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Characterisation of sludges — Guide to risk assessment especially in relation to use and disposal of sludges

ICS 13.030.40; 13.060.30

British Standards

National foreword

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Characterisation of sludges - Guide to risk assessment especially in relation to use and disposal of sludges

Caractérisation des boues - Guide pour l'évaluation du risque en relation avec l'usage et le mise en décharge des boues

Charakterisierung von Schlämmen - Anleitung zur Risikobewertung im Besonderen im Bezug auf Nutzung und Lagerung von Schlämmen

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Foreword

This document (CEN/TR 15584:2007) has been prepared by Technical Committee CEN/TC 308 “Characterisation of sludges”, the secretariat of which is held by AFNOR.

1 Summary

This report has been prepared within the framework of CEN/TC 308 on Characterization of Sludges. The Scope includes sludges from treating municipal, industrial and food processing wastewaters, sludge from treating raw water to make it potable, and other residues having similar potential environmental impacts.

The objectives of the report are to review the methodology of risk assessment, risk management and risk communication especially as they have been applied to sludges. It includes references to, and reviews of, some major risk assessments and abstracts of others that have been published.

Sludge is the inevitable residue of treating raw potable water and municipal and industrial wastewaters. Treatment of these waters is designed to remove unwanted constituents from the water and concentrate them into a small side-stream - “sludge”. The sludge may also contain surplus biomass cultured during biological treatment processes. The objective of treatment is to avoid adverse impacts on the environment and human health when the effluent is discharged into the environment or water is supplied for human consumption. The concentration of beneficial constituents and of pollutants in (and health risks associated with) a sludge depends on the initial quality of the wastewater or raw water, and the extent of treatment required to meet quality standards for effluent discharge, and potable water.

Where effluent quality standards are raised, in order to reduce pollutant loads on the environment, the quantity of sludge produced inevitably increases. To be consistent, the use or disposal of the sludge must also be environmentally acceptable, sustainable and cost-effective. Sludge management typically represents about half of the overall costs of wastewater treatment. Its management will become increasingly complex as environmental standards become more stringent, and if outlets for sludge become more constrained by legislation and public attitudes.

EU policy on waste is to promote waste avoidance, minimisation and recycling above disposal. Disposal of sludge to sea ceased at the end of 1998. Disposal of sludges to landfill, which is currently the major outlet for some sludges in Europe, is widely regarded as unsustainable. Sludge production cannot be avoided (although the quantity can be reduced by treatment). The only remaining significant options are recycling or destruction by combustion. Recycling options include use on land as an organic fertiliser or soil improver for farming, land restoration, etc. Destruction options include combustion with or without energy recovery, gasification, and using the sludge as a process fuel, with the ash being used or landfilled.

Many sludges and residues contain beneficial constituents and properties with positive environmental advantages. For example, recycling phosphate and thus reducing the need to extract primary raw material and extending the life of the planet’s reserves.

The EU has decided (CEC, 2000) that environmental policies should be proportionate to risk and non-discriminatory. When there is sufficient information, there should be risk assessment and, when there is insufficient information, measures should be put in place to fill the information gap and an interim precautionary approach applied.

In popular understanding, “safe” can be interpreted as “something we don’t have to worry about”. There is a social factor as well as the numerical factor. Some people talk of the “One-hit” model, especially for carcinogens, which assumes that interaction of a single molecule with DNA could trigger mutation that could replicate as cancer but if this were applied universally it would stop all activity. Doing risk assessment lets us understand the aspects that drive the risk and therefore enables us to target the regulation – it improves the way we regulate.

Risk assessment should inform a decision rather than support a decision that has already been taken, i.e. the science should come first and then the politics (informed by the science). Equally the performance of risk assessment needs to be adequately resourced (time, money, people, etc.), it needs to be transparent (i.e. the models and assumptions should be published) and stakeholders need to be involved at the earliest stages. The fundamental question is “risk of what to whom”. Risk communication has emerged as an essential activity.

In order to increase public and stakeholder confidence the views of non-expert audiences may be brought into the risk assessment process and supporting [background] documents should be published so that the assumptions and models are clearly visible.

There is abundant information about the fate and transport of the constituents of sewage sludges, but less information about the other sludges. However, relatively few risk assessments have been published.

2 Scope

The Scope of this document includes sludges from treating municipal, industrial and food processing wastewaters, sludge from treating raw water to make it potable, and other residues having similar potential environmental impacts.

The purpose of this document is to discuss risk assessment in general and especially as it has been applied to sludges for an audience of specialists and non-specialists. The objective is to set risk assessment in the context of policy making and operating sludge use and disposal.

3 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Not applicable

4 Terms and definitions

For the purposes of this report, the following terms and definitions apply:

4.1
harm
physical injury or damage to the health of people or damage to property or the environment

[ISO/IEC Guide 51]

4.2
hazard
potential source of harm

[ISO/IEC Guide 51]

4.3
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51]

4.4
perceived risk
sum of risk and “outrage” – outrage is what makes people upset

4.5
contaminant
substance, material or agent that is unwanted in a sludge

[CR 13455 : 1999]

4.6
pollutant
contaminant present in a sludge that due to its properties, amount or concentration causes harm

[CR 13455 : 1999]

4.7
potentially toxic element
chemical elements that have a potential to cause toxicity to humans, flora and fauna. Typically, this term refers to “heavy metals” and others such as arsenic, selenium, boron, fluorine that exhibits a typical, dose related, sharp toxicity curve

[CR 13455 : 1999]

4.8
user
anybody exposed to the product, including professional and non-professional (amateur) users, and general public exposed not from a user standpoint

[CR 13455 : 1999]

4.9
intended use
use of a product, process or service in accordance with information provided by the supplier

[ISO/IEC Guide 51]

4.10
reasonably foreseeable misuse
use of a product, process or service in a way not intended by the supplier, but which may result from readily predictable human behaviour

[ISO/IEC Guide 51]

4.11
safety
freedom from unacceptable risk

[ISO/IEC Guide 51]

4.12
protective measure
means used to reduce risk

[ISO/IEC Guide 51]

4.13
residual risk
risk remaining after protective measures have been taken

[ISO/IEC Guide 51]

4.14
tolerable risk
risk that is accepted in a given context based on current values of society

[ISO/IEC Guide 51]

4.15
risk analysis
systematic use of available information to identify hazards to estimate the risk

[ISO/IEC Guide 51]

4.16
risk evaluation
procedure based on the risk analysis to determine whether the tolerable risk has been achieved

[ISO/IEC Guide 51]

4.17
risk assessment
overall process comprising a risk analysis and a risk evaluation

[ISO/IEC Guide 51]

4.18
Monte Carlo Analysis (MCA) or Simulation
process of repeatedly sampling from probability distributions to derive a distribution of outcomes (i.e. risks or hazards)

5 Introduction

About 500 years ago, Paracelsus (1493-1541) wrote: "Dosis facit venenum." ("The dose makes the poison."). The relationship between dose and response (effect) is still one of the most fundamental concepts of toxicology (the science of poisons), but when we discuss environmental alarms and chemical health risks it is sometimes forgotten. A logical consequence of the dose concept is that all environmental risk analysis is more or less quantitative in nature.

Risk management is at the heart of European policy on the environment as well as other aspects of life. It is also at the heart of many businesses. For example, risk assessment is the foundation of the insurance and pensions industries.

In order for there to be a risk [4.3] to a receptor there must be a source of the hazard [4.2] and a pathway by which a sufficient (harmful) dose is delivered to the receptor. In the case of the use or disposal of sludges, the sludge could be a source of chemical or biological hazards, the receptors could be organisms living in soil or water or on the surface of the land, and the pathway could be direct ingestion of the sludge or via air, plants or water.

Risk assessment [4.17] is often portrayed incorrectly as being different from the precautionary principle, indeed they are sometimes portrayed as being incompatible. The precautionary principle was first recognised at international level in the World Charter for Nature, adopted by the UN General Assembly in 1982. It was enshrined at the United Nations' Conference on Environment and Development, meeting at Rio de Janeiro in June 1992 (Annex C principle 15) this and European Commission policy (CEC, 2000) show that they are both part of managing environmental risk.

Risk assessment has established itself as an essential tool for the management of environmental risk and has been widely adopted by businesses, regulators and the financial sector. However, the perception of risks by members of the general public can differ from the quantitative assessments of risks. For example, it was difficult to persuade people to wear seat belts in cars, not to smoke, etc. because members of the general public's perceptions of the risks differed from those calculated by actuaries. The realisation of this dichotomy led to awareness that "risk communication" is also important. Table 1 gives examples of actuarial risks associated with normal everyday activities to give some context and to put the subject into perspective.

Table 1 – Examples of risks involved in normal activities (from FWR, 2002)

Activity	Risk Of	Cases per million
Travel 1000 miles by air	Fatal accident	3
Travel 1000 miles by car	Fatal accident	20
Travel 1000 miles by motorcycle	Fatal accident	400
Working 10 years in a factory	Fatal accident	300
1 glass of wine per day for 10 years	Cirrhosis	1000
1 cigarette per day for 10 years	Heart attack or lung cancer	2500
Living 1 year at age 30	Death from all causes	1000
Living 1 year at age 55	Death from all causes	10000

Figure 1 gives a representation of the major components of the process of hazard identification, risk assessment, risk management and risk communication. It shows examples of the types of data that are required; if there are insufficient data the precautionary principle should be invoked, in a way that is proportionate to the likely risk and on a time-limited basis, until the data necessary to estimate risk have been obtained (CEC, 2000). Cultural and political values are also shown as components because, for example, levels of risk or practices that are acceptable in one community might be unacceptable in another. It would seem illogical to have measures for different regulated activities within the same population that give markedly different levels of protection so there needs to be some consistency and proportionality.

A number of assumptions have to be made when assessing risk (as indicated in Figure 1). For example, when assessing the risk of transmitting toxic chemicals from sludge, via soil to crops and then to humans it is necessary to make assumptions about the proportion of the diet that comes from sludge treated land. It is important to document these assumptions in order that the basis is transparent. If somebody finds the result difficult to accept, they can then check the assumptions and models to see whether they are reasonable.

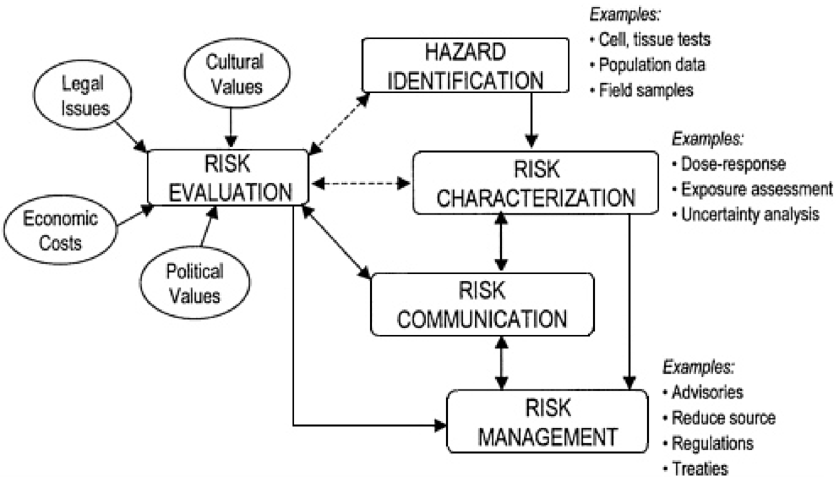

Figure 1 – The major components of the risk assessment and risk management process (from NAS, 2002)

5.1 Hazard, Risk and Communication

Crompton (2005) discussed the distinction of hazard and risk by the example of cyanide in a kitchen; the hazard is always very high but the risk depends on the exposure. If the bottle is clearly labelled and locked away in a safe the risk is small; if the bottle is unlabelled and in an unlocked kitchen cupboard the risk is much greater; if the cyanide is in a cup of tea the risk is very high indeed.

A newspaper headline "Cyanide found in kitchen" would be accurate and scary but it does not describe the risk. The same headline would be true if there were apples in the kitchen because apple pips contain small (non-harmful) amounts of amygdalin that breaks down to cyanide. The dose of cyanide from apple pips is so small that it is metabolised and is harmless, even if the coating is broken open by mastication.

5.2 Risk Assessment and the Precautionary Principle

Life is a continual process of managing and assessing risks. Take as an example crossing a road. By experience and example we learn to estimate the density and speed of the traffic and to assess when the risk [of being hit by a vehicle] is acceptably low to attempt to cross the road. If the traffic is so continuous and fast that there are no breaks for the risk to be acceptable we can walk to the nearest controlled crossing, i.e. employ risk reduction technology. However a person who is deaf and blind would not have the data required for assessing the risk; a deaf and blind person would be wise to employ the Precautionary Principle and not cross the road until their data gap was filled, e.g. by the assistance of a sighted person.

The authority responsible for the safety of pedestrians might decide that the risk of injury from crossing roads was unacceptable and all roads should be fenced. Traffic control lights would still entail the risk that vehicles might not stop; also, they disrupt traffic flow and cause delays. To eliminate the risk of pedestrian-vehicle collision, crossing would be permitted only at monitored subways (underpasses) or bridges. Monitoring would be in order to manage the risk of muggings. This approach is taken for motorways, autobahns, freeways and other very high-risk roads but it would be disproportionate to apply the policy to all roads. The cost of creating and maintaining the infrastructure and the inconvenience would be disproportionate to the risk. In practice, the authorities responsible for road safety assess the risks from data they have collected about accidents.

The Precautionary Principle is an integral part of risk assessment. If there are sufficient data to assess the risk with a reasonable degree of confidence, action/policy is based on the data. As with all scientific and engineering exercises, a margin of safety will be applied. The size of this margin is related to the confidence in the data and also to political choice. The tolerable level of risk for which the action/policy provides protection is also a political decision; the EU has decided this should be consistent and proportionate. If having examined the available data, they are considered to be insufficient or inconsistent, an interim and proportionate action/policy is established and at the same time the necessary measures are put in hand to fill that data gap so that a risk assessment is possible.

6 Source – Pathway – Receptor

It is fundamental that in order for there to be a risk there must be a receptor and that there must be a pathway by which the hazard is transmitted from the source to the receptor. If one of these elements in the chain is missing there can be no risk.

When considering sludge as a source of hazards, there are several possible receptors and several possible pathways; they are outlined in Table 2.

Table 2 – Generalised examples of possible source-pathway-receptor chains for use and disposal of sludges

Source →	Pathway →	Receptor	Consideration
Sludge →		human	Direct ingestion or via skin puncture etc.
Sludge →	soil →	human	Direct ingestion or via skin puncture etc.
Sludge →	soil → plant →	human	Dietary intake of plant material from sludge treated land diluted through food retail chain
Sludge →	soil → plant → animal →	human	Dietary intake of products from animals grazing or fed on crops from sludge treated land
Sludge →	soil → animal →	human	Direct ingestion of sludge treated soil by animals and transmission to humans
Sludge →	soil → airborne dust →	human	Respiration of dust from sludge treated land
Sludge →	(soil) → air →	human	Respiration of dust, odour, bioaerosols and airborne chemicals – includes incineration etc.
Sludge →	soil → ground/surface water →	human	Contamination of drinking water sources – includes landfill of sludges and ashes
Sludge →	soil → surface water → fish →	human	Dietary intake of contaminated fishes
Sludge →	soil → surface water →	fish	Toxicity to fishes from contaminated water, flora and fauna
Sludge →	soil → plant →	animal	Toxicity to animals eating plants growing in sludge treated soil
Sludge →	soil →	animal	Toxicity to direct ingestion of sludge treated soil
Sludge →	soil →	plant	Toxicity to plants growing in sludge treated soil
Sludge →	soil →	soil biota	Toxicity to soil organisms and impairment of soil functions
Sludge →	soil → soil biota →	predator	Toxicity to predators of soil organisms

When assessing risk it is essential to estimate the change [modulation] of “availability” or effective dose at each step in a pathway crucial. In the case of sewage sludge, the amount of research has been substantial (e.g. summarised in ICON, 2001 and Smith, 1996 and 2000). There has been less research on the other sludges but effects could be deduced judiciously from the sewage sludge data.

Table 2 lists examples of pathways and receptors that might be considered in a risk assessment for use and/or disposal of sludges. It is mainly concerned with chemical and biological risks. From a business or operational point of view, one could add the risk of legal action for not complying with regulations, for damage to the company's/organisation's reputation, for creating an actionable nuisance or for accidents to employees and others through a lack of regard to health and safety.

Individuals might be exposed to hazards via several pathways. Classically risk assessments have assessed each pathway in turn for receptors based on a number of assumptions. Assumptions would include exposure time, body weight, and other factors depending whether the assessment is being modelled for the average individual in the general population, individuals that are exposed more than the average. Risk management strategies are developed according to the pathway with the greatest risk to protect the average individual, the highly exposed individual (HEI) or the most exposed (MEI). This is called deterministic assessment, more recently there has been a trend to assess the probabilities of exposure to the different pathways etc. in combination (see clause B.8.6 for a discussion of deterministic and probabilistic risk assessment).

In some cases the product(s) of transformation and breakdown on the pathway from the source to the receptor are themselves hazards, for example the metabolites of DDT, DDE and DDD, also have toxic effects.

DDT is a pesticide once widely used to control insects in agriculture but now banned in many countries because of damage to wildlife, it breaks down to DDE, and DDD. They are all broken down rapidly in air by sunlight ($t_{½}$ = 2 days). They are strongly sorbed by soil; most DDT in soil is broken down slowly to DDE and DDD by microorganisms; the half-life of DDT in soil is 2-15 years, depending on the type of soil. DDT and DDE build up in plants and in fatty tissues of fish, birds, and other animals.

DDT is still used in some countries because it is inexpensive and very effective for controlling malaria mosquitoes and locusts.

This is an example of balancing risks and cultural and political values. When there is risk of millions of deaths per year because of malaria (mosquitoes) and starvation (locusts), the environmental risk from DDT might be considered acceptable until a preferable control is available.

7 A framework for environmental risk assessment and management

At the outset it is essential to decide and understand the purpose and context, i.e. the “risk of what to whom”. The analysis should be systematic and logical. It should consider how the output will be used, and the cost, social acceptability and effects of the risk management measures that will emerge.

Figure 2 shows a framework for environmental risk assessment and risk management (Anon, 2000 and Pollard and Guy, 2001).

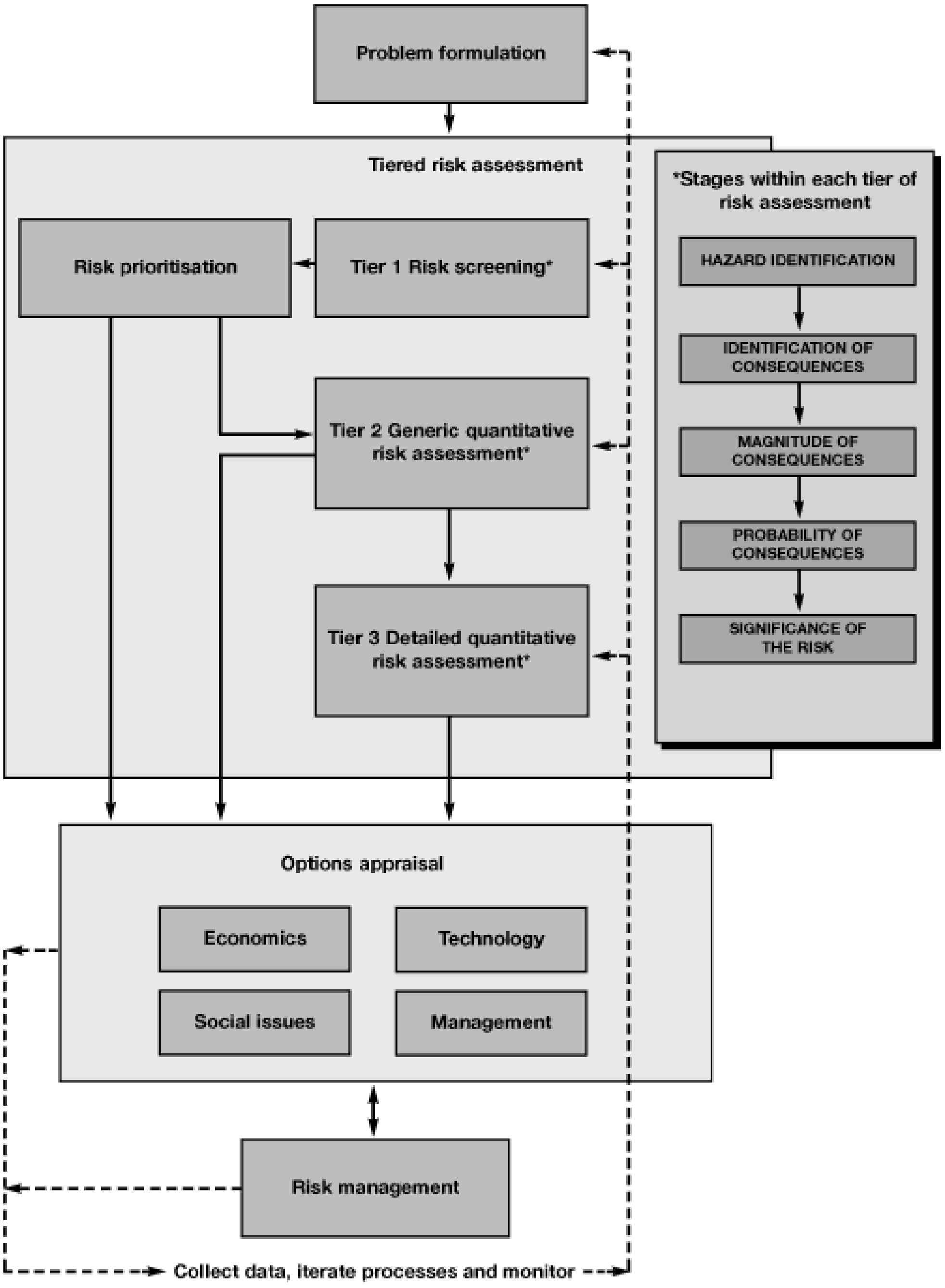

Figure 2 – An example of a framework for environmental risk assessment and risk management (from Anon, 2000)

A risk assessment framework is useful to show how the component stages relate to each other and inform the overall decision being made. Agreeing the framework early on can avoid misunderstandings between experts, stakeholders and the public later on. It is now agreed that it is good practice to involve stakeholders at the earliest stage so that they agree the model rather than presenting them with completed assessment only to find they argue about the fundamental basis.

