

All UK legislation must be interpreted in a way which is compatible with European Convention on Human Rights. The agencies as public bodies must act in a manner which is compatible with convention rights. In the event of a challenge being made in respect of an agency decision, not only will the court look at the terms of the statute which defines the function the agency has been asked to carry out, the statutory limits of agency's powers and duties, and the reasonableness of agency's decision making process, the

[8] Practical Guidance on Applying the Precautionary Principle. SNIFFER Project Reference UKCC05. SNIFFER (2006b)
[9] First Steps Towards Sustainability: A Sustainable Development Strategy for Northern Ireland. Office of the First Minister and Deputy First Minister (May 2006)
[10] Choosing Our Future: Scotland's Sustainable Development Strategy. (Scottish Executive, 2005)
[11] Securing the Future UK Government Sustainable Development Strategy. (HM Government, 2005)

court will now also examine the agency's conduct by reference to convention rights.

SEPA has produced guiding principles to enable consistent regulation which have regard to duties under the wider regulatory requirements including human rights[12] (SEPA, 2005).

The Human Rights Unit in the Northern Ireland Office of the First Minister and Deputy First Minister (OFMDFM) has developed guidance to help public authorities in Northern Ireland understand how the Human Rights Act 1998 and the European Convention on Human Rights affects their work[13] (OFMDFM, 2006).

[12] SEPA's Vision for Regulation: Protecting and Improving the Environment through Regulation (SEPA, 2005)
[13] Get in on the Act: Learning about the Human Rights Act. NI Office of the First Minister and Deputy First Minister (OFMDFM, 2006)

4 CONSULTATION WITH OTHER ORGANISATIONS

There is a requirement under some of the legislative frameworks (e.g. PPC) to consult with various external bodies including local authorities and the health sector (NHS mainly). The distinct processes for doing so are set out in the various regimes.

Responding to consultations is not normally a compulsory requirement and is therefore at the discretion of the individual agency concerned. The ability and willingness of a consultee to respond to invitations to comment will depend on a number of factors including:

- the response time scales and whether these are practical from the consultees perspective;
- who the consultation document is sent to i.e. if the document is received by the person expected to respond;
- the usefulness of covering documentation to explain what is expected of the consultee;
- knowledge of identified contacts within the regulator organisation for the consultee to liaise and discuss concerns with;
- competing priorities and lack of resources to comment on a consultation document;
- lack of expertise in the relevant area necessitating the consultee seeking additional advice from outside their immediate organisation;
- lack of understanding of the relevance or importance of the consultation process;
- availability of specific health data upon which to base a response or the effort required to generate the necessary data is disproportionate to the situation;
- availability of data on other hazards in the vicinity that might add to the exposure burden and add a cumulative effect to the process under consultation

Consultees are likely to rely on established evidence of health effects from exposure to environmental agents, either toxicological or epidemiological. Given the time scales for most regulatory regimes it is very rarely practical for Health agencies to undertake primary research into evidence in their local populations for evidence of an adverse health effect associated with a known source. Given the limitations of health data, such investigations are complex, time consuming and highly resource intensive and will not be considered on a routine basis. For these reasons Health agencies may well be reluctant to provide a definitive statement on the health risks of any particular emission or process.

Some of the above problems may be overcome by improving the level and quality of communication between regulators and consultees. Practical steps to improve communications might include:

- providing clear advice on the purpose of the consultation and what the regulator is looking for by way of response explaining the time constraints where applicable and where possible guiding the consultee to the appropriate sections in the application;
- making it clear what the consultee is not expected to provide and what the regulator will themselves cover by way of toxicological assessment and assessment of best practice;
- developing personal links with named individuals in the relevant health agencies and in the environment agencies, ensuring that consultation documents are sent directly to the most relevant person and offering to discuss issues relating to applications on an informal basis to assist the consultee formulate an

appropriate response;
- facilitating the provision of additional information and where practical additional time, where required to help the consultee respond appropriately;
- ensuring acknowledgement of receipt of a consultee response when sent;
- providing feedback to individual consultees on the outcome of decisions including sending copies of decision documents where relevant which would indicate if the consultees comments were material to the decision or affected any conditions granting the application or permit.

Of all these suggestions, making better personal contact with local health agencies and environment agencies in order to establish a rapport and a good working relationship is probably most likely to result in the greatest improvement in the response to requests for comments, combined with evidence suggesting that the regulator has been able to usefully apply any comments received.

It is important to recognise that health statistics may not be available to prove (or disprove) a causal link or impact on the health of the population from a particular source(s). Indeed health statistics may not be available for many of the potential environmental effects under consideration – the lack of reliable statistical data does not mean there is no impact on the population. The availability of information may vary regionally.

Table 11 below identifies some of the organisations that may be able to provide assistance in the assessment of potential risks to human health. Some of the organisations detailed below are statutory consultees under specific regimes.