A pragmatic approach to environmental risk assessment can transform what may sometimes appear to be an extremely detailed, complex and resource-intensive process into a practical aid to decision-making. Figure 2 provides a framework for a tiered approach to environmental risk assessment and management where the level of effort put into assessing each risk is proportionate to its priority (in relation to other risks) and its complexity (in relation to an understanding of the likely impacts); it also illustrates:

- the importance of correctly defining the actual problem at hand;
- the need to screen and prioritise all risks before quantification;
- the need to consider all risks in the options appraisal stage; and
- the iterative nature of the process.

The subject is discussed in more detail in Annex B the following is a summary.

7.1 Problem formulation

Defining the problem and the boundaries clearly and unambiguously is a critical step and it should be documented so that if the eventual decision is challenged or audited. If possible, stakeholders should be involved at this early stage to get agreement on this foundation of the assessment.

Defining the intention (e.g. to apply sludge to farmland without impairing the health of soil, wildlife or consumers of crops and livestock products, etc.) is also important and consists of four facets. What was the baseline (health of soil, wildlife, etc. and the pre-existing hazards before the intention) what are the components and the process, and what is the forecast for the situation after the intention?

Having defined the intention it should be justified: given the risks, benefits and costs does society want sludge applied to land or does it want it to be incinerated at location X? Not in my back-yard is clearly not appropriate in the context of not justifying an intention, the exercise presupposes that an issue exists and that a solution must be found.

When formulating the problem it is essential to consider the options that are available to control the risk(s), i.e. how the source, the pathway and the receptor can be influenced/changed to manage the risk. For example, can the content of chemical hazard be reduced by controlling the sources of discharge or by banning their inclusion in products? Can the biological risk be controlled by sludge treatment, preferably based on Hazard Analysis and Critical Control Point, and can restrictions on the cropping and grazing of treated land be implemented as a second barrier?

In the rich farming area of the Nile Delta in Egypt additional organic matter and plant nutrients are highly valued by farmers but the farming is intensive and on a very small scale with much hand-working. If sewage sludge is to be supplied into such a situation it is obvious that there can be no second barrier to control the risk and the sludge must be treated so that its biological risk is no greater than field soil. It would make little sense to reduce the risk below the ambient (baseline) level.

The problem is formulated as a conceptual model of the source-pathway-receptor such as Figure 3, which requires data about dietary composition, drinking water intake, bioconcentration factors and many more that are discussed in B.1.6.

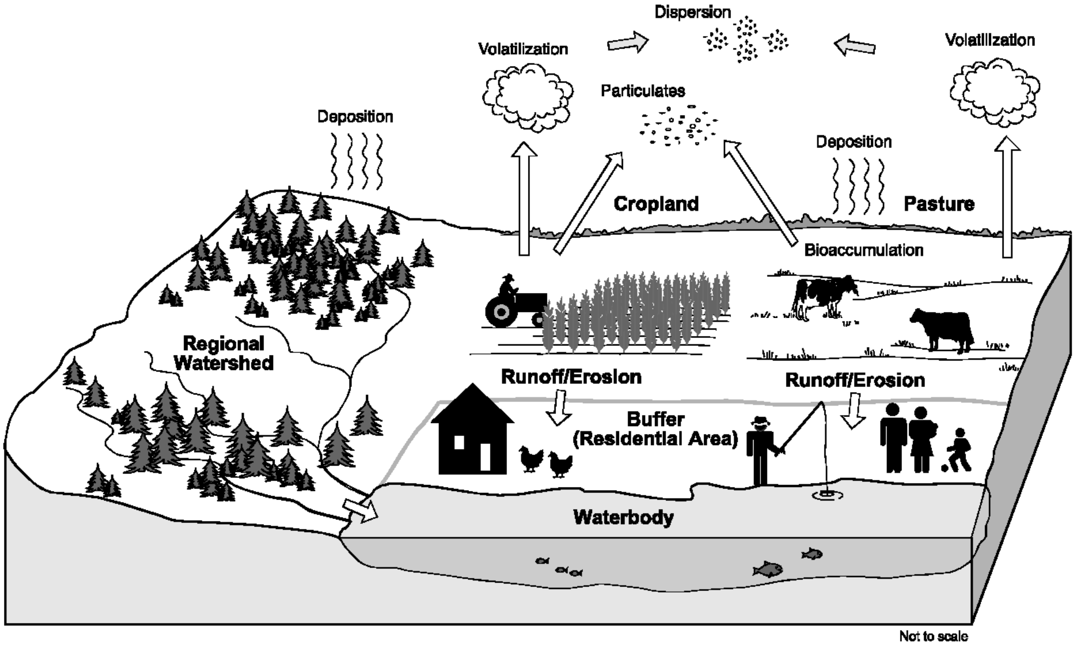

Figure 3 – Conceptual site model of sludge use in agriculture (from USEPA, 2002b)

7.2 Key stages of environmental risk assessment

Identifying (listing) the hazards is the first stage. This might seem obvious but it is essential that it is done objectively and comprehensively, including the secondary hazards. For example in the cases of application of PTEs to soils or the fallout of emissions from combustion, consideration should be given not only to the current land use and population but also to changes that could be reasonably expected in the future.

The next step is to identify the consequences that could result from these hazards and then the magnitude and spatial extent, longevity and time to onset of the consequences. These are the stages at which the magnitude of the source, the pathway of transmission and the dose that the receptor is likely to receive and its relation to the tolerable dose would be considered. All of this is compounded to give the tolerability of the risk that would be involved and an appraisal of the options that are available.

7.3 The social aspects of risk

In some ways this is the most difficult aspect but its importance has increased over recent years. For the most part society tolerated a process of “decide and dictate” until the mid/late 20th century but the public has become more sceptical about the credibility of politicians, scientists and engineers. Awareness of, and concern about, environmental issues has increased but often the issues on which choices and decisions have to be made are complex. Rapid mass communication means that people have access to information as never before. The internet is an especially powerful source of information. Some of this information is unauthenticated and can only be weighed and critically assessed by those who have sufficient information. It is because of this “new” culture of suspicion and concern that it is important to involve stakeholders, trusted ‘gatekeepers’ (e.g. NGOs and food retailers) and members of the public at an early stage and to communicate the technical information, explain it and make it widely available.

Lay reactions to risk (risk perception) can differ considerably from judgements based on scientific probability estimates. It is now recognised that these reactions are often predictable and frequently rational so it is important to understand how and why risk perception can differ from scientific probability estimates of risk. This is discussed in more detail in B.3, social and cultural values are involved as is the distinction of voluntary and involuntary risks, e.g. driving a car and emissions from an incinerator that complies with modern standards. Unfamiliar and technological risks are perceived differently from natural ones, e.g. nuclear power stations compared with radon releasing geology. Risks that become subject to controversy and contradictory information generally give rise to more concern so it is a good idea to forestall controversy if possible by early involvement of communication including listening to stakeholders.

Trust and credibility have been identified as important determents of perception. This can be earned by being open, accountable and taking different views into account rather than disregarding some as emotional or irrational. Perception of inequity of distribution of risks and benefits can be a factor, for example city-dwellers' sludge being spread in rural areas.

Successful risk communication is difficult to achieve, but it is better to be proactive and start communication at the earliest stage rather than wait and react if/when opposition arises. It is much more difficult to defuse and emotional argument than to debate and win a rational argument.

Market research techniques can be very useful to quantify the public's reaction to the scenarios that are being assessed. On the one hand it is useful to know the aspects that the public is really concerned about, because they can then be addressed, and on the other it is useful to know the aspects that are not of concern, because it can defuse single-issue activists.

Stakeholder involvement brings together diverse viewpoints and may help to resolve existing or potential problems by ensuring that stakeholders are involved in the development of the solutions. It can therefore bring long-term gains. However, it requires careful planning, large amounts of time and other resources, and cannot be expected to guarantee the resolution of conflict or controversy.

7.4 Risk screening and prioritisation

Risk assessments can be time-consuming and expensive so it is sensible that the amount of effort put into risk assessment should be proportionate to the severity of the problem; that is the reasoning behind recommending a tiered approach (Figure 2).

Sludges, especially sewage sludges, can contain a multitude of hazards reflecting everything in use by society. It is essential to prioritise these hazards in a consistent, transparent and documented manner to decide where to apply the resources for risk assessment, i.e. which hazards have the highest priority for the first (or subsequent) round. Prioritisation does not necessarily mean that a hazard is discarded. Prioritisation would look at the abundance of the hazard in the sludge, the pathway (including any decay) to the receptor and the relative toxicities/consequences. Likely public concern should also be included. For example in some countries the human population has high infection rates of gastro-intestinal parasites, which will be shedding eggs, the risk of parasite transmission via this sewage sludge would come out much higher in a prioritisation ranking than in a country where infection with such pathogens is virtually zero (e.g. Egypt compared with UK).

A preliminary sampling and analysis screening could provide the data for risk screening and prioritisation. If a toxic, persistent, bioaccumulative chemical was found only ever to be present in trace amounts, and the pathway(s) only conveyed a small proportion of that to the receptor the risk would rank very low. Controls to manage risk of a hazard found in greater concentration and with greater transmission to a receptor would control the risk of the trace hazard.

It is important that this ranking process is documented and available so that concerned individuals and subsequent workers can follow the logic of why a particular hazard was not taken forward to full risk assessment.

7.5 Quantification and dealing with uncertainty

Tools and techniques for risk assessment are developing continuously; http://riskworld.com is a useful source of information about these developments. Where information is limited, informed decisions can be based on extrapolation but it is important that the data gaps and assumptions are acknowledged. For example, there has been more research into the environmental impacts of sewage sludge than the other sludges one can therefore extrapolate from the sewage sludge data but it should be documented that this is an extrapolation so that users of the risk assessment are not deluded into thinking that real data from the sludge in question have been used. Sensitivity analysis can be used to identify the vulnerability of using such extrapolation: if plant-availability were 50% greater for this sludge than sewage sludge, how would that affect the dose?

Environmental risk assessments consider the probability of an event occurring. For sewage sludge applied to land there is a probability of 1 (i.e. it will happen) that some cadmium will be added to soil, because cadmium is in the human diet and therefore it is in sewage. However, there is a much lower probability that industrial accident will result in a significant discharge that gets all the way through the system undetected and elevates the cadmium content of the sludge applied to land. Historical monitoring data can demonstrate the frequency and probability of such an event. Fault tree analysis (Annex D) and event tree analysis (Figure B.3) are systems based on logic diagrams for representing the propagation of faults or events through a system.

Having estimated the probability of an event occurring, the next steps are to estimate the magnitude of the consequences and the probability of the consequences. Figure B.2 and Figure B.3 track the survival of *Salmonellae* through the sewerage system and wastewater treatment process, into the sewage sludge, onto the field, die off in soil and eventual numbers that might be found on potatoes. The next stage would be to estimate the consequences, i.e. the number of infections that might result and the significance of those infections; e.g. is it short-term diarrhoea or is it fatal?

At each step there are uncertainties in the data and assumptions. One approach is to construct “worst case scenarios” and assess the impact of each; it is important to document the scenarios. Another is to use statistical descriptions of the probability and frequency distributions. Safety factors can also be used to deal with uncertainty and again it is important to record the rationale used to assign safety factors.

7.6 Evaluating the significance of a risk

Along with the formal scientific assessment it is necessary to consider the broader significance. From the point of public policy and proportionality it is necessary to put the risk into the overall context, e.g. how does the risk of this source of transient minor infection compare with that from riding crowded commuter transport in winter with its warm, humid atmosphere?

There are legal standards for the composition of food and drink (e.g. cadmium in grain, nitrate in drinking water) and for these end-points, the target of risk assessment will be to not exceed these limits. In situations not covered by legislation, targets could be set by socio-economic analysis and expert judgement taking into account societal pressures. The best outcome is likely to be where there is the greatest excess of benefit accruing from the protection compared with the social and private costs of the control options.

The policy principles used in the EU for environmental and other risk are generally:

- ALARA (as low as reasonably achievable) normally for food standards for which it is implicit that there should be a sufficiently extensive database
- ALARP (as low as reasonably practicable) which implies reduction to “tolerable risk” and that any further risk reduction would be at hugely disproportionate cost.
- BATNEEC (best available technique not entailing excessive cost) and BPM (best practicable means) are commonly used for environmental protection. They imply that controls could change over time as new technological solutions become available. BPEO (best practicable environmental option) is a transparent, auditable approach to choosing between options that brings in practicability and cost and benefit.

It is implicit that the control that is considered achievable also gives an adequate and proportionate level of safety, so they should not really be considered a substitute for risk assessment.

7.7 Options appraisal and decision-making

Options appraisal is about identifying the best risk management option. For example, if a chemical constituent is assessed to present a risk of sufficient magnitude when sewage sludge is applied to land that it needs to be controlled, is it better to control the application rate of the sludge or to ban the use of the chemical in products so that it cannot get into the wastewater system? Options appraisal involves ranking costs and benefits; these could include encouraging new technologies and techniques and social issues, perceptions and aspirations.

Options appraisal could be between contrasting strategies, e.g. incineration, drying and combustion in cement kilns, local use on farmland and remote use on mining reclamation. In this example there are different exposure routes but one would also need to consider the impact of transport (accidents, emissions, energy, etc.) for each option.

If the project were large enough, options appraisal could entail a legal requirement for environmental impact assessment or the strategic environmental assessment directive (2001/42/EC).

Cost-benefit analysis is often part of options appraisal and one might want to give monetary value to environmental assets that cannot readily be valued. Environmental economics is a developing field (e.g. http://europa.eu.int/comm/environment/enveco/) partly, but certainly not exclusively, in response to the obligation for regulatory impact assessment.

Options appraisal may entail revisiting the risk assessments, in which case documentation of the assessment and the underlying assumptions will be invaluable. Dialogue with stakeholders is important during options appraisal as with all other steps of risk assessment.

7.8 Monitoring

Monitoring plays a central role in environmental risk assessment to provide:

- a baseline against which to measure actual and predicted impacts
- input data for models, forecasts and verification of the risk assessment and that the management options are performing satisfactorily
- as an early warning if adverse impacts are found

For example, monitoring the quality and function of soils to which sludges are applied and the crops and animals raised on them sets the baseline initially, verifies the management rules and, if the initial risk assessment were not cautious enough, would give early warning that crop quality or soil function were being impaired.

Another example is monitoring the risk of exposure to bioaerosols and odour from a sludge-composting site. One could monitor wind strength and direction and temperature and correlate off-site complaints with these data. One could also monitor records of respiratory problems reported at health services locally for a period of 12-18 months before the facility starts to operate in order to get the baseline and then during the site’s operation. The most exposed people are probably the workers on the site and a lung-function test for each employee before they start working on site and annually thereafter could give verification of the adequacy of management options, at least for occupational exposure if not for the population as a whole.

Technical expertise and knowledge of the systems that it is proposed to monitor are essential when designing and establishing monitoring programmes and when assessing the data. Where to sample, and when to sample, need to be assessed critically. There is no point sampling annually for a trace constituent that is accumulative and expect to build up very gradually because the concentration change would be invisible against the background noise of sampling error; equally there would be no point monitoring 5-yearly for a high-concentration biodegradable constituent because it would have decayed between sampling intervals. Data assessment and system review are essential.

Whenever possible the key stakeholders should have access to both the raw and the processed data so that they can see that nothing is being hidden. It is important that at the same time they are aware of the key assumptions and uncertainties.

7.9 Risk Management

Having established a policy framework to control risk it is necessary to put in place a management system to ensure that all of the critical aspects are completed every time and an operational or production process that achieves the required outcome every time.

The quality of goods used to be assessed by sampling from the production line and test (Quality Control) this was refined by statistical control of the sampling but inherently it means that one only knows the quality of the samples that have been tested. The untested units are assumed to be acceptable by interpolation. W. Edwards Deming is credited with introducing what is now known as Quality Assurance (QA) when assisting reinvigoration of Japanese industry in the early 1950s (http://en.wikipedia.org/wiki/W._Edwards_Deming). Japanese goods gained market share because they were reliable and consistent. QA involved standardising the way in which each step of a process is performed, documenting the Procedures and training personnel how to use them. The Procedures are tested and refined if necessary; the process is operated using the Procedures and the quality is monitored. Performance is reviewed, Procedures improved and re-documented etc. in a process of Continuous Improvement.

QA was first applied to engineering and manufacturing; it is now applied to every aspect of work. ISO 9000 and ISO 14000 series of standards (the latter brings in environmental aspects) give guidance and enable external accreditation.

Hazard Analysis and Critical Control Point (HACCP) was introduced in the late 1960s to assure that the food for the manned space flight programme would be safe. It has subsequently been adopted internationally (Codex, 1997) as the basis for food and drink safety and in some cases for engineering and waste treatment (Composting Association, 2003). HACCP requires the producer to consider the intended use of a product and then to assess the hazards that could be associated with that use (or reasonably expected misuse). One of the hazards could be non-compliance with legal obligations. Each step of the production process is assessed to see whether it controls the risk of one or more hazards to an acceptable level, if it does and it cannot be by-passed and recontamination is not possible further down the process, this step is a Critical Control Point for the hazard(s) and all that is necessary to ensure satisfactory control is to monitor that CCP and ensure that it stays within critical operating limits. A record of the operating conditions thus becomes proof of control. For example controlling incinerator temperature within critical limits will destroy dioxin and a continuous record of temperature is proof of continuous control; in this example flue gas sampling and analysis is really only confirmation that everything is working properly, it is not the prime control.

HACCP combined with QA is a very good and pragmatic approach to managing the risks of sludge use and disposal. Training, reviewing and refining in a process of continuous improvement are fundamental to both.

8 Examples of published risk assessments for use and disposal of sludges

There have been relatively few published risk assessments relating to the use and disposal of sludges.

8.1 USEPA risk assessment for the Federal Sewage Sludge Rules, 1992

One of the first and most comprehensive risk assessments into the use and disposal of sewage sludge was published by the United States Environmental Protection Agency in 1992 (USEPA, 1992). It modelled land application, ‘surface disposal’ (land-farming and landfilling) and incineration. It was a multi-pathway deterministic risk assessment for chemical contaminants. It was started in 1982, took 11 years to complete and cost US$15 million. The federal regulation that it underpins is "Part 503" of the Clean Water Act or 40 CRF Part 503 (USEAP, 1993). The steps in the RA were:-

- postulate the possible hazards
- select a sample of wastewater treatment works representative of the whole country on the basis of a the EPA ‘Needs Survey’ of 1986 which identified which of the 11,407 works had secondary treatment
- a 50 page questionnaire was sent to 479 works to gather more detailed information about treatment, disposal and use of sewage sludge
- sample the sewage sludge from a sub-set of 208 works and analyse the samples for the 412 analytes (342 organic, 70 inorganic) plus pathogens
- model 14 exposure pathways using all the available literature on crop uptake, food chain concentration etc., tolerable intakes and competing exposure. These pathways did not include soil bacteria as receptors because this subject had not much received research interest in connection with sewage sludge at the time.
- test the exposure levels for the hazards presenting the highest risk
- subject the proposed exposure limits and methodology to international peer review (1990)
- analyse the response from the peer review and modify the assessment
- publish the revised risk assessed tolerable exposure limits (1992)

The intention was to protect Highly Exposed Individuals (HEI) for each pathway at a $1:10^4$ risk from a 70 year lifetime’s exposure and 100 repeated applications at the maximum permitted rate and concentration of regulated constituents at yearly intervals. The postulates for these HEI are quite extreme and there are probably few in the whole population of the USA that come up to the criteria, therefore protecting HEIs at $1:10^4$ is probably more precautionary that protecting the whole population at $1:10^6$.