Table 11 : Details of some health-based organisations

Region	Organisation	
Scotland	NHS Boards	There are currently 14 NHS Boards in Scotland. NHS Boards have responsibility for the provision of all NHS health care services within their geographic area. Responsibility for monitoring the health of the local population is generally part of the remit of the Director of Public Health supported by staff in a Department of Public Health. Environmental matters would normally be delegated to consultant level staff working in Health Protection within these departments (designated as Consultants in Public Health Medicine (Communicable Disease and Environmental Health) (CPHM(CDEH)). These individuals would normally deal with requests for input involving health risk assessments or consultation processes. Where required they may request assistance in responding to a consultation request from HPS.
Scotland	Health Protection Scotland www.hps.scot.nhs.uk	HPS is part of the NHS in Scotland and is a distinct organisation from the Health Protection Agency (HPA) but you will note below HPA have some UK responsibilities, specifically radioactive substances. HPS is a national level organisation providing support to the NHS Boards, Local Authorities and national organisations such as SEPA, FSA (Scotland) and the Scottish Executive etc. HPS has a particular role in relation to the surveillance and control of Communicable Disease and Environmental Hazards to Health. HPS has a national remit for Health Protection and has a role in surveillance of environmental incidents and emissions for Scotland as well as in providing guidance, education and training in Health Protection matters. HPS has close working links with HPA but works independently. Where NHS Boards require assistance in dealing with a specific environmental or other issue they may request the support of HPS.
Northern Ireland	NI Health and Social Services Boards	The purpose of the Health Boards is to seek a comprehensive range of quality health and social services for local people including environmental public health.

UK remit	Health Protection Agency Chemical Hazards & Poisons Division www.hpa.org.uk	The Division provides advice to UK Government Departments and Agencies on human health effects from chemicals in water, soil and waste as well as information and support to the NHS and health professionals on toxicology. Developing a compendium of chemical hazards – available online http://www.hpa.org.uk/chemicals/compendium/default.htm Developing an environmental health public tracking system to quantify, characterise and monitor the impact of the environment on public health Undertake surveillance, mapping & modelling of emissions, discharges etc. and potential impacts on human health.
UK remit	Health Protection Agency Radiation Protection Division www.hpa.org.uk	The Division undertakes research to advance knowledge about protection from the risks of radiations; provides laboratory and technical services; runs training courses; provides expert information and has a significant advisory role in the UK.
UK remit	Small Area Health Statistics Unit www.sahsu.org.uk	The main aim of SAHSU has been to assess the risk to the health of the population to environmental factors with an emphasis on the use and interpretation of routine health statistics.
UK remit	Health and Safety Executive www.hse.gov.uk/scotland www.hseni.gov.uk	HSE look after health and safety in nuclear installations and mines, factories, farms, hospitals and schools, offshore gas and oil installations, the safety of the gas grid and the movement of dangerous goods and substances, and many other aspects of the protection both of workers and the public.
UK remit	Royal Commission on Environmental Pollution www.rcep.org.uk	The Royal Commission on Environmental Pollution is an independent standing body established in 1970 to advise Government and the public on environmental issues. The Commission's advice is mainly in the form of reports based on the outcome of studies of potentially affected populations.
All regions	Local Authorities/District Councils/Unitary Authorities	Regulate under environmental legislative framework including statutory nuisance – odour & noise etc

5 REFERENCES

Defra (2006) CLAN6/06 Soil Guideline Value: The Way Forward. Assessing Risks from Land Contamination – A Proportionate Approach. http://www.defra.gov.uk/environment/land/contaminated/pubs.htm#CLAN%206/06 (Accessed January 2007)

Defra (2006a) *CLR 13 (draft) Using RCLEA – The Radioactively Contaminated Land Exposure Assessment Model.* Available at http://www.defra.gov.uk/environment/land/contaminated/pdf/clr13.pdf (Accessed January 2007)

Defra (2006b) *CLR 15 (draft) The RCLEA Software Application* Available at http://www.defra.gov.uk/environment/land/contaminated/pubs.htm#tech (Accessed January 2007)

Defra and Environment Agency (2002a) *R&D Publication CLR 9: Contaminants in Soil: Collation of Toxicological Data and Intake Values for Humans* Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e (Accessed January 2007)

Defra and Environment Agency (2002b) *R&D Publication CLR 10 The Contaminated Land Exposure Assessment Model (CLEA): Technical Basis and Algorithms* Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e (Accessed January 2007)

Defra and Environment Agency (2002-2004) *R&D Publication Soil Guideline Value series* (SGV 1 - arsenic; SGV 3 – cadmium; SGV 4 – chromium; SGV 5 – inorganic mercury; SGV 7 – nickel; SGV 8 – phenol; SGV 9 – selenium; SGV 10 – lead; SGV 15 – toluene; SGV 16 – ethylbenzene)