40 CRF Part 503 includes rules for pathogen reduction in two classes (A and B: enhanced and conventional treatment) with land use restrictions for Class-B. However, these pathogen reduction rules were not based on risk assessment.

The 503 continues to be contentious because the results look different from pragmatically derived limit values. However, the technical support documents for the risk assessment and rule have been published, together with a further description of the risk assessment process, and these provide detailed descriptions of the assumptions, base data, models and formulae used. Rather than repeat them here, readers are referred to USEPA 1992 and 2002a.

8.1.1 National Academy of Sciences review of 503, 2002

In 2000, the National Research Council of the US National Academy of Sciences assembled a panel of experts in risk assessments and the relevant sciences to review the risk assessment underpinning 40 CFR part 503. This concluded (NRC, 2002) that the risk assessment methodology was valid at the time that it was done and recommended that it be repeated using the more advanced methodology (probabilistic techniques) that had been developed in the years since the original assessment and using the scientific results published in the intervening years. It also recommended studies of occupationally exposed workers and populations near treatment works and application sites, because it found so few published reports of such work.

The NRC found no evidence of an urgent public health risk from exposure to land-applied sewage sludge, based on its review of the scientific literature. It concluded that currently, there are no studies documenting adverse health effects from land application of sewage sludge, even though land application has been practiced for years.

8.2 USEPA risk assessment of dioxin-like substances in sewage sludge use and disposal, 2002

This was a multi-pathway probabilistic risk assessment for dioxins, furans and co-planar PCBs, which exhibit dioxin-like properties, for human (Figure 4) and ecological risk. Although not shown in Figure 4, human breast milk for the first year of a child's life was included, assuming the mother was a farmer. The conceptual model is shown in Figure 3. The multimedia models were run for 3000 iterations to make the probabilistic assessment. The process and support documentation are described in detail in USEPA (2002b) and interested readers are recommended to study this rather than reproduce it here.

The policy decision based on this risk assessment was that on the basis of the concentrations of these contaminants found in sewage sludge and the probabilistic risk assessment there was no need to introduce further regulatory requirements for monitoring or application of sewage sludge used on land.

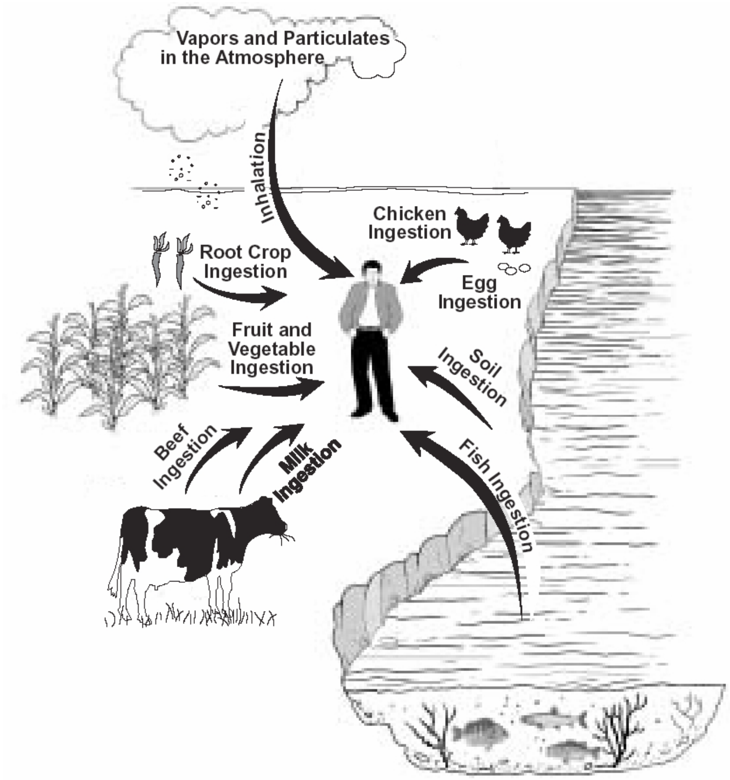

Figure 4 – Integrated human exposure pathways used in the USEPA, 2002b fully integrated assessment, all pathways were considered simultaneously in each iteration

8.3 UKWIR risk assessment of pathogen transmission associated with using sewage sludge on farmland, 2003

This risk assessment was the culmination of an extensive three phase research programme. The purpose of Phase 1 was to develop generic methodologies for the enumeration in sewage sludge of various bacterial pathogens (*Escherichia coli* O157, *Salmonella enteritidis, S. typhimurium, S. dublin, Listeria monocytogenes* and *Campylobacter jejuni*), protozoa (*Cryptosporidium parvum* and *Giardia lamblia*), and enteroviruses. It was also to assess the robustness O157 compared with indigenous *E. coli*, they proved to have similar susceptibilities to sludge treatment and that therefore indigenous *E. coli* was a valid indicator. Phase 2 studied the fate of these organisms and *E. coil* [indicator] during different types of sludge treatment. Phase 3, the risk assessment used the data from Phases 1 and 2, together with data from the published literature to assess the risk at the point of harvest for crops grown on land treated with sludge.

The event tree methodology used has already been discussed (B.5.2.5). A number of unrealistic assumptions were incorporated as precautions: e.g. it was assumed that (i) 2% of the raw sludge by-passed the sludge treatment stage without any diminution in pathogen numbers; (ii) die-off in soil was not extrapolated to the length of time reasonable between sludge application and harvest; (iii) no allowance was made for pathogen reduction during food preparation, such as washing or cooking. Even with these very precautionary assumptions the highest risk was calculated to be one additional human infection with *Cryprosporidium* in 44 years for the UK population (58 million) when root crops are eaten raw that had been grown on land treated with mesophilic anaerobically digested sewage sludge. The risks for the other organisms and for enhanced treatment processes that cause greater pathogen reductions were much less.

8.4 Abstracts of published risk assessments for sludges and related subjects

***A risk-based methodology for deriving quality standards for organic contaminants in sewage sludge for use in agriculture--Conceptual Framework*.**

Schowanek D, Carr R, David H, Douben P, Hall J, Kirchmann H, Patria L, Sequi P, Smith S, Webb S.

Regulatory Toxicology & Pharmacology 2004 Dec; **40** (3) 227-51.

http://www.ilsi.org/publications/index.cfm?pubentityid=21

Abstract: This paper describes a systematic methodology (Conceptual Framework) to derive quality standards for organic (anthropogenic) contaminants in sewage sludge added to agricultural land, in the context of revision of EU Sludge Directive 86/278/EEC and the broader Soil Thematic Strategy. The overall objective is to ensure, based on a risk assessment approach, a sustainable use of sludge over a long time horizon. ILSI-Europe's Conceptual Framework is in essence consistent with the EU Technical Guidance Document (TGD) for Environmental Risk Assessment of Chemicals in the soil compartment, or US-EPA's Sewage Sludge Use and Disposal Regulations, Part 503 Standards. A 'checklist' of different exposure pathways and transfer processes for organic contaminants needs to be considered, and the most sensitive relevant toxicological endpoint and its PNEC need to be identified. The additional complexity specific to deriving Sludge Quality Standards (SQS) is that the toxicity results may need (e.g., for [indirect] human toxicity) to be related back to maximum acceptable soil exposure levels (predicted environmental concentration - $PEC_{(soil)}$). In turn, the latter need to be back-calculated to the maximum acceptable levels in sewage sludge ($PEC_{(sludge)}$) at the time of application. Finally, for a sustainable sludge use, the exposure from repeated addition and potential chemical build-up over time (e.g., 100 years) needs to be assessed. The SQS may therefore vary with the (local) sludge application regime, and/or sludge pretreatment processes.

Health risk assessment for sewage sludge applied to land in France.

www.ineris.fr; www.ademe.fr, www.syprea.org, www.fp2e.org

Abstract: Sludge has been used on farmland for more than 30 years and is considered environmentally and economically sustainable. The law regulating this activity requires assessment of the human health impact of sludge spreading. The objective of this study was to develop standard methodologies for assessing both chemical and microbiological risks to human health; it includes two real case studies in which the methodologies are tested.

[Note: completion and publication are expected before the end of 2007]

Risk evaluation for pathogenic bacteria and viruses in sewages sludge compost

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Water Science and Technology (2002) **46** (11-12) 325-330

Abstract: Sewage compost samples were collected in Japan and analyzed for the presence of *Salmonella* spp., *Escherichia coli* O157, and Poliovirus 1. Subsequently, infection risks via vegetables grown in compost were quantified. Results showed that pathogenic bacteria and viruses were not detected in any of the compost samples. Results from infectious risks evaluated by Monte Carlo simulation suggested that 1.0 colony-forming unit/g should be set as the criteria for *E. coli* O157 and Poliovirus 1 in composts used for vegetable production, while the criteria for *Salmonella* spp. should be set at 0.001 colony-forming unit/g. 12 Refs.

Bioaerosol transport modelling and risk assessment in relation to biosolid placement

Dowd, Scot E.; Gerba, Charles P.; Pepper, Ian L.; Pillai, Suresh D.

Univ of Arizona, Tucson, AZ, USA

Journal of Environmental Quality (2000) **29** (1 Jan-Feb) 343-348

Abstract: A field study was performed in which bioaerosols were sampled at a field site undergoing land placement of anaerobically digested, de-watered biosolid material. The data from these field studies were then used to generate microbial release rates from the biosolids for use in modeling bioaerosol transport. Continuous-point sources represented by large biosolid piles (temporary storage before placement) in the field, and continuous-area sources represented by large fields upon which biosolids were placed by spraying, were modelled using microbial transport models; and downwind microbial concentrations were generated. These quantified transport data were then entered into microbial dose-response models in an attempt to characterize the risk of pathogenic bacteria and viruses infecting workers and nearby population centers. The risk of viral and bacterial infection to workers at biosolid land application sites is 3:100 and 2:100, respectively, under 2-m/s wind conditions and 1 hr of exposure. The route of exposure proposed in this model is the transport, inhalation, deposition, and swallowing of bacterial or viral pathogens. Note that these risk models by nature would tend to overestimate the actual risk to populations (wastewater workers) consisting primarily of immunocompetent individuals. Under these low-wind conditions, nearby population centers where such immunocompetent populations may exist (here considered to be 10000 m from the land application sites) are predicted to be at little risk (1.95 multiplied by 10^{-2}:100) of infection from aerosolized bacteria and at no risk from aerosolized viruses. 32 Refs.

[Note: the authors of this paper have found that there was an arithmetic error in the risk calculation; a formula that should have contained 39 as a divisor actually used 39 as a multiplier, even the small risk reported was therefore grossly and erroneously exaggerated. Tim Evans priv. comm.]

Giardia and its implications for sludge disposal

Hu, C.J.; Gibbs, R.A.; Mort, N.R.; Hofstede, H.T.; Ho, G.E.; Unkovich, I.

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Proceedings of the 1996 18th Biennial Conference of the International Association on Water Quality. Part 4, Singapore, 23-28 June 1996

Water Science and Technology (1996) **34** (7-8 pt 4) 179-186

Abstract: The beneficial use of wastewater sludge is to some extent restricted by the presence of human pathogens. Following a risk assessment and monitoring programme it was found that the pathogen which posed the highest potential risk of infection in treated sludge was *Giardia*. *Giardia* cyst concentrations were found to be approximately 900/g wet weight of sludge following anaerobic digestion, although not all of the cysts may have been infective. In further studies three methods of wastewater sludge disposal or treatment were investigated. Anaerobically digested and mechanically dewatered sludge was stored for up to 60 weeks, incorporated into sandy soil and composted on a laboratory scale. *Giardia* cysts remained at levels which could be considered a public health concern after storage of sludge for over one year and after composting. However, cysts appeared to be destroyed within 12 weeks following soil amendment. The implications of the presence of *Giardia* for sludge disposal are discussed.

Using event trees to quantify pathogen levels on root crops from land application of treated sewage sludge

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Journal of Applied Microbiology (2003) **94** (1) 35-47

Aims: To quantify the incremental exposure of root crops, at point of harvest, to enteric pathogens from sewage sludge applied to agricultural land according to current regulations and guidance (Safe Sludge Matrix).

Methods and Results: A quantitative risk assessment based on the Source-Pathway-Receptor approach is developed for Cryptosporidium and salmonellas. Event trees are constructed to model the partitioning of pathogens present in raw sewage into sludge at the sewage treatment works and to model to the pathways by which root crops may be exposed to those pathogens after treatment and land application of the sludge. The main barriers are sewage sludge treatment, and decay and dilution of the pathogens in the soil. The exposures are expressed in terms of the arithmetic mean. This represents the total loading and accommodates fluctuations not only in the levels of pathogens present in sewage but also in the removal efficiencies by the various barriers. One source of uncertainty is the degree of by-pass of sludge treatment at operational scale.

Conclusions: The models predict that land application of sewage sludge treated by conventional processes (achieving 2-log removal) increases the exposures of root crops to salmonellas and *Cryptosporidium* oocysts by counts of 0.070 and 0.033 kg^{-1}, respectively. These predictions are based on decay periods in the soil of 5 and 12 weeks, respectively, and are therefore worst case in not allowing for the full extent of no harvesting periods. A Monte Carlo simulation predicts that 0.01% of 1-kg batches contained > 50 salmonellas and demonstrates that, for risk assessment, it is acceptable to use the arithmetic mean exposure directly in the dose-response curve.

Significance and Impact of the Study: The predicted numbers of pathogens on root crops at point of harvest provide a basis for modelling the excess risks to humans consuming such crops. The approach underpins scientifically the Safe Sludge Matrix.

Hazard identification of pharmaceutical wastewaters using biodegradability studies

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3rd World Water Congress: Industrial Wastewater Treatment: Melbourne, 7-12 April 2002,

Water Science and Technology (2003) **47** (10) 197-204

A reliable wastewater characterization is an integral part of treatment and management strategies for industrial effluents. This is especially true for the pharmaceutical industry, which exhibits significant differences in its line of activity, generating effluents of very specific and complex natures. Any hazard or risk assessment of wastewater and/or determination of its treatability must include an evaluation of its degradability. Usually various non-standardized laboratory or pilot-scale long-term tests are run by measuring summary parameters for several days to determine the biodegradation potential of the effluent. A complex approach, based on stabilization studies, was proposed to determine the hazardous impact of wastewaters in terms of biodegradable and persistent toxicity. The objective of our work was to carry out complex hazard evaluation of pharmaceutical wastewaters. Whole effluent toxicity was determined using two different toxicity tests. First, we measured the inhibition of oxygen consumption by activated sludge. The test indicated toxicity of the wastewater and thus we performed an additional acute toxicity test with luminescent bacteria *Vibrio fisheri*. The next step was the determination of whole effluent ready biodegradability. It was determined with simultaneous measurement of oxygen consumption (ISO 9804) and carbon dioxide production (ISO 9439) in a closed respirometer, accompanied by DOC/IC measurements.

The pharmaceutical wastewater degraded readily (83%, lag phase was 2 days, biodegradation rate was 0.339 day^{-1}) on the basis of O_2 measurements. The biodegradation, calculated from the CO_2 measurements, was comparable. We also applied mass balances of DOC/IC at the beginning and at the end of biodegradation experiments to confirm the extent and rate of biodegradation. The determination of hazardous impact and treatability of the effluent was concluded with aerobic stabilization studies. Biodegradation of the wastewater during the study was followed by relevant biochemical analysis and DOC/IC mass balance.

Contaminant risks from biosolids land application: Contemporary organic contaminant levels in digested sewage sludge from five treatment plants in Greater Vancouver, British Columbia

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Journal: Environmental pollution (2003) **126** (1) 39-49

This study examines the potential for environmental risks due to organic contaminants at sewage sludge application sites, and documents metals and various potential organic contaminants (volatile organics, chlorinated pesticides, PCBs, dioxins/furans, extractable petroleum hydrocarbons, PAHs, phenols, and others) in current production biosolids from five wastewater treatment plants (WWTPs) within the Greater Vancouver Regional District (GVRD). There has been greater focus in Europe, North America and elsewhere on metals accumulation in biosolids-amended soil than on organic substances, with the exception of polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans. Another objective, therefore, was to evaluate the extent to which management of biosolids re-use based on metal/metalloid levels coincidentally minimizes environmental risks from organic contaminants. Historical-use contaminants such as chlorophenols, PCBs, and chlorinated pesticides were not detected at environmentally relevant concentrations in any of the 36 fresh biosolids samples, and appear to have virtually eliminated from sanitary collection system inputs. The few organic contaminants found in freshly produced biosolids samples that exhibited high concentrations relative to British Columbia and Canadian soil quality benchmarks included p-cresol, phenol, phenanthrene, pyrene, naphthalene, and heavy extractable petroleum hydrocarbons (HEPHs--nCl9-C34 effective carbon chain length). It was concluded that, with the exception of these petroleum hydrocarbon constituents or their microbial metabolites, the mixing of biosolids with uncontaminated soils during land application and based on the known metal concentrations in biosolids from the Greater Vancouver WWTPs investigated provides adequate protection against the environmental risks associated with organic substances such as dioxins and furans, phthalate esters, or volatile organics. Unlike many other organic contaminants, the concentrations of petroleum hydrocarbon derived substances in biosolids has not decreased within the last decade or more in the WWTPs studied, and--unlike persistent chlorinated compounds--the associated PAHs and other hydrocarbon constituents merit careful consideration, especially in the context of repeated land-application of biosolid.

Environmental risks of applying sewage sludge compost to vineyards: Carbon, heavy metals, nitrogen, and phosphorus accumulation

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Journal of Environmental Quality (2002) *31* (5) 1522-1527

Biosolids are applied to vineyards to supply organic matter. However, there is concern that this practice can increase the concentration of macronutrients and heavy metals in the soil, some of which can leach. We evaluated the environmental hazard of sewage sludge compost applied in March 1999 at 10, 30, and 90 Mg ha^{-1} fresh weight in a vineyard in southeastern France. Soil organic matter increased in all plots by 3 g kg^{-1} 18 mo after the amendment. Neither total nor available heavy metal concentrations increased in the soil. Mineral nitrogen (N) in the topsoil of amended plots of 10, 30, and 90 Mg ha^{-1} increased by 5, 14, and 26 kg (NO_{3}-N + NH_{4}-N) ha^{-1}, respectively, the first summer and by 2, 5, and 10 kg (NO_{3}-N + NH_{4}-N) ha^{-1}, respectively, the second summer compared with controls. At the recommended rate, risks of N leaching is very low, but phosphorus (P) appeared to be the limiting factor. Phosphorus significantly increased only in plots amended with the highest rate in the topsoil and subsoil. At lower rates, although no significant differences were observed, P added was greater than the quantities absorbed by vines. In the long run, P will accumulate in the soil and may reach concentrations that will pose a risk to surface waters and ground water. Therefore, although the current recommended rate (10 Mg ha^{-1}) increased soil organic matter without the risk of N leaching, total sewage sludge loading rates on vineyards should be based on P concentrations.

Soil remediation using biosolids

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Journal: Biocycle (2002) **43** (6) 41-44

also http://faculty.washington.edu/slb/sally/BioCycle-2002-June-41_44%20copy.pdf

Two risk assessment pathways were evaluated at sites where biosolids and alkaline by-products were used to remediate mine spoils and metal contaminated soils.

Assessment & management of risks arising from exposure to cadmium in fertilisers-I

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Science of the Total Environment (2002) **291** (1-3) 167-187

A risk assessment protocol has been developed for use by individual EU Member States with appropriate selection of input data, to assess the risks to humans and the environment arising from exposure to cadmium in fertilisers. The protocol comprises of three modules:

(1) the accumulation module, in which the net accumulation of cadmium in soil and soil solution, resulting from the application of fertiliser, is computed over time. The accumulation module allows for a range of inputs from different sources (atmospheric deposition, sludge addition, manure and fertiliser application) as well as for average and extreme rates of fertiliser application. A critical parameter i the solid/liquid partition coefficient, which in turn is a function of soil properties such as pH and is highly variable depending on the algorithm selected as being representative of national conditions.

(2) The exposure module, in which the uptake of cadmium from soil into plants and the subsequent intake of cadmium by humans is computed, using exposure parameters characterising both average and extreme exposure scenarios. The protocol focuses on food types known to be sensitive to cadmium uptake (grain, cereals, potatoes, root vegetables and leafy vegetables). Environmental exposure is also characterised.

(3) The risk characterisation module, in which Member States may estimate the incidence and severity of the adverse effects likely to occur due to actual or predicted exposure to cadmium.

This is undertaken by modelling the Predicted Environmental Concentrations (PECs) in humans and the environment using the accumulation and exposure modules, and then comparing these values against the relevant Predicted No Effect Concentrations (PNECs). A range of environmental PNEC values are reported in the literature; the European Commission recommends that normally the lowest No Observed Adverse Effect Level (NOAEL) should be used in the risk characterisation. For humans, the current WHO Provisional Tolerable Weekly Intake (PTWI) is equivalent to a daily intake of 70 µg Cd day^{-1}. Particular risk groups can be characterised, namely of: children; smokers; women with low iron stores; consumers of food items with high cadmium content; and extreme consumers of staple food items. At present, with the data available, it is not possible to characterise risk groups in detail, either at EU level or at Member State level. However, most Member States appear to have an average intake of cadmium which is lower than the WHO's PTWI.

Assessment & management of risks arising from exposure to cadmium in fertilisers - II

Cupit M, Larsson O, de Meeus C, Eduljee GH, Hutton M.

Science of the Total Environment 2002 May 27;291(1-3):189-206.

A preliminary, illustrative human health risk assessment of exposure to cadmium in phosphate fertilisers was performed using typical UK data and a protocol previously developed for application by individual Member States in the European Union. The risk assessment indicated that the for the most pessimistic population exposures characterised by both extreme (97th percentile) cereal and potato consumption and high susceptibility to cadmium uptake, the estimated dose was under the WHO Provisional Tolerable Weekly Intake (PTWI) for fertiliser cadmium concentrations ranging from 15 to 100 mg Cd/kg P_2O_5 applied over 100 years. However, the low margin of safety for high risk groups and the uncertainties inherent in the overall risk assessment suggested that a prudent risk management strategy would involve maintenance of low levels of cadmium in fertilisers and/or conditions that permitted low accumulation of cadmium in soils. On this basis, two main risk reduction measures were developed and assessed: (a) imposition of limits on cadmium concentration in fertilisers; and (b) imposition of charges on levels of cadmium in phosphate fertilisers. An assessment of the economic impact of these risk reduction measures indicated that, at all price elasticities, the most significant impact in terms of changes in demand and changes in consumer expenditure on phosphate fertilisers will be seen with cadmium charges where no thresholds are defined. The impact on the consumer (i.e. farmer) will be an increase in spending of approximately US $4000 per year, which is considered significant, accompanied by a decrease in demand above 20%. If a threshold is set at 60 mg

Cd/kg P_2O_5, the impact is significantly reduced, but stays relatively high compared to the other options. The analysis also indicates that the use of low-cadmium rock is the low cost option. At a likely rock price increase of approximately 5% and assuming a likely price elasticity of -0.2, the yearly costs to farmers will be approximately US $82 which is considered a minimal impact. In the worst case scenario (elasticity of -0.6 and a 10% increase in rock prices), the increase in spending by farmers will be of 3.9% or US $221 which is also considered to represent a minimal impact. At similar price elasticities, the use of decadmation technologies is predicted to be more costly than the use of low-cadmium rock but this option can still be considered as having a minimal impact on the consumer (increase in expenditure of 1.9-13.3% or US $106-748).

Effects and risk assessment of linear alkylbenzene sulfonates in agricultural soil. 1. Short-term effects on soil microbiology

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Linear alkylbenzene sulfonates (LAS) may occur in sewage sludge that is applied to agricultural soil, in which LAS can be inhibitory to biological activity. As a part of a broader risk assessment of LAS in the terrestrial environment, we tested the short-term effects of aqueous LAS on microbial parameters in a sandy agricultural soil that was incubated for up to 11 d [only – the $t_{½}$ is about 2 weeks]. The assays included 10 microbial soil parameters: ethylene degradation; potential ammonium oxidation; potential dehydrogenase activity; beta-glucosidase activity; iron reduction; the populations of cellulolytic bacteria, fungi and actinomycetes; the basal soil respiration; and the phospholipid fatty acid (PLFA) content. Except for beta-glucosidase activity, basal respiration, and total PLFA content, all soil parameters were sensitive to LAS, with EC_{10} values in the range of less than 8 to 22 mg/kg dry weight. This probably reflected a similar mode of LAS toxicity, ascribed to cell membrane interactions, and showed that sensitivity to LAS was common for various soil microorganisms. The extracellular beta-glucosidase activity was rather insensitive to LAS (EC_{10}, 47 mg/kg dry wt), whereas the basal soil respiration was not inhibited even at 793 mg/kg dry weight. This was interpreted as a combined response of inhibited and stimulated compartments of the microbial community. The PLFA content, surprisingly, showed no decrease even at 488 mg/kg. In conclusion, LAS inhibited specific microbial activities, although this could not be deduced from the basal respiration or the total PLFA content. The lowest EC_{10} values for microbial soil parameters were slightly higher than the predicted no-effect concentrations recently derived for plants and soil fauna (similar 5 mg/kg dry wt).

L'incinération des boues résiduaires urbaines: sous-produits formes et approche des risques sanitaires

(The incineration of sewage sludge : by-products types and approach to the health risks)

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TSM. Techniques sciences méthodes, génie urbain génie rural (2001) (4) 75-81

L'incinération des boues constitue une alternative a leur utilisation en agriculture, laquelle fait l'objet d'une opposition croissante de la part des acteurs du secteur agricole. Trente-huit unités d'incinération des boues ont été dénombrées en France. Celles-ci se repartissent grossièrement pour moitie entre les unités d'incinération spécifique et les incinérateurs de déchets ménagers. Sur les unités spécifiques adoptées surtout par les grosses collectivités, les boues sont au préalable déshydrates (30% de siccite) afin de permettre leur auto combustion. Les boues peuvent être incinérées en mélange, quelle que soit leur siccite. Le séchage des boues permet d'accroître le tonnage incinère si l'incinérateur n'est pas sature par les déchets ménagers. Le ratio boues/déchets est de l'ordre de 15% pour des boues a 20% de siccite. Avec des boues sèches, il est possible de dépasser ce ratio. L'incinération spécifique conduit a une production de l'ordre de 330 kg de cendres par tonne de boue. La valorisation de ces cendres est envisageable. Dans la co-incinération, les cendres issues de la combustion des boues se repartissent entre les mâchefers (80-90%) et les REFIOM (10-20%) [résidu de fumée d'incinération d'ordures ménagères]. Si les mâchefers présentent une composition plus hétérogène liée à la présence des boues, la gestion des REFIOM ne pose pas de problème particulier. La part de la gestion des résidus solides dans le coût de l'incinération peut être estimée a 16% pour l'incinération spécifique et 7% pour la co-incinération. Les risques sanitaires associes a l'incinération des boues paraissent limites. Les émissions de dioxines et de furanes sont plus faibles qu'avec l'incinération des déchets ménagers. Les métaux lourds se retrouvent principalement dans les mâchefers. Si Hg, Cd et pour partie Zn et Pb sont présents dans la phase gazeuse, seul Hg peut être émis a l'atmosphère.

Issues of risk assessment and its utility in development of soil standards: the 503 methodology an example

Contaminated soils: Paris, 15-19 May 1995 (Full proceedings on CD-ROM)

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International conference on the biogeochemistry of trace elements, 3 (Paris) 1995-05-15

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A risk assessment for land application of sewage sludge was required in the development of the Clean Water Act Section 503 Rule. The methodology reflects logical pathway analysis of transfer of pollutants to soils, plants, animals, and humans. Effects were considered on all receptors independently and the most conservative is considered the limit. As a specific example of the methodology a detailed analysis of human health effects from Cd is illustrated. All pathways for the sludge-applied Cd to be transferred to humans, and all processes in soils, plants, livestock, and humans were considered. Using appropriate data from field experiments, the transfer of soil Cd to diets of individuals who might grow a high fraction of the garden vegetables and fruits they consume for their lifetime was modelled. The model estimated that garden soils could reach 60 mgCd/kg before Highly Exposed Individuals (those who grow 59% of fruits and vegetables and 37% of potatoes they consume for 50 years on a garden containing the maximum allowable cumulative application) would consume a lifetime average of 70 µgCd/day (the WHO and EPA recommended maximum daily intake of Cd). Many sources of protection from Cd risk were identified, illustrating the hidden protection within even this analysis. Further, it was illustrated that no individual in the US may fit the many criteria of the Highly Exposed Individual. From a technical perspective we find this analysis correct and that all experimental evidence indicates that no individual would be harmed even if sludge amended soils reached 60 mgCd/kg. However, from a philosophical argument (i.e., because soil Cd has caused human disease, and because pretreatment can restrict sludge Cd to at least as low as 10-20 mg/kg) unrelated to risk we consider it prudent public policy to restrict utilization of sludges with Cd over these levels.

Threshold of Toxicological Concern

ILSI Europe Concise Monograph Series - 2005

Barlow, Susan

http://www.ilsi.org/publications/index.cfm?pubentityid=21

Man is exposed to thousands of chemicals whether naturally occurring or man-made. The human diet, for example, contains innumerable low molecular weight, organic compounds that could, at some level of intake, represent a risk to human health. Extensive toxicity studies, utilising many animals, are necessary to evaluate the safety of chemicals applied in food or to establish if contaminants to which humans are exposed may cause harm.

The Threshold of Toxicological Concern (TTC) as described in this Monograph is a principle that refers to the establishment of a generic human exposure threshold value for (groups of) chemicals below which there would be no appreciable risk to human health. The concept proposes that such a value can be identified for many chemicals, including those of unknown toxicity when considering their chemical structures. Evidently the establishment of a more widely accepted TTC would benefit consumers, industry and regulators. For example, there is an ongoing concern that humans are exposed to a diverse array of chemicals and there is a demand to evaluate large numbers of chemicals. At the same time there exists a strong pressure to reduce our reliance on animal experimentation and to rely increasingly on in vitro and in silico data. Use of the TTC principle would eliminate the necessity of extensive toxicity testing and safety evaluations when human intakes of a chemical are below a certain level of concern, would focus limited resources of time, funding, animal use and expertise on the testing and evaluation of substances with greater potential to pose risks to human health and would considerably contribute to a reduction in the use of animals.

In addition, the principle may be applied to the assessment of chemicals in sectors of health risk assessment other than food and could moreover be further developed for environmental risk assessment. For example, application of the TTC principle could also be extended to other categories of chemical use such as cosmetics and consumer products. In this case, of course, appropriate methodologies should be developed to allow for route to route extrapolation and to assess combined multi-route exposure. In addition, the TTC principle can be used to indicate analytical data needs (as, for example, it is used in the USA for indirect food additives), or for setting priorities among chemicals for levels of “inherent concern”.

In addition, since the principle is based on safety evaluations relating to daily intake throughout life, the approach may further be used in the assessment of impurities present in compounds, for contaminants at large, and as a science-based approach to indicate potentially acceptable concentrations of chemicals present in nature, which could be utilised in the application of the precautionary principle. An International Life Sciences Institute (ILSI) – Europe expert group has examined this TTC principle for its applicability to food safety evaluation. This Monograph describes the history and development of the principle and its application to chemicals in food that humans are exposed to at low levels.

Annex A
(informative)

Glossary of acronyms commonly used in risk assessment

ADI	acceptable daily intake (mg per kg bodyweight per day)
ALARA	as low as reasonably achievable
ALARP	as low as reasonably practicable
BAF	bioaccumulation factor
BATNEEC	best available technique not entailing excessive cost
BCF	bioconcentration factor
BPEO	best practicable environmental option
BPM	best practicable means
BTF	biotransfer factor
CBA	cost-benefit analysis
CF	conceptual framework
EC_{10}	effective concentration that produces 10% inhibition
EIA	environmental impact assessment
EUSES	European Union system for evaluation of substances
GIS	geographic information system
HACCP	Hazard Analysis and Critical Control Point
HC_n	hazardous concentration for n% of species
HEI	highly exposed individual
IPC	integrated pollution control
IPPC	integrated pollution prevention and control
LC_{50}	lethal concentration (in a toxicity test)
LD_{50}	lethal dose (in a toxicity test) for half the population
LAEL	lowest adverse effect level
LOAEL	lowest observed adverse effect level
LOEC	lowest observed effect concentration

MATC	maximum acceptable toxic concentration
MEI	most exposed individual
NAEL	no adverse effect level
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
PBT	persistent, bioaccumulative and toxic
PEC	predicted environmental concentration
PLFA	phospholipid fatty acid
PNEC	predicted no effect concentration
POP	persistent organic pollutant
PPE	personal protective equipment
PTE	potentially toxic element
PTWI	provisional tolerable weekly intake
QA	quality assurance
RCF	root concentration factor
RfD	reference dose
SEA	strategic environmental assessment
$t_{½}$	half-life; the time for the concentration to decrease by 50%
TGD	EU Technical Guidance Document on risk assessment of chemicals
TOR	tolerability of risk

Annex B
(informative)

Extended text on risk assessment, communication and management

B.1 Problem formulation

B.1.1 Introduction

Clearly setting out the problem and the boundaries within which any decisions are to be applied is important in risk assessment. Risk assessments are generally employed where the outcome of a given activity is uncertain. It is often tempting to omit any formal documented definition of the problem (particularly where there is pressure to complete the risk assessment quickly) but failure to define the problem clearly risks losing the focus of the assessment, and may even result in an inappropriate output.

Stakeholders have an important role to play in problem formulation and their early involvement will tend to make risk management decisions more effective and durable (clause B.3.8).

Describing the problem in clear and unambiguous terms will assist in selecting the level and type of assessment methodology used, and improves the risk management decision. It will also provide an important baseline if the process or eventual decision should be challenged or audited. A range of issues pertinent to problem formulation that should be considered before undertaking any risk assessment is set out below.

B.1.2 Defining the intention

An important prerequisite to formulating the problem is to define the intention. The intention might be to carry out an activity that adds to existing risks, or it might be to act in order to reduce risks; neither would alter either the need for, or the nature of, the risk assessment.

For risk assessors intimately concerned with a particular intention, it is easy to make implicit assumptions when defining the intention or take account of knowledge that will not be known to anyone who uses the risk assessment later. Consequently, recording the definition of the intention from the outset provides significant benefits by making clear to anyone using the assessment exactly what was taken into account. A good statement of the intention will also facilitate monitoring and feedback and help to determine whether discrepancies between forecasts and outcomes were caused by poor judgement, lack of knowledge or other factors.

To assist in defining the intention, it is helpful to consider the following four facets.

- What was the situation before the intention - the baseline?
- What are the characteristics of each contributing element of the intention - the components?
- How are the components related and what steps or processes are involved in the intention - the process?
- What will be the situation after the intention - the forecast?

B.1.2.1 Baseline

The baseline refers to the state of the environment both in the locale of the hazards arising from the intention, and over the area where harm may be expected. Whereas the temporal and spatial boundaries of a hazard may be easily defined, the effects can be far more wide-ranging; the risk assessment should reflect this. The baseline will also include a record of all other relevant pre-existing hazards that may affect the outcome of the risk assessment. For example, if the intention is to use sludge as a soil improver in a land reclamation project, the pre-existing composition of the soil-forming material would therefore be an important piece of baseline information.

B.1.2.2 Components

A unifying principle to bear in mind during problem formulation and throughout risk assessment is the connection (the pathway) between the source (of the hazard) and the receptor. It is important that connectivity, or potential connectivity, between these components can be shown. If any of these components is missing then the risk assessment need go no further.

Each of the risk components will have characteristics that may affect the consequences of an intention. For example, the chemical composition and effects of lime-stabilised sludge differ from digested sludge. To assess the risks associated with restoring land using limed and digested sludges, it would be necessary to estimate their relative, and, thereby, their relative effects on soil quality. A restoration project dominated by limed sludge will have different effects from one dominated by digested sludge.

B.1.2.3 Process

Each component of the intention can relate to other components as part of an overall process. For instance, the risk that nitrate will reach a water body depends on the relationship between such things as site drainage, rainfall, plant uptake, buffer strips, etc. In bringing together each of the components, further factors will be brought in to play that may affect the risk. Continuing with the planned land restoration example, there are important factors to consider before, during and after the project. Some of these factors include:

- before – clearing the site, shaping its contours and selecting and placing soil forming materials before sludge application starts;
- during – traffic, soil compaction, drainage, control on sludge application and incorporation, planting; and
- after – the maintenance and intended use of the site.

B.1.2.4 Forecast

The forecast reflects the need to be able to define what may happen as a consequence of the intention. This is clearly very difficult, but some of the most important consequences may be determined here.

B.1.3 Justifying an intention

Clause B.3 provides a broad overview of the social aspects of risk, stressing that such issues should be considered at all stages of the risk assessment process. Having defined the overall intention and the problem facing the decision-maker, it should then be possible to address the benefits to society from the intention, for comparison with the risks that society is being asked to accept, in order to judge whether society is prepared to tolerate the risk or not.

The assessment of both proposed and existing risks includes economic factors (costs and benefits). Increasingly, socio-economic analysis is used for this purpose. Given the risks, benefits and costs, does society want sludge applied to land or does it want it to be incinerated at location X?

B.1.4 Setting the boundaries

An important requirement for any risk assessment is ensuring that its boundaries are clearly and logically selected. The boundaries can relate to factors such as:

- the spatial extent and time-scales over which the intention and any consequences may be considered;
- when the output from the risk assessment is required;
- the resources that can be assigned to the risk assessment;
- the purpose for which the output from the assessment is required; and
- the weight of decision to which the risk assessment will contribute.

It is important to document the grounds for selecting these boundaries.

B.1.5 The controlling factors

It is rare for hazardous events to occur without one or more factors controlling their timing, intensity and duration. This may appear self-evident, but it is important for the selection of risk reduction options. If controlling factors are not considered in the problem formulation stage, difficulties may arise when choosing the most appropriate risk reduction options. For example, whether sludge treatment is based on HACCP, whether there is Quality Assurance, the performance of plant operators, the levels of investment, training and staff morale are all important factors in controlling risks from sludge use or disposal.

Some of the factors that control policy may initially be difficult to identify, but they are as important in their link to the hazard itself as are the more specific risks mentioned above. The policy options to reduce the environmental impact of organic micropollutants via the hazardous substances directive has greatly reduced the risk associated with using sludge on land.

The factors controlling the hazards need to be clearly defined in the problem formulation stage in carrying out a policy-level or project-level risk assessment. Modifying these factors will often be a key consideration in the options appraisal stage (clause B.7).

B.1.6 Developing a conceptual model

Table 2 gave a generalised summary of source, pathway, receptor for sludge use or disposal, this could be expanded using a table such as Table B.1 and an overall combination such as Figure B.1.

In the context of this model it is important to assemble reliable data such as:

- developed and published distributions for soil ingestion by children,
- drinking water intake for children and adults,
- height and weight for adults, body surface area for adults,
- bioconcentration of lipophilic chemicals in fish,
- distributions for children's body weight,
- lipid intake by nursing infants,
- fish consumption,

- uptake of contaminants by plants in relation to soil content and
- the fraction of indoor dust in single-family homes originating from outdoor soils.

These data need to be screened and the most reliable and appropriate selected. For example, it is well established that the uptake of contaminants by plants growing in pots is greater than by plants growing in the open ground because root exploitation is more intensive in pots and other factors in the root-zone also differ, such as temperature. Thus, data from pot trials should be used with caution and if good field trial data are available, they should be used in preference. If the only data available are from pot trials, the authors should state this and acknowledge that transfer might be overestimated as a consequence. Ideally, a risk assessment using on data from pot trials should be identified as an interim work in progress that will be finalised when reliable data are available from field trials.

Table B.1 – Conceptual model for possible exposure to dioxins, furans and co-planar PCBs in food from sludge treated land

Primary source	Secondary source	Hazard	Transport mechanism	Pathway	Medium of exposure	Receptor
Sludge	None	Dioxins ingestion	Volatilisation and deposition on vegetation	Consumption of contaminated produce	Vegetable produce	Humans
Sludge	Grazing animals	Dioxins ingestion	Deposition of sludge on foliage	Consumption of contaminated produce	Animal products	Humans
Sludge	None	Dioxins ingestion	Root uptake and translocation	Consumption of contaminated produce	Vegetable produce	Humans

B.2 Key stages in each tier of environmental risk assessment

Stage 1: Hazard identification

Examples of hazards [4.2] associated with sludge use and disposal are:

- excessive PTEs in crops grown on sludge treated soil,
- impairment of a soil microbial function because of chemical contamination,
- transmission of pathogenic (disease causing) organisms,
- causing odour nuisance,
- supplying inadequate agronomic advice to a farmer so that yield is reduced,
- groundwater contamination by leachate from landfill and
- emissions from incinerators.

The identification of hazards, both in the problem formulation stage (clause B.1), and in subsequent tiers in the process, will have an important bearing on the breadth of the overall assessment and the credibility of the final output.

One common pitfall in establishing the hazard is to overlook secondary hazards that may arise. For example, if agricultural land that has been treated with sludges is sold for housing, will the soil be acceptable for gardens?

Stage 2: Identifying the consequences

The potential consequences that may arise from any given hazard are inherent to that hazard; the dose and the sensitivity and vulnerability of the receptor also determine the consequences. Although the full range of potential consequences must be considered at this stage, no account is taken of likely exposure and therefore likely consequences. It is necessary to take a broad look at the potential environmental damage that may occur, if only to be clear why some potential consequences are rejected for further assessment.

Stage 3: Estimating the magnitude of consequences

The consequences of a particular hazard may be harm to human health, property or the natural environment. The magnitude of such consequences can be determined in different ways depending on whether they are being considered as part of a risk screening process, or as part of a more detailed quantification of risk. At all stages of risk assessment several key features need to be considered, as described below.