DETR (2000) *Guideline for Environmental Risk Assessment and Management: Revised Departmental Guidance.* Available at http://www.defra.gov.uk/environment/risk/eramguide/index.htm (Accessed January 2007)

Environment Agency (2003) *Review of the Fate and Transport of Selected Contaminants in the Soil Environment.* Draft Technical Report P5-079/TR1 Available at https://publications.environment-agency.gov.uk/epages/eapublications.storefront (Accessed January 2007)

Environment Agency (2004a) *Contaminated Land Report 11 Model Procedures for the Management of Land Contamination* Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/881475/?version=1&lang=_e (Accessed May 2007)

Environment Agency (2004b) *CLEA Briefing Note 2 Version 1.1 Update on Estimating Vapour Intrusion into Buildings* Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e (Accessed January 2007)

Environment Agency (2004c) *CLEA Briefing Note 3 Version 1.1 Update of Supporting*

Values and Assumptions Describing UK Building Stock Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e (Accessed January 2007)

Environment Agency (2005a) *CLEA Briefing Note 1 Version 1.1Update on the Dermal Exposure Pathway* Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e (Accessed January 2007)

Environment Agency (2005b) *CLEA Briefing Note 4 Version 1.0 An Update on Deriving Soil Guideline Values Based on Combined Intake from Individual Routes of Exposure* Available at http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e (Accessed January 2007)

Environment Agency (2006) *Remedial Targets Methodology – Hydrogeological Risk Assessment for Land Contamination.* Available at http://www.environment-agency.gov.uk (Accessed May 2007)

OFMDFM (Office of the First Minister and Deputy First Minister NI) (2006) Get in on the Act: learning about the Human Rights Act. Published by The Equality and Human Rights Unit Available at www.ofmdfmni.gov.uk/index/equality/human-rights.htm (Accessed March 2007)

Scottish Executive (2006*) Environmental Protection Act 1990: Part IIA Contaminated Land Statutory Guidance Edition 2 (SE/2006/44).* Available at http://www.scotland.gov.uk/Publications/2006/06/05131212/0 (Accessed January 2007)

SEPA (2005) SEPA's Vision for Regulation: Protecting and Improving the Environment through regulation. Available at http://www.sepa.org.uk/pdf/publications/vision_for_regulation_2005.pdf (Accessed January 2007)

SNIFFER (2003) *Method for the Deriving Site-Specific Human Health Assessment Criteria for Contaminants in Soil.* Report No. LQ0, prepared by Land Quality Management Ltd. Available at http://www.sniffer.org.uk/results.asp?start=5&keywords=&code=&year=&output=&bool=OR&proposed=1&active=1&complete=1&theme=[Land%20Quality]&location=research_areas&refer=res_area_land_1.asp&title=UK%20Research%20Programme%20-%20Land%20Quality&research_area= (Accessed January 2007)

SNIFFER (2006a) Development of a Methodology for use by Staff Assessing Impacts on Human Health Associated with PPC Licensing. Project Ref: UKCC01. Available at http://www.sniffer.org.uk Accessed January 2007

SNIFFER (2006b) *Practical Guidance on Applying the Precautionary Principle*. Project Ref: UKCC05. Available at http://www.sniffer.org.uk Accessed January 2007

SNIFFER (2007) *Assessment of Environmental Legislative and Associated Guidance Requirements for the Protection of Human Health*, Project Ref: UKCC02 dated August 2007, prepared by Land Quality Management Ltd

Appendix I List of currently available Defra and Environment Agency R&D PublicationTOX reports

List of Currently Available Toxicological Reports

Available from http://www.environment-agency.gov.uk/subjects/landquality/113813/672771/675330/?lang=_e

Report No.	Substance	Date published
TOX 1	Arsenic	2002
TOX 2	Benzo(a)pyrene	2002
TOX 3	Cadmium	2002
TOX 4	Chromium	2002
TOX 5	Inorganic Cyanide	2002
TOX 6	Lead	2002
TOX 7	Mercury	2002
TOX 8	Nickel	2002
TOX9	Phenol	2003
TOX 10	Selenium	2002
TOX 11	Benzene	2003
TOX 12	Dioxins, furans & dioxin-like PCBs	2003
TOX 14	Toluene	2004
TOX 16	Tetrachloroethane	2004
TOX 17	Ethylbenzene	2004
TOX 18	Vinyl Chloride	2004
TOX 19	Xylene	2004
TOX 20	Naphthalene	2003
TOX 21	Carbon tetrachloride	2005
TOX 22	1,2-dichloroethane	2004
TOX 23	Tetrachloroethene	2004
TOX 24	Trichloroethene	2004
TOX 25	1,1,1-trichloroethane	2004