The spatial scale of the consequences

The geographical scale of harm resulting from an environmental impact could extend considerably beyond the boundaries of the source of the hazard. Failure to consider this at an early stage may result in the scope of the risk assessment being too limited. For example, stockpile failure and run-off could have significant effects on the environment well beyond the local area. Airborne emissions from an incinerator could affect a large area and emissions from a composting facility could cross the site boundary.

The temporal scale of the consequences

The duration of the harm that results is worthy of consideration. For example LAS (linear alkyl sulfonate) might suppress nitrification in soil but its $t_{½}$ is only 2 weeks; a sludge with excessive carbon could immobilise soil nitrogen for a whole season, *Salmonella* would die off in soil within a season but anthrax (this is an extreme example from hides or bones from countries where it is endemic) would persist for years.

The time to onset of the consequences

A further factor to consider is how quickly harmful effects might be seen. Standard economic techniques tend to discount impacts that will happen in the future but sustainable development emphasises the need to protect the interests of future generations. Risk assessment and management must therefore pay as much attention to long-term problems as to the more immediate risks. For example, contamination of an underlying aquifer may compromise the value of that aquifer as a source of water for future generations.

The ability to forecast the time-scale and magnitude of the environmental impact through robust and long-term modelling is therefore valuable, particularly at the quantifiable end of the risk spectrum.

Stage 4: Estimating the probability of the consequences

All stages to this point have assumed that realisation of the hazard will lead to environmental harm. However, the probability of the consequences occurring must also be taken into account. This has three components:

- The probability of the hazard occurring
- The probability of the receptors being exposed to the hazard and
- The probability of harm resulting from exposure to the hazard

The probability of the hazard occurring

Assigning probabilities might be quite straightforward or might require a sophisticated approach depending on the circumstances. For example, at a screening level, it might be as simple as stating (on the basis of experience) that on a scale of 1 to 5 (low to high) a pin-hole leak in a particular pipe in a chemical plant has a probability of, say, 4. On the other hand, there will be situations in which it is necessary to assign a probability distribution to the likelihood of the event occurring - for example, that a tobacco smoking gardener who uses sludge in the vegetable garden lives in the area affected by incinerator emissions and eats fish caught in a contaminated lake (Table 2). In many instances this information can be obtained from monitoring data, or based on 'worst-case' or 'reasonable worst-case' scenario estimates.

The probability of the receptors being exposed to the hazard

It is important to establish, at an early stage in the process, whether or not a pathway exists between the hazard and the receptor. If it can be shown that no actual or potential connection exists, then the risk requires no further attention. For example, soil contamination will not pose a risk to farm animals if the land is not used for agricultural purposes. But care is needed not to overlook less obvious pathways, or changes in future circumstances.

Having established one or more pathways, the degree of exposure via those pathways should be quantified. A range of factors will affect the probability and degree of exposure. For example, the exposure of a receptor to airborne emissions will depend on the direction and strength of the prevailing wind at the time of release. The impact of pathogens in untreated sludge applied to land will depend on the time of the year at which application and harvest occur.

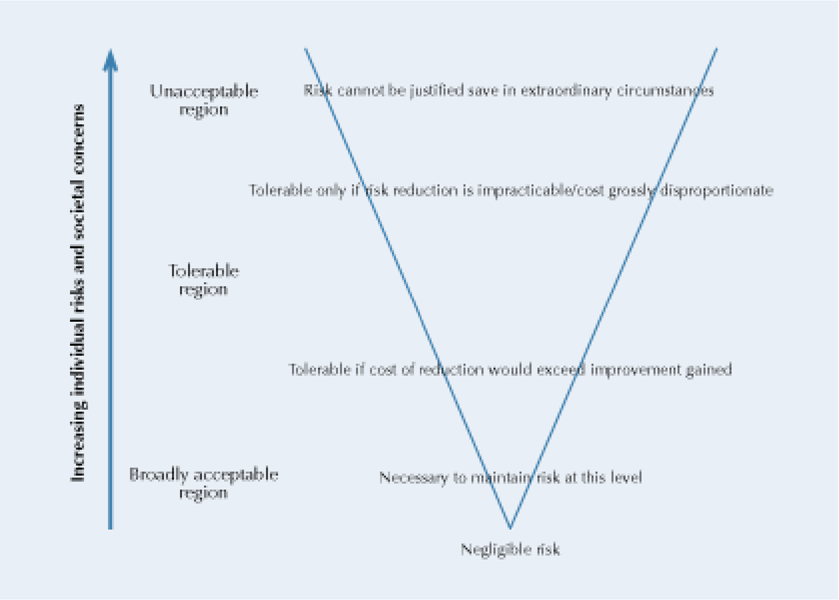

Figure B.1 – Tolerability of risk framework (Bouder, 2005)

The probability of harm resulting from exposure to the hazard

Even following exposure, the likelihood of harm resulting is probabilistic and will depend on the likely susceptibility of an individual receptor to the hazard and the amount and duration of exposure. This is often simplified in terms of a dose-response relationship, which directly relates exposure to the magnitude of harm for certain receptor types. Such relationships frequently embody 'safety' or uncertainty factors to account for the extrapolation of data from experimental or generalised studies. These relationships simplify the probabilistic nature of harm, because for any exposure, the likelihood of harm at a certain magnitude will be dependent on many individual factors. Few risk assessments allow for this level of sophistication, and the magnitude of harm is usually taken as a direct result of exposure.

Stage 5: Evaluating the significance of a risk – (risk characterisation)

Having determined the probability and magnitude of the consequences that may arise as a result of the hazard, it is important to place them in some sort of context. It is at this point, therefore, that some value judgements are made, either through reference to some pre-existing measure, such as a toxicological threshold, environmental quality standard or food quality standard, or by reference to social, ethical, or political standards. In some circumstances, a formalised quantitative approach to determining significance may be possible, for example the tolerability of risk (TOR) framework (Figure B.1). In other instances, the risks of various options might be compared against one another.

B.2.1 Options appraisal

Having estimated the magnitude and the significance of the risks posed by the hazard(s), the options for risk management are identified and evaluated. It is important to carry out this procedure as a distinct preliminary step because ill-considered risk management strategies may otherwise result in wasted effort and expenditure on the part of the decision-maker. Options appraisal provides a framework for doing this (clause B.7). The options that will usually be available are:

- exploring with society the acceptability, or otherwise, of the risk - this can include rejecting unacceptable risks altogether or accepting the risk being imposed;
- reducing the hazard through new technology, procedures or investment; and
- mitigating the effects, through improved environmental management techniques.

The decision on precisely which option or combination of options to choose will involve a balance of risk reduction, costs, benefits and social considerations.

B.3 The social aspects of risk

B.3.1 Background

Economic, political, legal and social concerns play important roles throughout the assessment, evaluation and decision-making stages of risk management. Ensuring dialogue between interested parties at all stages requires an understanding of the social aspects of risk along with an appreciation of the mechanisms by which stakeholders can be actively engaged in the process.

The evaluation of risk entails a judgement about how significant the risk is to the receiving environment and to those concerned with, or affected by, the decision. It is, therefore, a process that necessarily involves the question of risk acceptability. In conjunction with formal scientific input, this requires the examination of public and political judgements about risks alongside the measurable costs and benefits of the activity in question. The precise knowledge required for an objective evaluation is often lacking for environmental risk assessment and an element of judgement is often needed. Furthermore, environmental quality involves both scientific elements and social elements. There is, therefore, a need to consider carefully the social dimensions of a risk as a part of the decision-making process.

The clauses below highlight some of the factors that should be considered when evaluating risks and making decisions about environmental protection. These include some of the key elements that shape individual and social responses to risk.

B.3.2 Why consider the social dimensions of risk?

Society is increasingly conscious of the harm that its activities can cause to the environment, and the harm to people or the loss of quality of life that can result from environmental degradation. Recent experiences such as the BSE crisis and the Brent Spar controversy have led to a decline in public confidence in conventional risk assessment and management processes. Decisions about environmental risks should take account of social issues because:

- general awareness of environmental risks has increased and this is often associated with heightened levels of concern;
- recent experience has shown how essential it is to have in place a framework which ensures transparency in decision-making and which forms a justifiable basis for policies on environmental protection;
- calls have been made for a greater degree of public involvement in decision-making processes for environmental protection; and
- there is increasing pressure on those who create and regulate risk to inform the public about the risks to which they and their environment are exposed.

In conjunction with the assessment of a risk, the decision-maker should ask whether the risk is likely to be acceptable to those concerned with, or affected by, the risk or consequent management decision. Evaluating the social significance of a risk can guide decision-making and help towards communicating about the risk to interested parties. It is, therefore, essential that the decision-maker considers social dimensions as part of the processes to identify, assess, evaluate and manage risks to the environment. Key objectives of doing so are to:

- engage all stakeholders in issues that affect them and their communities to ensure that policies reflect the values of the society to which they are directed;
- ensure that decisions about the acceptability of environmental risks recognise that environmental protection is part of the wider context of sustainable development - this includes objectives of economic growth, social progress and prudent resource management as well as environmental protection and enhancement;
- help to identify difficult cases in advance by highlighting what types of risk are likely to be seen as unacceptable; and
- aid the communication of risk messages to encourage desired actions and behaviour, or to meet legal requirements.

B.3.3 Risk perceptions

It is now well-established that lay reactions to risk can differ considerably from judgements that are based on scientific probability estimates. Since the 1960s, a large body of research on reactions to risk has developed (e.g. Corvello and Sandman, 2001). Much of this work has demonstrated that differences between lay and expert judgements on risk can be attributed to the complex concepts of risk that lay people and scientists apply.

Counter to traditionally held views, these reactions can often be predictable, and are frequently rational. It is, therefore, important to understand how and why particular reactions to risk arise.

Perceived risk is driven by a complex mixture of factors, including individual attitudes and beliefs as well as wider social and cultural values. Risk perceptions may be based on accurate or inaccurate information, and the existence of uncertainties in the evaluation of hazards can also be important. Thus, risk judgements not only depend on the physical characteristics of the hazard itself but are also determined by broader psychological and sociological considerations.

Questions about the role and credibility of institutions charged with the management and communication of risk also constitute a significant factor in shaping perceptions. Furthermore, the perception of risk is multi-dimensional, with particular hazards meaning different things to different people depending on underlying values and the context of the risk.

Consideration of what factors may cause (or fail to cause) anxiety and alarm about a particular risk at an individual level is important. This can help the decision-maker to identify (in advance) the types of risk that are likely to cause general concern. Risk perception research has also explored the cultural dimensions that shape individual and group responses to risk. Beliefs, attitudes, values and behaviour can all affect perceptions of hazard and risk. Risks that pose a threat to social group values are likely to lead to heightened risk perceptions.

Important factors (sometimes termed fright or outrage factors) which may cause a risk to create anxiety or be less acceptable; factors that can influence risk perceptions are:

- Risks which are involuntarily imposed (e.g. pollution from an incinerator or odour from spreading smelly sludge) tend to be seen as less acceptable than voluntary ones (e.g. driving a car or undertaking dangerous sports).

- Unfamiliar risks (e.g. genetically modified organisms) tend to cause greater concern, particularly if they are considered to be poorly understood by science.

- Activities that pose a threat of a dreaded form of death, injury or illness (e.g. cancer) are viewed with alarm and are less acceptable.

- Man-made or 'technological risks' (e.g. pesticides, nuclear power stations) are less acceptable than natural ones (e.g. floods and radon).

- A risk that may cause a single large-scale consequence (e.g. civil aviation accident) causes more concern than risks that result in numerous small-scale consequences (e.g. car accidents).

- Alarm may be caused by risks when the consequences of exposure are delayed and cause hidden or irreversible damage (e.g. exposure to ionising radiation).

- Inequitable distribution of risks and benefits as a result of a particular activity is likely to make a risk less acceptable.

- Activities that pose a risk to certain groups such as children and future generations are generally more worrying.

- Risks that are the subject of controversy and contradictory information generally cause concern.

- The attitudes of trusted “gatekeepers” such as environmental NGOs and food retailers can have a very significant influence on public attitude.

Table B.2 – The twelve principal components of "outrage"

“Safe”	“Risky”
Voluntary	Coerced
Natural	Industrial
Familiar	Exotic
Not memorable	Memorable
Not dreaded	Dreaded
Chronic	Catastrophic
Knowable	Unknowable
Individually controlled	Controlled by others
Fair	Unfair
Morally irrelevant	Morally relevant
Trustworthy sources	Untrustworthy sources
Responsive process	Unresponsive process

Whether a risk is acceptable or not depends on broad societal issues and scientific assessments. At a general level, the issues raised above can help to guide decision-making by highlighting likely responses to different types of risks. The main issues are summarised below.

- While risk perceptions sometimes differ considerably from scientific probability estimates, individual and social responses to risk often represent rational and defensible judgements. While decisions about environmental risks should have a sound scientific basis, it is also important to give explicit consideration to social dimensions.

- Risk is multi-dimensional and context-driven and it is over-simplistic to represent risk as a single-scale concept such as probability estimates.

- Fright or outrage factors may highlight the types of risk that are likely to cause concern. They may also be used to identify particular cases where the risk is perceived to be lower than suggested by probability estimates, and may explain why such patterns exist.

- Risk perceptions and responses are linked to wider attitudes, beliefs and behaviour and, therefore, have a strong social as well as individual dimension.

- Perceptions can be distorted through social amplification. The role and likely reactions of the media therefore need to be anticipated.

B.3.4 Trust and credibility

Conflict and controversy have characterised some recent risk debates, and distrust in the risk assessment and management process plays a central role in these cases.

Trust and credibility are frequently identified as important determinants of risk perception. It is important to be open and accountable, and to take differing views into account rather than disregarding them as 'emotive' or 'irrational'. While such a climate may help to build confidence, it should be stressed that trust is eroded very easily and once lost is difficult to restore.

B.3.5 Equity

Inequity in the distribution of risks and benefits is an important factor influencing attitudes to risk. It can result, for example, in a particular community having to bear the disadvantages of a facility or development while not necessarily gaining the benefits. Examples may include the sitting of a waste incineration plant or a wastewater treatment plant. The community perceives that it will suffer from the consequences of such activities through both environmental degradation and stigmatisation of the locality, which in turn may have broader economic impacts such as loss of tourism or lowering property prices. Although sometimes dismissed as expressions of self-interest (the Not In My Back Yard - NIMBY - response), recent challenges about the distribution of risk have raised not only questions of location and scale but also the fundamental issue of necessity.

B.3.6 Responses to risk and the role of the media

It is commonly held that 'the media' tend to portray environmental risks as more serious than estimated by scientific risk assessments, although in reality the role of the media in generating responses to risk is not clear-cut. Journalists respond that they just ask the questions that their readers/listeners/viewers would like to ask and that they are just the messenger: “if you shoot the messenger you are left with the message”. Thus, it is better to work with the media to and feed information in order to increase understanding of the science. Because it is likely that public and media interest reinforce each other (rather than the media generating initial interest), it is useful for the decision-maker to consider factors that may amplify media interest in a particular issue. This can help to identify environmental risks that may be controversial and may also help in developing a strategy for dealing with the media on a particular issue. There are clearly outrage factors that exacerbate perceived risk that can be altered, thus bringing perceived risk closer to [actuarial] risk.

B.3.7 Risk communication

Communication about environmental risks serves many important purposes. Communication can be used either as a tool to provide information, explain and warn, or to encourage collective partnership approaches to decision-making through greater public participation in the risk management process.

The various functions of risk communication are to:

- ensure compliance with the legal requirements to warn or inform individuals about certain risks – e.g. the correct behaviour to adopt in the event of a major industrial accident under the 'Seveso II' (Control of Major Accident Hazards) Directive;
- encourage desired changes in knowledge, attitudes, opinions and/or behaviours;
- ensure that information aimed at encouraging desired risk reducing behaviour is available - this may include, for example, the provision of information about air quality and measures which may be taken to reduce certain polluting activities;
- create trust and confidence in risk decision-making processes and in risk management institutions;
- ensure that experts and regulators discuss all issues relevant to the decision-making process for a particular risk to the environment; and
- engage stakeholders in two-way communication, thereby ensuring that decision-making reflects broad social values.

B.3.7.1 Risk communication to inform and explain

Risk communication can be implemented in many different ways. Successful risk communication is difficult to achieve and it will frequently be necessary to engage diverse audiences. These audiences may hold different values and have different levels of understanding, and the interpretation of a message can be dependent on a variety of social factors. Provided these complexities are borne in mind, and the objectives are clearly defined, communication can achieve its desired outcome.

Many of the points made earlier about risk perceptions are salient to the development of risk communication. Efforts simply aimed at the provision of quantitative risk estimates are likely to be of limited value because of the complex nature of risk judgements. Communication should be sensitive to a broad concept of risk, encompassing not only quantitative information, but also other dimensions such as individual attitudes and issues of trust and credibility.

B.3.7.2 Risk comparisons

Describing risk

Risk communication has frequently used a wide range of hazards to place a particular risk in perspective (e.g. Table 1). While this approach may help individuals to envisage very small or very large probabilities, their use as a more sophisticated communication tool requires caution. Individuals distinguish between hazards along a range of qualitative dimensions, and risk comparisons must take this into account wherever possible. For example, making a comparison between two activities that have similar statistical probabilities and similar outcomes but are not comparable with regard to whether they are taken voluntarily or not, is likely to be viewed with scepticism.

A common language

It could be helpful to develop and use a common language for communicating risks. For example, 'roughly one person in a small town' is more familiar than '1 in 10,000' but in this example it might be worth checking whether people would think of 10,000 as a ‘small’ town.

A risk spectrum

A risk spectrum can provide a useful means for describing risk. This approach has been used in flood alert warnings, whereby the likely impact from flooding is communicated via a scale of:

- yellow (a warning of flooding to low-lying farmland and minor roads near rivers or the sea, but flooding of property is not expected);
- amber (flooding of isolated high risk properties, roads and large areas of farmland near rivers or the sea); and
- red (a warning of serious flooding to a significant number of residential and commercial properties, roads and large areas of farmland).

It is also used for terrorist alert warnings, but it probably does not have much application for sludge use and disposal.

B.3.8 Stakeholder participation

Public response to and perception of sludge use in agriculture is speculated about and sometimes it has been used to justify policy decisions, but it has seldom been measured. Where objective surveys have been conducted and the results published they have shown the majority supports the practice. The extent of support has been found to be related to the amount of information people have about the practices, controls and benefits (SAS, 2004 and WERF, 2003).

B.3.8.1 What is stakeholder participation?

An important objective of sustainable development is the adoption of collective partnership approaches to decision-making for environmental protection. Experience suggests that risk management decisions made in collaboration with stakeholders tend to be more effective and durable. Stakeholders are parties concerned about, or affected by, a risk management problem (clause 7). The use of participatory approaches in the development of risk management strategies is important for many reasons.

- Public involvement is an essential part of a sustainable development strategy.
- Risk management is often implemented outside traditional government arenas, for example by individual citizens, industry and workers. This has led to calls for greater involvement in the decision-making process of those affected by risk problems.
- While decisions may largely be based on the best available scientific and technical information, their success is also dependent on sensitivity to a range of social, economic and political considerations.
- Environmental protection is a societal goal and there is a need to engage the public in issues that affect individuals and their communities.
- Participatory approaches provide a process by which expert and lay perspectives can inform each other. By clarifying the nature of disagreements about risk, they may help to resolve conflicts over controversial issues (consensus building).
- Participation can help people to make a more informed decision and help to reduce resentment from individuals or groups who feel they are excluded from decisions that directly affect them.

Stakeholders may include a wide range of Government departments and other agencies, individuals, interest groups and other institutions that have an interest in the decision-making process. Since Government, the public, industry, environmental and consumer groups, etc., often have different views about what constitutes an acceptable risk, it is important to explore possibilities for engaging these stakeholder groups at all points in the risk management processes. At the same time, it is necessary to recognise that the nature and extent of stakeholder involvement must reflect the scope and impact of the particular risk in question.

Members of the food industry (from commodity purchasers through to the retailers) are important stakeholders when considering the use of sludges on farmland. If they will not buy the produce from treated land, then farmers will not have their land treated. The food industry is part of society, shares responsibility for sustainable development and has a duty to ensure the safety of food is not impaired. It is important that they understand the risks, how they have been evaluated and the controls to manage them.

B.3.8.2 Identifying stakeholders

If a decision has been made to involve stakeholder participation in the decision-making process, it is important to identify at an early point which stakeholders should be involved. To aid this process the following questions may be asked:

- Who will potentially be affected by the risk and the consequences of any management decision?
- Which parties or individuals have knowledge and expertise that may be useful to inform any discussion or decision?
- Which parties or individuals have expressed an interest in this particular, or a similar type of, risk management problem?
- Which stakeholders will be prepared to listen, respect diverse viewpoints and be prepared to negotiate?