Appendix II Lists of guidance relevant to the protection of human health under environmental legislative frameworks

Contaminated Land
COMAH
PPC/IPC
Radioactive Substances
Strategic Environmental Assessment
Sustainable Development
Waste Management
Water Environment

Land Contamination		
Guidance Document	**Issued By**	**Date**
Circular 01/2006 Contaminated Land Implementation of Part 2A of the Environmental Protection Act 1990	Defra	2006
Scottish Executive Paper SE/2006/44, Environmental Protection Act 1990: Part IIA Contaminated Land Statutory Guidance: Edition 2	Scottish Executive	2006
Contaminated Land: National Assembly for Wales guidance to enforcing authorities under Part IIA of the Environmental Protection Act 1990	National Assembly of Wales	2006
Guidelines for Environmental Risk Assessment and Management	DETR	2002
Model Procedures for the Management of Land Contamination (CLR 11)	Defra & Environment Agency	2004
Guidance for the Safe development of Housing on Land Affected by Contamination.	NHBC & Environment Agency	2000
Assessment of risks to human health from land contamination	SEPA	
CLR7: Assessment of Risks to Human Health from Land Contamination: An Overview of the Development of Soil Guideline Values and Related Research**.**	Defra & Environment Agency	2002
CLR8: Potential Contaminants for the Assessment of Land	Defra & Environment Agency	2002
CLR9: Contaminants in Soils: Collation of Toxicological Data and Intake Values for Humans	Defra & Environment Agency	2002
CLR10: Contaminated Land Exposure Model (CLEA): Technical Basis and Algorithms (& associated updates in the form of CLEA Briefing Notes)	Defra & Environment Agency	2002
R&D TOX series	Defra & Environment Agency	2002-2005
R&D Soil Guideline Value series	Defra & Environment Agency	2002-2005
The UK Approach for Evaluating Human Health Risks from Petroleum Hydrocarbons in Soils	Environment Agency	2005
Planning Policy Statement (PPS) 23: Planning and Pollution Control	ODPM	2004
Planning Advice Note (PAN) 33: Development Of Contaminated Land	Scottish Executive	2001
Planning Policy Wales	National Assembly of Wales	2002
Method for Deriving Site Specific Human Health Assessment Criteria for Contaminants in Soil	SNIFFER	2003
Technical Guidance on Special Sites	EA	2001
Measurement of Bioaccessibility of Arsenic in UK soil	RA	2002
Guidance on Assessing and Managing Risks to Buildings from Land Contamination	EA	2001

Land Contamination		
Guidance Document	**Issued By**	**Date**
Approved Document C - Site Preparation and Resistance to Contaminants and Moisture	ODPM	2004

Control of Major Accident Hazards		
Guidance Document	**Issued By**	**Date**
Guidance on the Environmental Risk Assessment Aspects of COMAH Safety Reports	The COMAH Competent Authority	Version 2 December 1999
COMAH Guidance L111 DRAFT FOR CONSULTATION		
Guidance on the Interpretation of Major Accident to the Environment for the Purposes of the COMAH Regulations	DETR	Jun-99
Safety Report Assessment Guidance	HSE	
Guidance on Assessing " as low as reasonably practicable (ALARP)" decisions in control of major accident hazards (COMAH)	HSE	
Part A: Statutory Information required by the Competent Authority	HSE	
Part B: Non-Statutory information required by the Competent Authority and Statutory information not to be disclosed on the public register	HSE	

Pollution Prevention Control		
Guidance Document	**Issued By**	**Date**
Integrated Pollution Prevention and Control - A Practical Guide Fourth Edition	Defra & Welsh Assembly Government	Jun-05
IPPC - Guide for Applicants	EHS	Nov-03
IPPC - Guide for Applicants for Pig and Poultry Rearing UNits	EHS	Apr-04
IPPC Guidance - Guidance on the Protection of Land Under the PPC Regime: Application Site Report and Site Protection and Monitoring Programme	EHS	
IPPC (Northern Ireladn) A Practical Guide Edition 1	EHS	May-03
PPC(NI) Guidance for Operators on Odour Management at Intensive Livestock IPPC installations	EHS	Oct-03
Pollution Prevention Guidance		
PPG01 General guide to the prevention of water pollution	SEPA; EA; EHS	2004
PPG02 Above ground oil storage tanks	SEPA; EA; EHS	2004
PPG03 The use and design of oil separators	SEPA; EA; EHS	2004
PPG03 : Oil Separator Manufacturers	SEPA; EA; EHS	2004
PPG04 Disposal of sewage where no mains drainage is available	SEPA; EA; EHS	2004
PPG05 Works in near or liable to affect watercourses	SEPA; EA; EHS	2004
PPG06 Working at construction and demolition sites	SEPA; EA; EHS	2004
PPG07 Refuelling Facilities	SEPA; EA; EHS	2004
PPG08 Storage and disposal of used oils	SEPA; EA; EHS	2004
PPG09 Pesticides	SEPA; EA; EHS	2004
PPG10 Highway depots	SEPA; EA; EHS	2004
PPG11 Preventing pollution at industrial sites	SEPA; EA; EHS	2004
PPG13 High pressure water and steam cleaners	SEPA; EA; EHS	2004
PPG14 Marinas and craft	SEPA; EA; EHS	2004
PPG15 Retail stores	SEPA; EA; EHS	2004
PPG16 Schools and other educational establishments	SEPA; EA; EHS	2004
PPG17 Dairies & other milk handling operations	SEPA; EA; EHS	2004
PPG18 Control of spillages and fire fighting run-off	SEPA; EA; EHS	2004
PPG19 Garages and vehicle service centres	SEPA; EA; EHS	2004
PPG20 Dewatering underground ducts and chambers	SEPA; EA; EHS	2004
PPG21 Pollution Incident Response Planning	SEPA; EA; EHS	2004
PPG22 Dealing with spillages on highways	SEPA; EA; EHS	2004
PPG23 Maintenance of Structures over Water	SEPA; EA; EHS	2004
PPG24 Stables, Kennels & Catteries	SEPA; EA; EHS	2004

Pollution Prevention Control		
Guidance Document	**Issued By**	**Date**
PPG25 Hospitals and Health Care Establishments	SEPA; EA; EHS	2004
PPG26 Pollution Prevention Storage and Handling of Drums & Intermediate Bulk Containers	SEPA; EA; EHS	2004
PPG27 Installation, Decomissioning and Removal of Underground Storage Tanks	SEPA; EA; EHS	2004
PART A Practical Guide: The Pollution Prevention and Control (Scotland) Regulations 2000 - a practical guide for Part A Activities - Issue 2	SEPA	
PPC PART A Installations: Guide for Applicants	SEPA	
LOW IMPACT - Benchmark Guidance for Determining "Low Impact Installations" under the PPC Charging Scheme	SEPA	
NOISE - Guidance on the Control of Noise at PPC Installations	SEPA	
NOISE - Summary guidance for PPC applicants	SEPA	
A practical guide for Part B activities	Scottish Executive & SEPA	
BAT Reference Documents (BREFS)	European IPPC Bureau	
Pulp and Paper Manuufacture		Dec-01
Iron and Steel Production		Dec-01
Cement and Lime Production		Dec-01
Cooling Systems		Dec-01
Clor-Alkali Manufacture		Dec-01
Ferrous Metal Processing		Dec-01
Non-ferrous metal processing		Dec-01
Glass Manufacture		Dec-01
Tanning of Hides and Skins		Feb-03
Textile Processing		Mar-03
Monitoring Systems		Mar-03
Refineries		Feb-03
Large Volume Organic Chemicals		Feb-03
Smitheries and Foundries		May-05
Intensive Livestock Farming		Jul-03
Common Waste water and waste gas treatment and management systems in the chemical sector		Feb-03
Slaugther Houses and Animal Byproducts		May-05
Horizontal Guidance Notes		
H1 Environmental Assessment and Appraisal of BAT	**SEPA; EA; EHS**	Updated, July 2003
H2 Energy Efficiency	**SEPA; EA; EHS**	Working Draft, Version 3, February 2002
H3(1) Noise Part 1	**SEPA; EA; EHS**	Published September 2002
H3(2) Noise Part 2	**SEPA; EA; EHS**	Published September 2002
H4(1) Odour Pt 1		Draft for consultation 2002
H4(2) Odour Pt 2	**SEPA; EA; EHS**	Draft for consultation 2002
		--
H7 Application Site Report and Site Protection and Monitoring Programme-published (applicable to England & Wales only)	**EA**	Aug-03
H8 Protection of Land Guidance – PPC Surrender Site Report & IPPC H8 - Template - PPC Surrender Site Report	SEPA; EA; EHS	draft June 2004
Sectoral Guidance (A1)		
IPPC S0 UK Technical Guidance		
IPPC S0.01 General Sector Guidance	SEPA; EA, EHS	Complete/Published, Version 2, June 2001
IPPC S1 UK Technical Guidance		
IPPC S1.01 Combustion	SEPA; EA, EHS	Version 2.03 issued July 2005