Participatory approaches

Participation can take many forms, including collaboration between Government, industry and interested parties to identify common goals and mutually acceptable solutions, stakeholder-based decision-making committees, focus groups, consensus-building conferences (round-table process) and citizens' juries. In a publication entitled Consensus Building for Sustainable Development, the Environment Agency provides several case studies to illustrate the use of different participatory initiatives in environmental protection. There are some key considerations to guide the approach:

- The decision-makers should make explicit the extent to which they are prepared to respond to stakeholder involvement.
- The aims of stakeholder participation must be clearly stated and stakeholders should be involved as early in the process as possible. If a decision is non-negotiable, stakeholder involvement should not be considered.
- The nature and extent of stakeholder involvement must reflect the scope and impact of the risk management decision.
- Participation should aim to confront the key issues of a risk management problem rather than confronting individuals or stakeholder groups.

The selection of a particular participatory approach requires creative and constructive thinking about the various aims of the process and the decision options available. The techniques that may facilitate open discussion about contradictory objectives, responsibilities and interests in relation to the particular environmental risk in question must also be considered.

The concept of a participatory approach is primarily bottom-up, whereby stakeholders are engaged in the processes of problem formulation, appraising the preferred management options and proposing solutions to a particular risk problem. It relies on communication as a two-way process to exchange information and opinions between various institutions, groups and individuals.

Stakeholder involvement brings together diverse viewpoints and may help to resolve existing or potential problems by ensuring that stakeholders are involved in the development of the solutions. It can, therefore, bring long-term gains. However, it requires careful planning, large amounts of time and other resources, and cannot be expected to guarantee the resolution of conflict or controversy.

B.4 Risk screening and prioritisation

B.4.1 Background

Setting priorities is important for decision-making. In environmental risk assessment and management, prioritisation may be undertaken at several stages. In the initial stages, hazards may have to be scored and ranked to prioritise those that are of most concern. Later, risks and risk management options may be scored and ranked to identify priorities for further risk assessments and for risk management decisions.

Screening and prioritisation can be applied at all levels of risk assessment and management, and across a diverse range of activities that may impact on the environment. Given the wide variety of uses, there is no single ranking or prioritisation system appropriate to all applications in environmental risk management. Nevertheless, the aim should be consistency across a broad range of activities by common principles of priority-setting. Priority-setting can help to promote transparency in decision-making by ensuring an explicit and justifiable basis for those decisions.

B.4.2 Why screen and prioritise?

In general, screening will be used to determine which hazards or risks should be investigated in more detail. Ranking each of these, based on their screening scores, will provide a priority list for further action.

In the past, there has been a tendency to apply quantitative methods at the outset of a risk assessment, and thereby miss issues that are difficult to quantify. The ability to screen all risks for a given problem consistently is therefore vitally important. Risk screening (Tier 1 of the framework for environmental risk assessment in Figure 2) to identify and subsequently prioritise relevant risks helps to minimise unnecessary effort and reduces the chance of potentially important risks being overlooked. It also provides an auditable trail to support or explain the omission of certain risks from further consideration.

B.4.3 Key criteria for risk screening

Various approaches to risk screening have been developed both in the health and safety field and for environmental risk. Although they differ in their structure and the measures used to determine the priority of any risk, the key elements of the screening process reflect the framework for a full risk assessment as described in clause 7, but are quantified in much less detail.

B.4.3.1 Identification and magnitude of consequences

Characterising the nature of the hazard requires a consistent measure to be used and usually reflects the importance of the hazard in relation to others. For example, where the hazard is a chemical, its relative toxicity to the likely receptor organisms might be an appropriate measure.

Exposure may not always follow on from a hazard. Screening and prioritisation can be based on an initial evaluation of likely pathways between source and effect. Factors such as the degree of sorption of the hazard by soil, the ability of the contaminant to move through soil, cross the root barrier and to be translocated within a plant will all affect the probability of exposure.

B.4.3.2 Probability of consequences

The likelihood of the hazard being realised can be roughly estimated using coarse indicators. For instance, the effectiveness of existing flood defences and typical meteorological conditions could be used to predict the probability of a flood.

B.4.3.3 Significance of the risk

This reflects the harm that may result if exposure to the hazard actually occurs. The screening of impacts or consequences should take account of their nature, geographical extent, timing and duration and their likely importance. Likely public concern (clause B.3.3) should also be considered.

B.4.4 Methods for risk screening and prioritising

Depending on the risks in question, different methods for screening and prioritisation can be applied. The key to effective screening and prioritisation is consistency and transparency of approach.

B.4.4.1 Numerical approaches

Scoring systems and scales (e.g. low (1) to high (5)) should be designed with reference to the factors outlined in clause B.4.3 and must be appropriate and meaningful to the application under study. The overall score for the risk is the product of each criterion score. The data and information used to assign scores can come from a variety of sources:

- experience of the same issue;
- experience of similar issues;
- experience elsewhere in the world (e.g. generic information); and
- worst-case scenario estimates.

B.4.4.2 Qualitative approaches

For some environmental problems, the complexity of the issues to be addressed may be considerable. This is particularly true when risk assessment is employed to assess policy-level issues or where the sources of risk are diverse. Sometimes there may be no prior experience on which to base risk judgements and worst-case assumptions have to be made. In such cases, it may be difficult to determine the scores that should be assigned to each of the criteria listed in clause B.4.3, and another approach needs to be adopted.

Expert judgement and preference elicitation have been used by many organisations as a way of screening risks and prioritising future work. The technique involves a panel of people scoring each risk through a structured discussion. Expert groups are regularly used by governments to advise them on the priorities that should be assigned to particular risks.

B.4.5 Prioritising effort

Risk screening and subsequent prioritisation has a number of benefits:

- it clearly identifies why some risks will not be investigated further;
- it identifies some risks where action, as opposed to any further investigation, may be preferable; and
- it prioritises resources for the subsequent stages of risk assessment.

It is important that risks identified through screening processes as being of low priority are not discarded entirely from the remainder of the process. For instance, a future risk management option targeted at a high priority risk may also reduce risks of lesser priority. The value of this option would therefore be increased. Equally, some risk management options may worsen low priority risks.

There may be situations in which the cost of carrying out the required risk assessment would exceed the expected benefits of the intention. If this is still the case after taking all reasonable steps to reduce the costs of the risk assessment to a minimum, and after taking account of the full socio-economic value of the intention, then the sensible course of action would be to decide not to proceed with the intention.

B.5 Quantification and dealing with uncertainty

B.5.1 Introduction

Risk assessments for complex, high priority risks can be time-consuming and expensive. In clause 7, the principle was introduced that the amount of effort put into the risk assessment should be proportionate to the severity of the problem. The tiered approach shown in Figure 2 is intended to help match effort to severity by providing a series of clear stages, after each of which decisions are taken about whether or not further effort would be justified. If an initial assessment of risk based on a reasonable 'worst-case' scenario indicates little cause for concern then there is little point in moving on to more sophisticated analyses. Alternatively, cause for concern may become apparent at an early stage and there would then be little point delaying the identification of risk management options in order to complete the risk assessment. More detailed data and sophisticated analysis may be required where initial estimates indicate the need for further refinement of the estimation.

Previous and ongoing monitoring programmes are important information sources and modelling and simulation are useful techniques for analysing information. Tools and techniques for risk assessment are being developed all the time. The RiskWorld internet site (http://www.riskworld.com/) provides some useful pointers to models for quantifying the probability of release, estimating the consequences and dealing with uncertainty.

Where information is limited, informed decisions can be based on assumptions or extrapolations. It is important, though, that data gaps or assumptions are acknowledged. Sensitivity analysis offers a useful approach to dealing with such uncertainties. It provides a means to examine the behaviour of a model by measuring the variation in outputs resulting from changes to its inputs.

B.5.2 Types of quantification

B.5.2.1 Estimating the probability of events

In environmental risk assessment, there can be situations in which the probability of an event is 1 (i.e. it will happen). For example, once the decision to build a dam has been taken, its construction will certainly lead to the loss of habitats, landscape features and structures in the flooded area. In this case, the important parameters to consider are the probability and magnitude of consequences arising from the construction rather than the probability of the event (construction) itself. Another example of such a situation would be the release of planned, routine emissions. In situations outside the system design (e.g. accidents or malicious releases), the probability of the initiating event becomes more important. More usually, the event has a probability less than 1, and an estimate of its probability will be required. There are various techniques available to do this, some of which are briefly outlined below.

B.5.2.2 Actuarial or historical information

This involves looking at the reliability of components or other factors within a system based on past experience or data. To be useful there has to be a statistically significant number of data points. If the event relates to a novel process or is very rare (such as a major industrial accident), then it will not be possible to gather sufficient data for a probability estimate. Other circumstances lend themselves more easily to the use of historical data. For example, the frequency of collisions involving road tankers that can then lead to environmental pollution might be estimated from direct data on past road tanker accidents.

B.5.2.3 Synthesised analysis

Many processes, industries or sectors do not have sufficient data on which to base such estimates and other techniques involving synthesised analysis are needed. Two of the most widely used and well-known techniques to deal with operation or process failures are fault tree analysis and event tree analysis. These are similar in that logic diagrams are employed to represent the propagation of events or faults through a system.

B.5.2.4 Fault tree analysis

Fault tree analysis can be used to assess the probability of a system failure. The technique requires information on the failure rates of components within a system. Combining such data can provide an estimate of the probability of system failure over time or of failure on demand (e.g. failure of a safety system to operate). The aim is to take an undesired event (system failure) and describe how it might occur (see Annex D for an example).

B.5.2.5 Event tree analysis

Event tree analysis operates in the opposite way to fault tree analysis by taking a situation and asking to what system states it might lead. Event tree analysis has been used extensively for estimating biological risk.

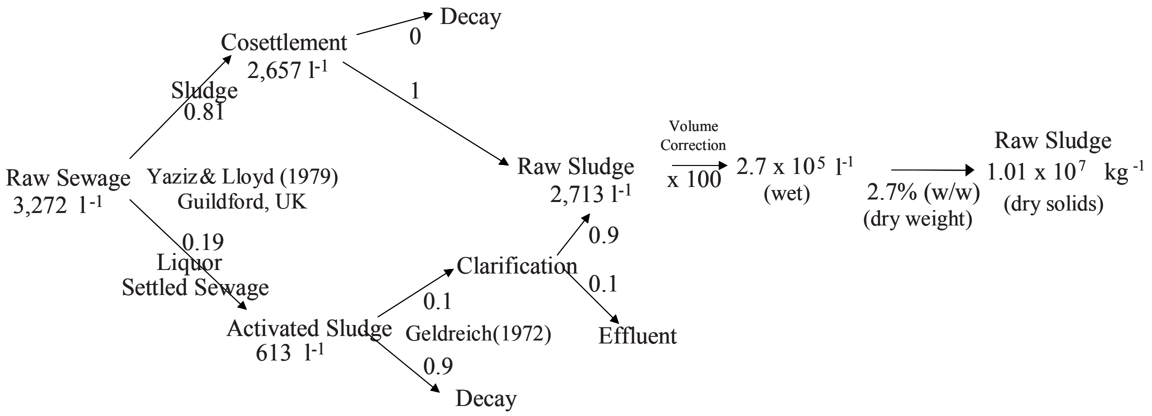

Figure B.2 – Event tree for partitioning of salmonellas into raw sewage sludge at a sewage treatment works

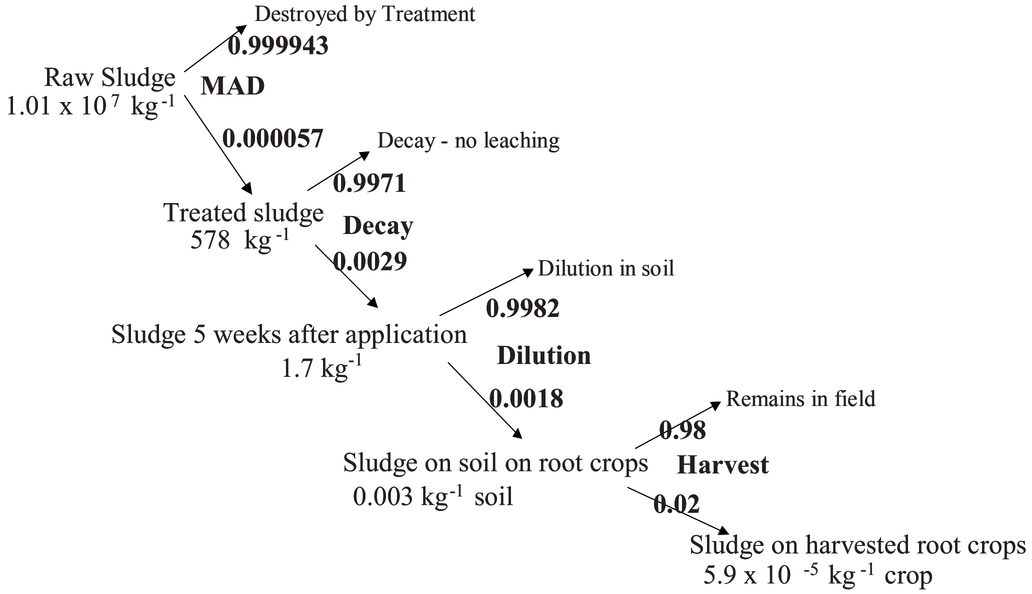

Figure B.3 – Event tree for transmission of salmonellas in sewage sludge to root crops

Figure B.2 and Figure B.3 are from UKWIR (2003). Figure B.2 shows an estimated prediction of the number of salmonellas likely to be found in raw sewage sludge based on a literature value for the numbers found in a survey of raw sewage and the estimates of decay at each stage through a wastewater treatment works1).

At each process step the proportion of the population is attributed, thus 81% of salmonellas are predicted to settle in the primary clarifier and 19% remain in the liquor. Of this 19%, 90% decay in the activated sludge treatment and 90% of the survivors of activated sludge are settled in the final clarifier and combined with the raw sludge. This mixed sludge passes forward to the sludge treatment plant (Figure B.3) where 99.9943% are destroyed by mesophilic anaerobic digestion.

In the first 5 weeks after the treated sludge has been applied to soil there is 99.71% destruction of salmonellas and because the sludge has been incorporated into and mixed with the soil there is a 99.82% dilution (to find the population in the soil). When root crops are harvested there is assumed to be 2% of the harvested weight is assumed to be soil thus giving a worst-case estimate of the salmonellas on the potatoes or other root crop. It should be noted that Figure B.3 only uses the decay of salmonellas over 5 weeks in soil because that was the longest estimate that the author found in the literature. It would take longer than 5 weeks to grow a crop from time of sludge application to harvest but in this case the author decided it was not appropriate to extrapolate the die-off and has recorded the decision.

B.5.2.6 Estimating the magnitude of consequences

In some cases there will be a high level of uncertainty in the estimation of the magnitude of consequences, and making some judgement on the possible consequences may be the best option. For example, there is often great uncertainty in ecological risk assessment, and it becomes very difficult to predict the extent to which a target population may decline and the degree of seriousness of the subsequent effects on community and ecosystem function that may result. In such cases cost-effective measures to avoid serious or irreversible harm must be adopted, even in the face of uncertainty.

In some cases it will be possible to quantify the magnitude of the consequences, and possibly even to place a monetary value on them (which will facilitate socio-economic analysis) but even this is difficult because of the wide spread of monetary values that have been attributed to avoidance of death, see for example UK Department of Health (1999) which reported that the financial estimates of the health benefit from reducing air pollution have ranged from £2,600 to £1.4 million for each life saved in different studies (€4,000-€2 million). The significance of the magnitude of a consequence, at least to a certain extent, is a matter of judgement. Where no guidance exists regarding the significance, a rough, ad hoc scale can be developed. An example is presented below ranging from negligible to extremely severe effects. Approaches using coarse scales of this sort have proved useful in risk assessment related to a range of environmental problems, for example assessing suitable clean-up standards for contaminated land.

- Negligible - Sub-lethal effects in individuals that do not cause a change in population structure or size.
- Mild-Moderate - Effects occurring at the population level. Effects on ecosystems that are not regarded as being of high value for whatever reason.
- Severe - Local extinctions (depending on the species) and local dysfunction of communities and ecosystems.
- Very severe - Global extinctions (depending on species) and widespread effects on the functioning of communities and ecosystems.
- Extremely severe - Impacts on the functioning of global ecosystems.

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1) The concentration values and partition/decay percentages cited are from the literature; clearly the accuracy is less than the number of significant figures quoted but rounding at each step would be equally spurious.

B.5.2.7 Estimating the probability of consequences

Estimating the probability of consequences is likely to be at best semi-quantitative. There are three primary factors to consider when estimating the probability of consequences (clause B.2) - whether the event will be initiated; whether exposure to the hazard will occur; and whether harm will result following exposure.

For example, there are well-developed techniques for estimating the probability that a chemical released to the environment will lead to harm to organisms. These are based on comparing a known concentration at which effects occur with a predicted or measured concentration in the environment.

In some cases it might be possible to base exposure predictions on measured levels in environmental compartments. There will be uncertainty in these measurements and, where this uncertainty is unacceptable or data are unavailable, the use of surrogates, models and assumptions will usually be of value. For example, physico-chemical properties of a substance and details of the amounts released into the environment can be used to predict its environmental partitioning and environmental concentrations. Mass-balance models are then used to quantify the amounts of a chemical expected to be present in different compartments within a particular environment.

Where strict quantitative analysis is not possible, expert opinion may be needed. For example, it is often less feasible to carry out a detailed quantification when the risk being considered is from living organisms (genetically modified organisms or alien species, for example). Hence in such cases regulatory decisions are usually based on the opinion of an expert advisory committee.

B.5.3 Dealing with uncertainty

B.5.3.1 Sources of uncertainty

Analysing the sources and magnitudes of uncertainty can help determine how much confidence can be placed in the risk assessment as a basis for decision-making. Uncertainties can arise from several sources, including natural or inherent variability over space and time, variability in the accuracy of measurements and data manipulation, and knowledge gaps due to lack of data. They can also arise when models and test systems do not accurately reflect the environment or exposed population of concern.

B.5.3.2 Analysing uncertainty

Methods for analysing and describing uncertainty may be simple or complex. Where significant knowledge gaps exist a useful approach is to estimate consequences based on alternative scenarios, presented as a series of estimates with different assumptions and descriptions of uncertainty. A common approach to dealing with uncertainty is to adopt a worst-case scenario, which assumes that the consequences will definitely occur, or to assign given magnitudes to the consequences. Uncertainty can, in many cases, be reduced by collecting more information (i.e. increasing the sample size). On the other hand, natural variability (e.g. chemical sensitivities within and between species) cannot usually be reduced by further measurement and must be expressed through the use of statistical descriptions such as probability and frequency distributions. Sensitivity analysis should always be carried out where the degree of uncertainty is critical.

Because many risk estimates will be subject to uncertainty from various sources, 'safety' factors (sometimes called 'protection' or 'uncertainty' factors) are often applied, especially in standard-setting and decision-making. Safety factors are typically applied when extrapolating from animal data to humans, from data derived from a small number of individuals to a population or from a species to a mixed ecosystem.

The decision process for developing safety factors can involve scientific judgements on a wide range of quantitative and qualitative information to produce a single number expressing those judgements and uncertainties. Safety factors can take account of scientific uncertainties in available data and allow, for example, for the protection of the more susceptible parts of the environment. Determining an appropriate safety factor requires a combination of experience and judgement. Recording the rationale behind such judgements is important.

B.6 Evaluating the significance of a risk

B.6.1 Introduction

Along with the formal scientific assessment of the probability and magnitude of adverse impacts on the environment, the broader significance of an identified risk needs to be established as a basis for decision-making. To ensure that the outputs from a risk assessment help in decision-making a number of questions should already have been addressed (see clauses B.1, B.4 and B.5).

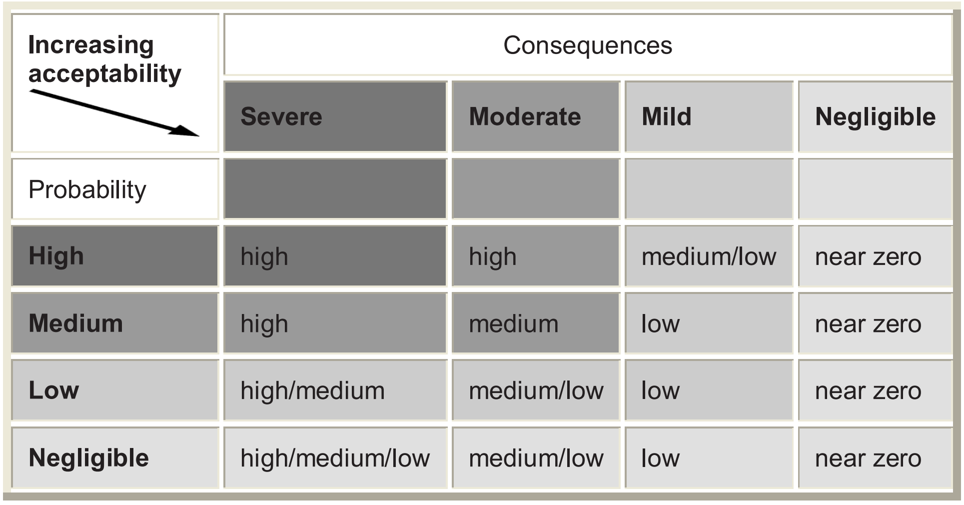
- What impacts to the environment may occur?
- How harmful are these impacts to the environment?
- How likely is it that these impacts will occur?
- How frequently and where will these impacts occur?
- How much confidence can be placed in the results of the risk assessment?
- What are the critical data gaps and can these gaps be filled?
- Are further iterations to the risk assessment needed?