Pollution Prevention Control		
Guidance Document	**Issued By**	**Date**
IPPC S1.02 Carbonaceous material, Mineral Oil, Gas, Coke & Coal.		Consultation Draft Issue 3 July 2005
IPPC S2 UK Technical Guidance		
IPPC S2.01 Guidance for the Coke, Iron and Steel Sector	SEPA; EA, EHS	Issued June 2004
IPPC S2.02 Guidance for non ferrous metals sector		Working draft, Version1, January 2002
IPPC S2.03 Guidance for the Ferrous Foundries Sector (consultation)		Issue 1, June 2002
IPPC S2.04 Guidance for the Hot Rolling of Ferrous Metals and Associated Activities Sector		Updated, Feb 2004
IPPC S2.07 Guidance for the Surface Treatment of Metals & Plastics by Electolytic & Chemical Processes		Consultation Draft February 2004
IPPC S3 UK Technical Guidance		
IPPC S3.01 Guidance for the Cement and Lime Sector	SEPA; EA, EHS	Working draft, Version 1, April 2001
IPPC S3.03 Guidance for the Glass Manufacturing Sector (A1 processes)		Working draft, Version 1, October 2001
IPPC S3.04 Mineral Fibres		In Progress
IPPC S4 UK Technical Guidance		
IPPC S4.01 Large volume organic chemicals sector	SEPA; EA, EHS	Issue 4 April 2003
IPPC S4.02 Speciality Organics		Issue 6 April 2003
IPPC S4.03 Inorganic Chemicals		Consultation Draft v1.1,
		Deadline 24th Sep 04
IPPC S5 UK Technical Guidance		
IPPC S5.01 Guidance for the Incineration of Waste and Fuel	SEPA; EA, EHS	Issue 1, July 2004
IPPC S5.06 Guidance for the Recovery and Disposal of Hazardous and Non-Hazardous Waste		Version 3 October 2003
IPPC S6 UK Technical Guidance		
IPPC S6.01 Technical Guidance for the Pulp and Paper Sector	EA; SEPA; EHS	Complete/Published, Version 2, 7 November 2000
IPPC S6.05 Guidance for Textile Sector		Issue 2 July 2002
IPPC S6.08 Tanneries		Complete/Published, Version 3, May 2002
IPPC S6.10 Guidance for Food and Drink Sector		Issue 1: Modified on 25th Oct 2003
IPPC S6.11b Guidance for the Poultry Processing Sector		Issue 3: Modified on 1st Oct 2003
IPPC S6.12 Guidance for the Red Meat Processing (Cattle, Sheep and Pigs) Sector		Issue 1: Modified on 3rd Oct 2003
IPPC S6.13 Guidance for the Dairy and Milk Processing Sector		Issue 1: Modified on 26th Oct 2003
IPPC S6.14 Coating Activities etc using organic solvents including timber treatment		2004
Other Guidance		
IPPC S(A2)5.07 Hazardous Waste Incineration A2		Not Started
SRG 6.02 Livestock Poultry and Pigs		Complete/Published
A2 Sector Guidance Notes		
IPPC SG1 SoS's Guidance for the Particleboard, Oriented Strand Board and Dry Process Fibreboard Sector	Secretary of State	37773
IPPC SG2 SoS's Guidance for Glass Manufacturing Activities with Melting Capacity More than 20 Tonnes per Day	Secretary of State	37773
IPPC SG3 SoS's Guidance for the A2 Ferrous Foundries Sector	Secretary of State	38718
IPPC SG4 SoS's Guidance for A2 Activities in the Non ferrous Metals Sector	Secretary of State	38718

Pollution Prevention Control		
Guidance Document	**Issued By**	**Date**
IPPC SG5 SoS's Guidance for the A2 Galvanizing Sector	Secretary of State	37956
IPPC SG6 SoS's Guidance for the A2 Surface Treatment Using Organic Solvents Sector	Secretary of State	37895
IPPC SG7 SoS's Guidance for the A2 Ceramics Sector including Heavy Clay, Refractories, Calcining Clay and Whiteware	Secretary of State	38047
IPPC SG8 SoSs Guidance for the A2 Rendering Sector	Secretary of State	38261
IPPC SG9 SoS's Guidance for A2 Roadstone Coating, Mineral and Other Processes that Burn Recovered Fuel Oil	Secretary of State	38443
IPPC SG10 SoS's Guidance for the A2 Animal carcass incineration with capacity of less than 1 tonne per hour	Secretary of State	
IPPC H1 Environmental Assessment and Appraisal of BAT		