Evaluating the significance of a risk also involves determining the broader implications of the risk problem including social, political and economic considerations. Once these judgements are made about a risk's acceptability, decisions can be taken about how to reduce or manage the risk (clause B.7).

B.6.2 Risk estimation as a basis for risk management decisions

For most activities it is likely that more than one hazard will be identified. For each separate hazard, combining the probability of the consequences and the magnitude of those consequences yields an estimation of risk. Both components are likely to be at best semi-quantitative and so each component will to some extent represent judgements on the basis of the knowledge and experience available. Issues relating to the probability of environmental consequences and how to deal with uncertainty are discussed in clause B.5.

A simple matrix (Figure B.4) can provide a consistent basis for decision-making. It should of course be used with caution, recognising the over-simplification that it will normally represent. The probability and consequences are defined according to parameters relevant to the situation; the boundaries of risk acceptability (and tolerability, where relevant) indicated on the matrix can be tailored to the factors influencing the significance of the risk (clause B.6.3). Individual situations are mapped onto the matrix to provide a ready and consistent indication of their acceptability or tolerability.



Increasing acceptability	Consequences			
	Severe	**Moderate**	**Mild**	**Negligible**
Probability				
High	high	high	medium/low	near zero
Medium	high	medium	low	near zero
Low	high/medium	medium/low	low	near zero
Negligible	high/medium/low	medium/low	low	near zero

Figure B.4 – Estimation of risk from consideration of magnitude, consequences and probabilities (from Anon 2000)

B.6.3 Factors influencing the significance of a risk

B.6.3.1 Legal and policy requirements

A wide range of standards for pollution control exists including exposure standards, environmental quality standards, emission standards, process or operating standards, food standards and product standards. Clearly if these are legally mandatory and a risk assessment demonstrates that an intended activity is likely to breach them, the risk is unacceptable and measures to reduce it to acceptable levels should be adopted. There is also a substantial amount of legislation and numerous policy objectives that may affect the significance of a risk.

In situations not covered by legislation, or where policy is to seek environmental improvements beyond those aspired to by law, targets should be set through socio-economic analysis and expert judgement, taking account of the societal pressures which lead to policy or political decisions.

B.6.3.2 Value judgements

Defining what constitutes unacceptable harm to an ecosystem is a difficult task and ultimately depends on what values society places on ecosystems. Some hold the opinion that maintenance of ecosystem function is the main objective and that the loss of individual species may not be of consequence with respect to this. Maintaining ecosystem integrity, at local and global scales, is clearly important to the maintenance of an environment that provides the resources and conditions required for man's survival and development. The preservation of biodiversity in its own right has received much attention in recent years and many arguments have been put forward in support of this. Some habitats and species are considered to be of particularly high value for conservation, as a result of value judgements made on the basis of rarity, attractiveness, fragility and so on. Governments have set out priorities and strategies for biodiversity conservation and these are reinforced by national implementations of the EC Wild Birds Directive and the EC Habitats Directive.

B.6.3.3 Social aspects of risk

The acceptability of a risk can be significantly influenced by a range of psychosocial and political factors. These may include individual risk perceptions and attitudes, cultural values, questions of trust and credibility about risk proponents and managers, and questions of equity in risk distribution (clause B.3). While risk management decisions should be based on the best scientific information available, these factors should also be considered when evaluating the significance of a risk. An important step is the creation of a constructive dialogue between stakeholders affected by or interested in risk problems (clause B.3.8).

B.6.3.4 Economic considerations

Economic factors can have a significant influence on the decision-making process and may affect the acceptability of a given option.

The best option is likely to be the one with the greatest excess of benefits over costs, where the benefits are those accruing from protection (e.g. the damage or loss of property, materials, crops, human health and environmental assets that is avoided) and the costs are those social and private costs of the control options, including construction, maintenance and environmental damage. This should include both those benefits and costs that can be monetised and those that cannot (or for which robust monetary valuations are not readily available) - the latter need to be assessed in physical and qualitative terms. Because monetary values can more readily be assigned to some impacts than others, care is needed to ensure that adequate consideration is given in any decision-making to all non-monetised items that may be thought significant, relative to the monetised elements.

B.6.3.5 The changing environment and changing baselines

Baselines against which alternative risk assessment scenarios can be compared are likely to change over time. Changing baselines may be the result of a diverse set of factors including, for example, climate change, increasing urbanisation, demographic changes and changes in social attitudes towards risk acceptability and advances in technologies available to reduce risk. This can result in a new set of conditions against which existing risks and management options should be compared and altered if necessary. Clearly, the possibility of such changes can have an impact on risk significance and should always be borne in mind.

B.6.4 Other significant factors

According to circumstances, law or policy may subject an activity to requirements or principles to limit risk, as listed below:

ALARA	as low as reasonably achievable
ALARP	as low as reasonably practicable
BATNEEC	best available technique not entailing excessive cost
BPEO	best practicable environmental option
BPM	best practicable means

None of these terms is exactly equivalent to another. Generally they are used within a strict legal context, and consequently the use of one criterion rather than another needs to be considered carefully in each situation.

ALARA has been applied for some food quality standards. It is important that there is a sufficiently extensive database of analyses to be confident that the value is “reasonably achievable”.

ALARP is a wide statement of principles and forms the cornerstone of nuclear plant safety. A risk that has been reduced to ALARP corresponds to the concept of tolerable risk. This implies that any further reduction in the risk can be achieved only at grossly disproportionate cost and that the benefits afforded by the risk are judged to outweigh the costs.

Other criteria commonly used in environmental risk assessment are described as BPEO and BATNEEC. Both these criteria involve balancing the reduction in risk with the practicability and cost of reducing that risk.

The application of BATNEEC normally means that the additional costs of avoiding environmental damage are justified by the benefits. Therefore, BATNEEC would not require the reduction of risk from 'low' to 'negligible' if that would require very expensive techniques. Under the Environmental Protection Act 1990, the BATNEEC criterion is applied in integrated pollution control (IPC).

Importantly, the application of BATNEEC means that the estimation of the risk associated with a particular activity can change over time as new techniques and technologies are developed, and the costs of existing techniques vary. Such changes may warrant another iteration of the whole risk assessment process. The BATNEEC criterion relies not only on technological solutions, but includes other approaches such as environmental management systems and staff training.

The BPEO is a term of policy guidance. It is the option that provides the most benefit or least damage to the environment as a whole, at an acceptable cost in both the long and short term. The BPEO, as a concept with legal basis, was introduced with IPC. Operators of prescribed industrial processes which produce releases to more than one environmental medium must ensure that BATNEEC is used to minimise pollution to the environment as a whole, having regard to BPEO. Again, an element of cost versus environmental benefit/risk is brought into play in deciding which process option constitutes BPEO. A key feature of the BPEO approach is that decision-making is transparent and that an audit trail exists so that all stages in the choice of the BPEO can be scrutinised.

B.7 Options appraisal and decision-making

B.7.1 Introduction

Options appraisal is the process of identifying the 'best' risk management technique. This may involve scoring, weighting and reporting different risk management options. Various criteria are used for identifying the 'best' option, according to context, but a common framework is to seek to maximise some long-term definition of human well-being such as sustainability, net social benefit or value for money. Key inputs for this process are the controlling factors for each risk identified during the problem formulation stage (clause B.1). For instance, if a controlling factor is the level of investment in monitoring and control equipment, then options appraisal can focus on those issues immediately.

An appraisal process normally involves identifying and reporting the benefits and costs of options, and then ranking those options with regard to the appropriate criteria, and risk management is no different. Relevant options may include emerging technologies and management techniques that reduce a risk's frequency or consequences. Social issues and the perceptions and aspirations of the public should also be considered as part of the process (clause B.6). Combining all of these elements permits a systematic comparison of options for risk management. The process may be iterative, with options appraisal feeding back to the various tiers of risk assessment (Figure 2 and clause B.7.4).

B.7.1.1 General risk management options

There are three main options available to the risk manager when presented with a risk problem. The options are to:

- reject the intention altogether because it poses unacceptable risks;
- accept whatever risk is imposed; or
- reduce the risk in some way, by doing one or more of the following:
  - modifying the receiving environment or hazard;
  - modifying or avoiding exposure; or
  - modifying the effects or consequences of a risk.

B.7.2 Trade-off analysis: methods for decision-making

This clause outlines some of the systematic methods that can be used for comparing and evaluating (or trading off) alternative risk management options. There is no universal decision-focused method suitable for all circumstances, rather, selection or adaptation of an existing methodology or development of a new methodology will be necessary.

All good policy decisions rely on the effective analysis of alternative options. Therefore, a systematic appraisal is important to ensure that the decision-maker is clear about the objectives and how to decide where the balance lies between the benefits from the reduction of the risk and the implications for society of introducing potential control measures. A systematic appraisal of the options will be the process of identifying, quantifying and weighting the costs and benefits of the measures that have been identified as means of implementation. This process must include all implications of the potential options, and not just those that can be quantified.

All appraisals should involve a systematic approach. This is generally best achieved through a step-by-step process to help guide the decision-maker through the development of the strategy in a structured way. Each appraisal will require varying degrees of emphasis at different stages depending on the individual circumstances, but a common framework can be envisaged consisting of the following steps:

- Identify the objective, ensuring a clear and common understanding of what is the desired outcome.
- Identify the options. In most cases, there will be options that are obvious to the decision-maker. Some will be less applicable than others and it will be necessary to identify those that have the potential, either in whole or in part, to meet the objective.
- The options identified will need to be implemented using various tools, such as policy instruments, economic measures or regulations. Consideration should be given to the selection of those most appropriate while recognising that they will not be mutually exclusive and a combination of one or more may be appropriate for one or more options.
- Identify the impacts of the options. This will require collection of data from those stakeholders that will be affected by potential measures. Close consideration should be given to the implications of changes in working methods (good and bad) to meet the objective.
- Clarify the decision criteria such as the economic costs, the implications of change, and the human health and environmental benefits.
- Compare the advantages and drawbacks for each option including the trade-off between quantified and qualitative data to draw conclusions.

Some of the techniques for taking forward such a systematic appraisal are summarised below.

B.7.2.1 Environmental impact assessment

Environmental impact assessment (EIA) is a widely used procedure for systematically assessing the environmental impacts of proposed projects, for example a new [centralised] sludge treatment centre or incinerator. It is a legal requirement for certain projects likely to have significant effects on the environment. Information on the environmental effects of a project, and the main alternatives, is documented in a form that provides a focus for public scrutiny of the project. It enables the importance of the predicted effects, and the scope for mitigating them, to be evaluated before a decision is made as to whether the project can proceed. Under EIA there is no requirement to produce monetary evaluations of environmental impacts and no requirement to consider formally the costs of risk management options.

B.7.2.2 Strategic environmental assessment

Strategic environmental assessment (SEA) is closely allied to EIA but focuses on the potential environmental effects of policies, plans or programmes (PPPs) as opposed to individual projects or developments. PPPs may be concerned with programmes of development (e.g. transport or power networks), geographical areas (e.g. local authority areas, regions or countries), types of area (e.g. cities or shorelines), or economic sectors (e.g. mining or agriculture). SEA uses a range of techniques to predict both the direct effects of PPPs and their interaction with other PPPs and activities.

The SEA Directive 2001/42/EC (CEC, 2001) became effective from 21st July 2004; a wide range of plans and programmes implemented after that date require SEA. This could include regional or national plans for sludge.

B.7.2.3 Cost-benefit analysis

Cost-benefit analysis (CBA) involves expressing as many costs and benefits as possible in terms of the monetary or other value placed on them by society, and deriving the net benefit. This is a very general technique, but it has stringent information requirements. A particular area of difficulty is choice of a discount rate, which may discriminate unduly against long-term options.

In many CBAs there will be effects that cannot be given a monetary value and there will sometimes be key environmental assets that cannot readily be valued. Where there is no market for an environmental good, techniques for monetary valuation exist that measure people's preferences. These techniques need to be used with caution, as the values they produce may not always be robust for their intended (or unintended) uses. There is always a danger with valuation techniques of placing too much emphasis on those attributes that can be measured at the expense of those that cannot.

B.7.2.4 Environmental capital

Consideration of environmental capital is a more recent approach. It rests on the idea that the environment consists of assets that can provide a stream of benefits or services as long as care is taken not to damage them. A distinction is often made between 'critical', 'constant' and 'tradable' environmental capital.

B.7.2.5 Ranking, rating and weighting

Further methods have been developed involving ranking, rating or scaling and weighting to compare alternative options. These involve summarising both quantitative and qualitative information on alternative options using the assignment of a rank, rating or scale value relative to each of a number of decision factors or criteria. These decision factors can include the economic costs and benefits of the intention, social and political perspectives, and so on. Ranking involves placing options from best to worst; scaling refers to the assignment of algebraic or letter scales; and rating employs a pre-defined range. The rank, rating or scale value is then presented in a matrix to aid decision-making.

A trade-off analysis using a weighting approach involves weighting the relative importance of each decision factor. Such an approach will always be open to criticism because the weights may be seen as arbitrary or biased. Although some methods are available, experience indicates that it may be difficult to reach a consensus about the appropriate weights to be allocated. It is desirable to undertake sensitivity analysis on the scores and weights attached to different criteria (clause B.5.3).

The techniques summarised above can be incorporated into what is termed multi-criteria, or multi-attribute, analysis. This approach involves multiplying the weighting for each decision factor by the rank, rating or scale value of each option. The resulting products are then totalled to arrive at an overall score for each option.

B.7.3 Which technique?

Any particular technique selected for trade-off analysis will have inherent assumptions and limitations and these should be stated for the purposes of openness and transparency. The results of a particular analysis should be seen as an aid to decision-making, rather than providing a definitive answer on the preferred option.

Iteration

Unless the intention is very simple, it will be necessary to revisit some or all stages in the risk assessment process. Certainly, the decision-making process may highlight significant information gaps not identified at an earlier stage. The problem is in balancing an understandable desire to gather ever more information before choosing a course of action with the need to make a timely decision. Lack of information should not be used as an excuse for postponing or avoiding decision-making. Significant information gaps may be cause to invoke the precautionary principle (clause 5).

If the risks associated with an intention are acceptable then the intention can go ahead. If an intention presents unacceptably high risks, however, then mitigatory options will be required. This can include not undertaking the intention and thereby completely avoiding the risk (but also forfeiting any benefits that might have resulted). Each risk management option should be reassessed through the risk assessment process to determine whether it reduces the risks to an acceptable level. Each option may introduce new risks and the reassessment should not just be a review of what has already been considered.

B.7.4 Risk communication and decision-making

During options appraisal it will normally be necessary, as in all preceding stages, to engage in dialogue with relevant stakeholders. The guidance provided in clause B.3 is as relevant to the risk management process as it is to risk assessment.

B.8 Monitoring

B.8.1 Introduction

Monitoring plays a central role in environmental risk assessment and management and is undertaken to gain continuous or periodic information about aspects of an intention before it starts, during its lifetime and after its completion. Information from monitoring programmes is integrated into environmental risk assessment and management in various ways:

- as the baseline against which to compare actual and predicted impacts;
- as an input to models, forecasts and quantification stages;
- to provide information to feed back into the risk assessment in an iterative process;
- to confirm that risk assessments and management options are meeting their desired aims; and
- as an alert mechanism if adverse impacts are found.

B.8.1.1 Baseline information

Describing the situation before the intention is one of the first steps in the problem formulation stage (clause B.1). Where possible, this baseline should be derived from sampling and monitoring in the immediate vicinity of the intention. Where this is not possible (for example, where the operation being assessed has already commenced) the baseline can be derived from a reference area unaffected by the intention. In this case, the reference area should be similar in physical, environmental and ecological character. In some situations, it may be useful to use such a reference area as a control, in which case baseline monitoring will be needed both at the reference area and in the immediate vicinity of the intention.

The baseline is not static and may change over time within a given area. Impacts that may appear at first to be attributable to the intention may in fact be the result of natural variation or other indirect changes (clause B.6.3). It is also important to consider the effect that socio-demographic changes can have on the significance of a risk.

A related issue is distinguishing effects of previous or nearby activities from effects stemming from the intention. Only with a well-defined baseline can such a distinction be made. For instance, complaints that respiratory problems have increased in the neighbourhood since a sludge treatment facility opened could not be assessed easily, if at all, without baseline monitoring.

B.8.1.2 Models and forecasts

Monitoring programmes can provide valuable data for modelling and forecasting the environmental effects of an intention. The information need not be new (i.e. gathered specifically for the purpose). For example, actuarial data are used to help predict when components in a system will fail (clause B.5.2). The more specific the information is to the intention, the more certainty can be placed in predictions or models based on it.

While monitoring can help predict trends, it is less useful where events are rare or where an event is not easily distinguishable from the baseline.

B.8.1.3 Audit and alert

Because of the inherent uncertainty in environmental risk assessment, some forecasts may not be on target. Monitoring thus becomes a useful tool for either confirming or contradicting forecasts. For example, the validity of risk assessment of crop uptake of PTEs as a result of sludge use on land can be verified by crop monitoring in relation to cumulative loading and/or soil analysis.

B.8.2 What to monitor

It is rare to be able to monitor every parameter relating to the intention. It is therefore important to tailor a monitoring programme to the particular situation; it should be designed with specific goals and questions in mind in order to increase its usefulness and cost-effectiveness.

B.8.2.1 Problem formulation

Deciding what to monitor will to a great extent depend on the intention in question and on the outcome of the problem formulation stage (clause B.1). The problem formulation should have identified the most important risk components associated with a given intention and it is these components that require monitoring. The problem formulation will also define the temporal and spatial scale of the risk assessment and thereby define the monitoring boundaries.

B.8.2.2 Controlling factors

Hazardous events are often subject to factors that control their timing, intensity and duration (clause B.1.5). These factors are an ideal focus for a monitoring programme. For example, it will be difficult to predict odour complaints or bioaerosol emissions without monitoring wind direction and strength.

B.8.2.3 Expertise and knowledge

A prerequisite for the design of an effective environmental monitoring programme is a good understanding of the local ecosystem and the possible effects of the intention. This understanding underlies the identification of the possible risks of the intention. In addition, projects or policies can have effects that extend beyond local ecosystems and have regional, national or even global significance, such as acid rain or global warming.

Two key considerations to note when choosing measurement parameters are natural variability and sensitivity to risk exposures. For instance, a simple approach in ecosystem monitoring is observing changes in population levels of important, relevant species. If there is no change in population then there is deemed to be no significant effect. Such an approach is not sufficiently refined, however, to detect sub-lethal effects, and for this purpose, more descriptive measures of status of the environment are employed, such as reproductive rates and bioconcentration levels.

B.8.3 Designing the monitoring programme

Having decided what information is needed for assessing and managing the risk, and from this deciding what to monitor, the next stage is to design the monitoring programme. Normally, specialist advice will be needed in order to ensure that the appropriate parts of the environment (air, water, soil, biota) are monitored and that the programme delivers the information required at an optimum cost. Preliminary surveys to obtain data on which to base the design may be needed. A poorly designed monitoring programme will almost certainly result in considerable waste of time and effort and, worse, fail to produce the information required to assess or manage the risk.

B.8.3.1 Where to sample

Sampling locations will normally be located either close to the risk being assessed, or in an appropriate reference area (clause B.8.1). The precise location of the sampling point within that area can be of critical importance. For example, when sampling a river for water quality measurements, it is important to know whether or not water quality is homogeneous across the river at the sampling point. If it is not, a decision will need to be made about where within the cross-section of the river the best information about environmental impact will be obtained.

B.8.3.2 When to sample

Sampling frequency will depend on the precision with which information is required, the natural variability of the receiving environment and the nature of the hazard. Statistical analysis of these factors will indicate the minimum sampling frequency necessary to deliver the required information. A lower sampling frequency will reduce the monitoring programme costs, but at the expense of reduced precision. A judgement will often be needed about the costs and benefits of improved precision.

B.8.3.3 Sampling pattern

If the feature being monitored is intermittent (for example, a non-continuous discharge to air) it will be necessary to determine the most useful sampling pattern. This will not always be a regular pattern. For example, sampling air quality at the same time of day, on the same day each week will only provide limited information on general air quality. If this happens to coincide with a regular discharge then the monitoring programme will provide information about the instantaneous effect of the discharge on air quality. If the long-term or average impact of the discharge on air quality is required, then a different sampling pattern will be necessary (for example, a randomised or regularly rotating programme).

B.8.3.4 Sampling technique

The way in which the sample is taken, the type of material in which it is collected and stored, and the length of time between sampling and any further investigation (for example chemical analysis) can all substantially influence the validity of the derived data. Factors to be considered include the dangers of cross-contamination from the sampling container, disturbance of the sample by inappropriate handling or storage, and, when sampling birds, fish or mammals, the need to avoid inflicting unnecessary suffering.