Radioactivity		
Guidance Document	**Issued By**	**Date**
Guidance on the high-activity sealed radioactive sources and orphan sources regulations 2005	SEPA	Jan-06
Guidance for the Environment Agencies' Assessment of Best Practicable Environmental Option Studies at Nuclear Sites	EA & SEPA	Feb-04
Improved regulatory arrangements for the conditioning of intermediate level radioactive waste on nuclear licensed sites	EA & SEPA	Dec-03
Authorisation of Discharges of Radioactive Waste to the Environment Principles for the Assessment of Prospective Public Doses	SEPA; EA; DoE; FSA; NRPB;	Dec-02
Conditioning of intermediate level radioactive waste on nuclear licensed sites	EA; SEPA; HSE	
UKRSR05: BPM for the Management of Radioactive Waste	SNIFFER	Mar-05
Improving environmental performance: Sector plan for the nuclear industry	EA	Nov-05
Process and Information Document for: Applications for New Authorisations; Applications for Variations to Existing Authorisations; Environment Agency review of existing authorisations issued under RSA 1993 to Nuclear Sites in England and Wales	EA	Dec-05
Considerations for Radioactive Substances Regulation under the Radioactive Substances Act 1993 At Nuclear Sites in England and Wales	EA	Dec-05
The Environment Agency's interim guidance to users of high-activity sealed radioactive sources and orphan sources regulations 2005 Version 3*	EA	Feb-06
Radioactive Substances Act Guidance (RASAG)	EA	Dec-05
M12 Monitoring of Radioactive Releases to Water from Nuclear Facilities	EA	1999
M11 Monitoring of Radioactive Releases to Atmosphere from Nuclear Facilities	EA	1999
Initial radiological assessment methodology – part 1 user report Science Report: SC030162/SR1	EA	May-06
Initial radiological assessment methodology – part 2 methods and input data Science Report: SC030162/SR2	EA	May-06
Self Support and Advice for Non Users of Radioactive Substances	EA	Mar-05
Technical Support Materials for the Regulation of Radioactively Contaminated Land R&D Technical Report P307	EA & DETR	1999

Strategic Environmental Assessment		
Guidance Document	**Issued By**	**Date**
Good Practice Guidelines for Strategic Environmental Assessment	Environment Agency	Jan-05
A Practical Guide to the Strategic Environmenta Assessment Directive	ODPM, Scottish Executive, Welsh Assembly Government and DoD NI	Sep-05

Sustainable Development		
Guidance Document	**Issued By**	**Date**
The Environment Agency's Objectives and Contributions to Sustainable Development	Defra	2002
SEPA and Sustainable Development (Paper 2004/10)	Scottish Executive Environment Group	Jul-04
A Sustainable Development Strategy for NI	DoE	2006

Waste on Land		
Guidance Document	**Issued By**	**Date**
Statutory guidance to the Environment Agency on the exercise of its functions with regard to the Waste Management Licensing (England and Wales) (Amendment & Related Provisions) Regulations 2005	Defra	Dec-05
Depollution Guidance for End-of-Life Vehicles over 3.5 tonnes	Defra	2004
Guidance to businesses with regard to the Waste Management Licensing (England and Wales) (Amendment & Related Provisions) Regulations 2005	Defra	Dec-05
Depolluting End-of-Life Vehicles Guidance for Authorised Treatment Facilities	Defra & DTI	2004?
EHS Waste Management and Contaminated Land Technical Competence for Operators of Authorised Waste Facilities	EHS	Dec-03
Assessment of the Best Practicable Environmental Option for Waste Management in Northern Ireland: Development and Analysis	EHS	Jun-05
Best Practicable Environmental Option for Waste Management in Northern Ireland: Guidance Document	DoE	Jun-05
PPS 11: Planning and Waste Management	DoE Planning Service	
Framework for Waste Prevention in Northern Ireland	EHS	Sep-05
Producer Responsibility Obligations (NI) 1999	DoE EHS	Jan-01
Annual Registration of PCB Holders: Guidance Notes	DoE EHS	
Tackling Fly tipping: A guidance note and response protocol	DoE EHS	
Waste Management: The Duty of Care Code of Practice		
Hazardous waste: WM2 Interpretation of the definition and classification of hazardous waste	EA, SEPA, EHS	Second edition Nov 2005
Hazardous Waste Regs (NI) 2005: How they affect you	DoE EHS	2005
Composting Guidance	DOE EHS	Sep-05
The Landfill Allowance Scheme: Guidance for landfill operators	DOE EHS	2005
The Landfill Allowance Scheme (Northern Ireland) Regulations 2004 Interim Monitoring Guidance for District Councils	DOE EHS	Aug-05
Capping for Landfill Sites	SEPA	Jan-03
Closure, restoration and aftercare plan for submission to SEPA	SEPA	25-Jun-03
Closure Procedures for Landfill Sites currently operating under Waste Management Licences	SEPA	Sep-03
The Disposal in Landfills for Non-Hazardous Waste Of Asbestos, Wastes.	SEPA	Jul-04
The Disposal in Landfills for Non-Hazardous Waste of Gypsum Wastes.	SEPA	Jun-04
The Disposal in Landfills for Non-Hazardous Waste Of Stable, Non-Reactive Hazardous Wastes	SEPA	Jun-04
Guidance on gas treatment technologies for landfill gas engines	SEPA & EA	2004

Waste on Land		
Guidance Document	**Issued By**	**Date**
Hydrogeological Risk Assessment for Landfills and the Derivation of Control and Trigger Levels, Version 2.12	SEPA	Apr-05
Guidance for monitoring landfill gas engine emissions	SEPA & EA	Septemeber 2004
Guidance on Monitoring Of Landfill Leachate, Groundwater And Surface Water v 2	SEPA	Jul-03
Framework for Risk Assessment for Landfill Sites	SEPA	Aug-02
Guidance for monitoring trace components in landfill gas	SEPA & EA	Sep-04
Guidelines for Thermal Treatment of Municipal Waste	SEPA	Aug-04
Agricultural Waste	SEPA	2005
The 4 point plan: Straightforward guidance for livestock farmers to minimise pollution and benfit your business	SEPA, SE, NFU, SAC, SNH,WWF, BOC Foundation, FWAG Scotland	
Guidance on the Keeping and Treatment of Waste Motor Vehicles and Conditions of Site Licences	Scottish Executive	Dec-03
Aguide to consigning special waste	SEPA	Dec-04
Guidance on the Recovery and Disposal of Controlled Substances Contained in Refrigerators and Freezers	SEPA & EA	2002
National Waste Strategy	SEPA	1999

Water		
Guidance Document	**Issued By**	**Date**
GUIDING PRINCIPLES ON THE TECHNICAL REQUIREMENTS OF THE WATER FRAMEWORK DIRECTIVE	SEPA	May-02
Controlled Activities Regulations Guidance for operators of abstractions and impoundments	SEPA	Nov-05
Guidance on general principles for pressures & impacts analysis	UKTAG WFD	2003
Draft principles for an objective setting framework for river basin management planning in accordance with the Water Framework Directive	UKTAG WFD	Sep-04
Environmental standards for use in classification and the Programme of Measures for the Water Framework Directive	UKTAG WFD	Jun-05
PREVENTION OF POLLUTION FROM CIVIL ENGINEERING CONTRACTS: SPECIAL REQUIREMENTS	SEPA	Jun-06
Regulatory Method (RM_03) Sewage Discharges to Surface Waters	SEPA	Apr-06
Regulatory Method (RM_12) Discharges from Water Treatment Works	SEPA	Apr-06
Prevention of Environmental Pollution From Agricultural activity	Scottish Executive	2005
Scotland's bathing waters - a strategy for improvement	Scottish Executive	
Regulatory Impact Assessment: Priority List of Substances under Article 16 of the WFD	Defra	Jan-02
Guidance on the Groundwater Regs 1998	DETR	2001
Groundwater Protection Code: Use and Disposal of Sheep Dip	Defra	2001
Groundwater Protection Code: Petrol stations and other fuel dispensing facilities involving underground storage tanks	Defra	2002
Groundwater Protection Code: Solvent Use and Storage	Defra	2004
Guidance note for the Control of Pollution (Oil Storage) (England) Regulations 2001	Defra	2001
The Code of Good Farming Practice Wales		
Code of Good Agricultural Practice for the Protection of Water		
The Groundwater Regs (NI) 1998 Disposal of List I and II Substances to L a n d : General Guidance on Compliance	DoE	Guidance Note 2
Policy and Protection for the Protection of Groundwater in NI	EHS	Jul-01
The Groundwater Regs (NI) 1998 Disposal of Waste Agricultural Pesticides to Land: Guidance on Compliance for Fa r m e rs and Grow e rs	DoE	Guidance Note 1
Guidance on the Groundwater Regs 1998	Scottish Executive	
Code of Good Agricultural Practice	Scottish Executive	2003
Code of Practice for the Safe USE AND Disposal of Sheep Dip	Scottish Executive	2003
REGULATORY POLICY DOCUMENT ON CONTROLLING WATER SERVICE DISCHARGES	DOE EHS	

Water		
Guidance Document	**Issued By**	**Date**
GP3 Groundwater Policy & Practice	EA	
Groundwater and Planning	SEPA	
Discharges to Groundwater	SEPA	
Groundwater and Contaminated Land	SEPA	
Groundwater Abstractions	SEPA	
Groundwater and Chemical Storage	SEPA	
Groundwater and Agriculture	SEPA	
Groundwater and Waste	SEPA	
Groundwater and Cemeteries	SEPA	
Groundwater and Engineering Activities	SEPA	
Be Oil Aware Series	EA	
Chemical Pollution and How to Avoid It	EA	
A guide to good environmental practice for trading estates and business parks	EA	2002
CLR 1 A framework for Assessing the Impact of Contaminated Land on Groundwater and Surface Water	DoE	1994
Costs and Benefits Associated with the Remediation of Contaminated Groundwater: A Framework for Assessment	EA	2000
ConSim: Contamination impact on groundwater	EA	2003