B.8.4 Interpreting and dealing with monitoring data

Even simple monitoring and sampling programmes produce large amounts of raw data that, to be of most value to risk assessment and management, must be interpreted and processed appropriately. The methods used for this will depend on the type of data gathered and their proposed use. Data presentation can range from simple graphs, figures or tables, to more complex methods using mapping techniques or Geographic Information Systems.

The various parameters in a monitoring programme are sometimes aggregated or represented as an index (such as 'ecosystem health'), or expressed in terms of one parameter that integrates other factors. For example, the parameter 'species abundance' can reflect anthropogenic factors such as chemical contamination, physical disturbance and harvesting rates as well as natural variables. However, indices such as ecosystem health may not be transparent or comprehensible to either the public or decision-makers.

Wherever possible, the key stakeholders and the general public should have access to both the raw and the processed data, making sure that the key uncertainties and assumptions made are duly described.

B.8.5 Hazard Assessment – identification of consequences

Developed and published distributions for soil ingestion by children, drinking water intake for children and adults, height and weight for adults, body surface area for adults, bioconcentration of lipophilic chemicals in finfish, distributions for children's body weight, lipid intake by nursing infants, fish consumption, and the fraction of indoor dust in single-family homes originating from outdoor soils.

B.8.6 Deterministic and Probabilistic Risk Assessment

Deterministic Analysis is the calculation and expression of health risks as single numerical values or "single point" estimates of risk. In risk assessments, the uncertainty and variability are discussed in a qualitative manner. Deterministic risk assessments combine a set of average, conservative, high, and worst-case assumptions to derive "conservative" point estimates for exposure and risk. The major drawback of this approach is that no one can say how conservative the combined combination of these estimates really is. For example in the case of cadmium risk from using treated sewage sludge in a garden, one could assume that the most exposed individual smoked 40 cigarettes per day2), lived in the same house for 70 years and that 60% of his food came from the garden whose only source of fertiliser was sludge. It is a combination of very conservative estimates, but is there such an individual? This was one of the scenarios in USEPA (2002a). Risk managers may not know whether the estimated risk represents the 90th, 99th, 99.99th, or some higher percentile of risk.

Probabilistic Analysis is the calculation and expression of health risks using multiple risk descriptors to provide the likelihood of various risk levels. Probabilistic risk results approximate a full range of possible outcomes and the likelihood of each, which often is presented as a frequency distribution graph, thus allowing uncertainty or variability to be expressed quantitatively. The Monte Carlo method - now 50 years old and widely used throughout science and engineering – is frequently used. The input variables are treated as random variables described by probability distributions (i.e., not as point values). With appropriate precautions to consider correlations, dependencies, and other pitfalls, Monte Carlo techniques give risk assessors the proper tools to estimate full distributions of risks in a population and, as appropriate, full distributions for cleanup targets (acceptable exposure point concentrations).

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2) Tobacco is a cadmium accumulator and because the cadmium is volatilised when the tobacco burns, the kidney cortex of a smoker contains twice the cadmium concentration of a non-smoker.

B.9 Risk Management

B.9.1 Quality Assurance

The principle of QA is to standardise the way that each step in a process is performed in order that it is performed the same way throughout the coverage of the programme and by every individual, be they experienced or a new recruit to the job. Figure B.5 illustrates the QA cycle. After deciding the Scope of the scheme, a Procedure is designed for each step in the process; it is then tested to check that it is practicable before it is put into operation. Performance is monitored and if weaknesses or areas for improvement are found the Procedure is re-designed and the cycle starts again.

One of the features of QA is that actions are recorded so that they can be verified and traced. Some criticise QA for being cumbersome and generating paperwork. However many people nowadays expect traceability; they expect that if there is an incident it will be possible to track down its origin. This is not possible without documentation (paper or electronic).

One of the earliest applications of QA to sludge use and disposal was in late-1989. This was a sewage sludge recycling operation serving about 6.5 million people recycling sewage sludge from about 80 production centres.

There are international standards for QA (ISO 9000 and ISO 14000 series) but registration and accreditation under these schemes is not essential for practising QA. QA can be practised using an in-house scheme based on these standards without going all the way to independent accreditation.

Accreditation to ISO 14001 can be daunting. BS 8555:2003 “*Environmental management systems – Guide to the phased implementation of an environmental management system including the use of environmental performance evaluation”* aims to overcome this challenge*”.* It is likely to be the model for an international standard and provides phased implementation of environmental management systems. The initiative is supported by the Acorn Trust with a website of resources and support by mentors: http://www.theacorntrust.org/.

It is important that QA is kept alive by reviewing the scheme regularly. To ensure that this happens it is advisable to make it part of somebody’s job. In large organisations, there will be a full-time QA manager but for more modest sized operations, this can be a part-time activity, however the responsibility for maintaining the scheme is no less important.

B.9.2 Hazard Analysis and Critical Control Point (HACCP)

QA will assure that operations are performed in a consistent, traceable manner. HACCP (Hazard Analysis and Critical Control Point, pronounced hassup) is a very useful complement to QA when it is applied to the design of the process. It is a risk management tool. HACCP was developed in the 1960s by the Pillsbury Company to improve the confidence in the safety of food supplied to astronauts for the USA’s manned space-flight programme.

The HACCP process produced by Pillsbury involves "Critical Control Points" (CCP) through which all of the production passes. These reduce the risk from specific hazards to levels that are acceptable. In the case of food, a CCP to prevent food poisoning might be the cooking step; if all of the food is cooked for a particular time and temperature then biological risk will be controlled provided the food cannot be recontaminated after cooking. By monitoring the cooking time and temperature and ensuring that it does not deviate from the prescribed tolerances (the Critical Limits) one can be sure that risk in all of the food will have been controlled. The records of the operating conditions of the CCPs provide auditable records that risk has been controlled.

Prior to HACCP there had been reliance on “end-of-pipe” testing, but it was realised that this only told you that the sample you tested was acceptable. You did not know about the material that had not been tested, i.e. the food that was going to be sent into space because it had not been tested. HACCP has been adopted by the United Nation’s Codex Alimentarius Commission and Food & Agriculture Organisation / World Health Organisation Food Standards Program (Codex, 1997) and by national governments. Today HACCP is the basis of food safety and has also been adopted by some non-food industries; it is being adopted for public supplies of potable water, but it is not yet widely recognised by the recycling industry.

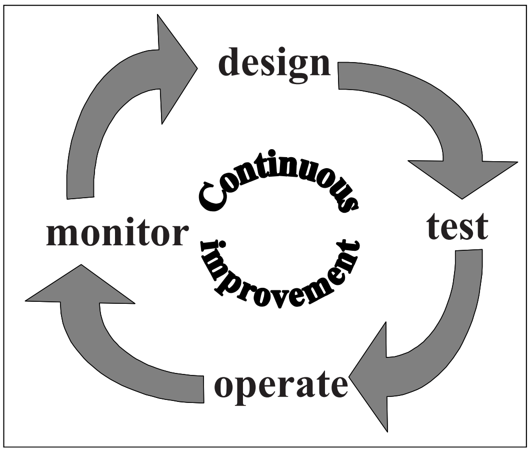

Figure B.5 – Quality Assurance cycle

EU food legislation is moving responsibility for food safety back up the production chain to the primary producers and will require that HACCP-based working is adopted. If or when sludge recyclers adopt HACCP, all parties will be speaking the same language. But the benefits go much deeper than semantics and building confidence in a major stakeholder. Important though that is, it has actually proved a better way to design the management of a process.

The first step in HACCP (after getting management acceptance to use it) is to decide what is being produced and the intended uses of the product (for example, sludge that will be used to improve soil for growing a range of crops) and then determine the associated hazards. They might include inorganic or organic contaminants, pathogens, odour, public hostility, litter, water pollution, prosecution for non-compliance, etc. Each step in the production process is then examined, using a decision tree (Figure B.6) to see whether it is capable of bringing the risk from any of the hazards associated with the product to acceptable levels. If the process step is capable of controlling the risk it is a **Critical Control Point (CCP)** for that risk, unless there is possibility of unacceptable re-contamination further down the process. The minimum operating conditions (capable of controlling the risk) are the **Critical Limits (CL)** of the CCP. Thus if every part of the production goes through the CCP, and if the CCP continuously operates within its CL, you know the risk is controlled. CCPs have to be monitored and the results recorded; these records are the proof of satisfactory control. End-of-pipe testing is then merely used to *verify* that the CCP is operating and the CL are appropriate. Another element of HACCP is defining **Corrective Actions** – what do you do when the CL or verification go out of range? The requirement to define Corrective Actions is a very important feature because it forces you to plan for the downside.

HACCP does not mean that every kitchen has to cook food at the same temperature; it allows innovation and solutions that are appropriate to the particular circumstance. The main thing is that it does not matter whether it is established technology or a unique new approach, it has to be verifiably effective and traceable and plans have to have been made for the inevitable occasion when something does not go right.

HACCP is complementary to QA; it is not an alternative. HACCP comes first because it is the tool to design the process; QA standardises the operating procedures. People coming from a tradition of regulation often (wrongly) resist defining CCPs because they think of them as points of regulation whereas they should regard CCPs as a defence because they demonstrate due diligence. It takes some time (and help) to get into the HACCP way of thinking; to get full value the facilitator should understand the composting business. HACCP enables innovation. It is proactive, verifiable, and focuses resources where they are needed. It creates solutions that are appropriate to each individual situation. This is in marked contrast to prescriptive regulation, which is very unlikely to anticipate every possible local variation and peculiarity. Another frequent confusion is between CCP and CL; a CCP is a process step (or sequence of steps); the CL are the ranges of conditions (time, temperature, pH, etc.) within which the CCP needs to be operated in order to be effective.

HACCP with its systematic approach to hazard identification and risk-control is a better way to design a process. Of course, HACCP cannot help to control hazards that are not identified so it is important that those doing the HACCP analysis are honest and dispassionate. The last thing a composting programme needs is a hostile front-page news story.

HACCP can be applied to the whole sludge use or disposal process, from control of pollutants at the source through treatment to land-application. It can increase the confidence of producers, users, and stakeholders, and thus help to assure longevity to a composting programme.

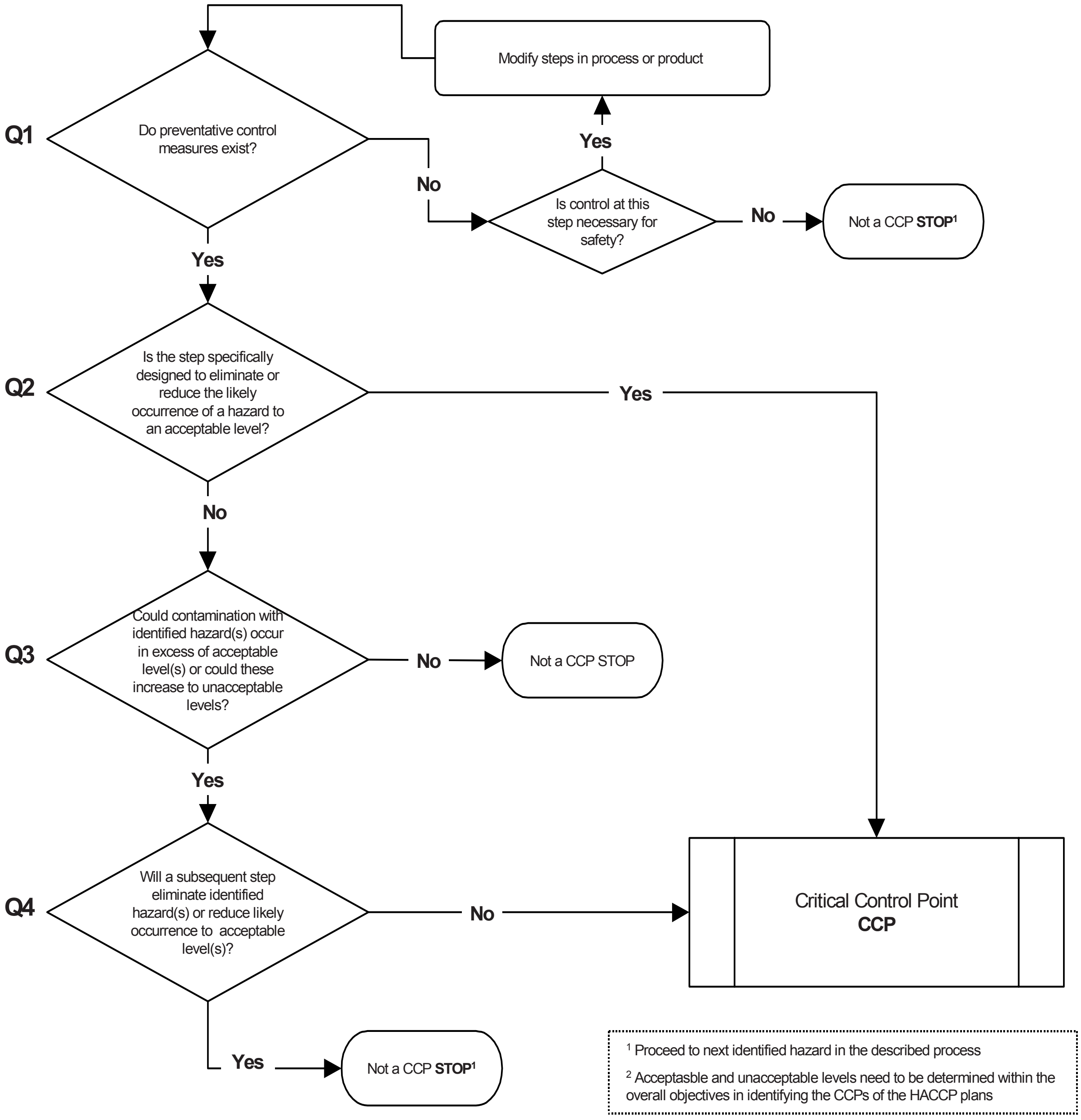

Figure B.6 – HACCP decision tree

Sometimes people suggest there should be a *de minimus* limit below which QA (and HACCP) is an unwarranted burden. The case of Walkerton in rural Southern Ontario, Canada demonstrates the error of such a suggestion. Walkerton is a small town with 4900 residents. In May 2000, it was struck by infection of *E. coli* O157:H7. Seven people died and 2,300 became violently ill. The town water supply comes from three wells; the chlorine dosing equipment was poorly maintained. One of the wells was not sealed to the rock around the shaft, and it was downhill from a small, cattle farm. The ground was swampy and the aquifer below was covered by only 2.4 metres of sand, gravel and rock - not enough to filter out bacteria before water reached the well. Another well was artesian and had a very weak overflow flap valve. The laboratory had repeatedly reported bacterial contamination of Walkerton's water. In May 2000, there was heavy rain, which caused run-off from local farmland. Run-off water got into the wells, the chlorine dosing was not working properly [again] the water superintendent put the laboratory's report of failing water aside [again] thinking he could solve the problem and *E. coli* O157:H7 was pumped into the town's water supply with disastrous consequences. HACCP and QA would have prevented this tragedy of errors.

HACCP could also have prevented the Clopyralid incident at Spokane WA, USA. The use of a persistent herbicide on grounds from which greenwaste (yardwaste) was collected for composting was probably a reasonably foreseeable eventuality. Especially since grounds maintenance by professional contractors is a feature of the area, which means that large areas of are likely to be treated with a product during a relatively brief time window. Control of the potential input at source would have been the CCP, i.e. by a warning such as "do not put out for composting grass treated with persistent herbicide for the first two cuts after treatment" with plant-growth phytotoxicity testing as a Verification. An alternative CCP would be a batch release scheme based on plant-growth phytotoxicity testing.

B.9.2.1 Principles of the HACCP System

The HACCP system consists of the following seven principles:

Table B.3 The Seven Principles of HACCP

PRINCIPLE 1	Conduct a hazard analysis.
PRINCIPLE 2	Determine the Critical Control Points (CCPs).
PRINCIPLE 3	Establish critical limit(s).
PRINCIPLE 4	Establish a system to monitor control of the CCP.
PRINCIPLE 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
PRINCIPLE 6	Establish procedures for verification to confirm that the HACCP system is working effectively.
PRINCIPLE 7	Establish documentation concerning all procedures and records appropriate to these principles and their application.

B.9.2.2 Guidelines for Applying the HACCP System

Prior to application of HACCP to any facility, it should be operating according to legislation and permits. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, operating practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to safety.

The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard that must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

B.9.2.3 Application

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Figure B.7).

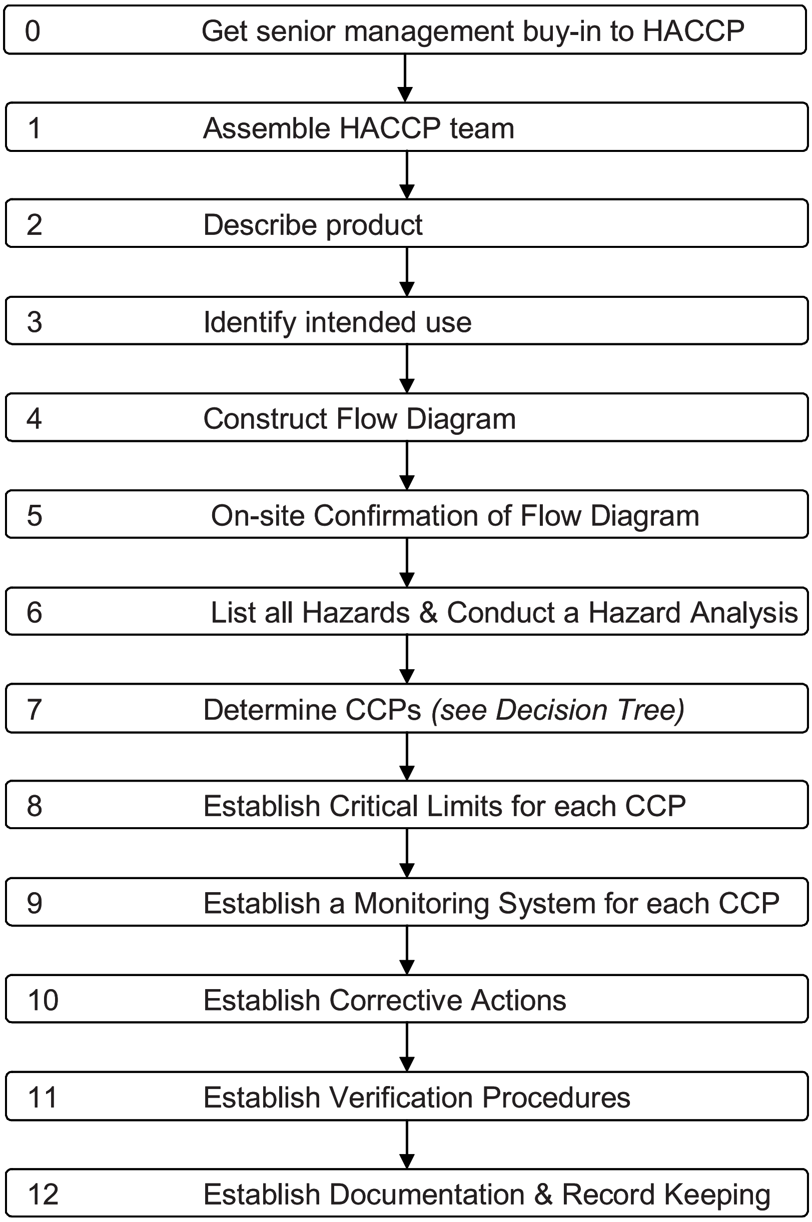

Figure B.7 – Logic sequence for application of HACCP

1. Assemble HACCP team

The composting operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the composting chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure, microcidal/static treatments (heat-treatment, magnetic/air/ballistic-separation, etc.), packaging, durability and storage conditions and method of distribution.

3. Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. It might also be appropriate to include reasonably-expected unintended-use.

4. Construct flow diagram

The HACCP team should construct the flow diagram. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. On-site confirmation of flow diagram

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

6. List all hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (SEE PRINCIPLE 1)

The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption of foods that have been associated with the sludge.

The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of compost that is acceptable for its intended uses.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in composts of toxins, chemicals or physical agents; and,
- conditions leading to the above.

The HACCP team must then consider what control measures, if any, exist that can be applied for each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. Determine Critical Control Points (SEE PRINCIPLE 2)

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g. Figure B.3), which indicates a logic reasoning approach. The decision tree should be used for guidance when determining CCPs. It has been found to be widely applicable to the treatment and use of organic resources, including composting. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at an earlier or later stage, to include a control measure.

8. Establish critical limits for each CCP (SEE PRINCIPLE 3)

Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, and sensory parameters such as visual appearance and texture.

Critical Limits are not necessarily parameters that can be measured by instruments. Where they are sensory parameters there is a greater personal involvement and it is therefore important that the people are adequately experienced and trained. Training records, staff retention and attendance records could all be part of the records showing that appropriate people were involved.

9. Establish a monitoring system for each CCP (SEE PRINCIPLE 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. Establish corrective actions (SEE PRINCIPLE 5)

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

11. Establish verification procedures (SEE PRINCIPLE 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, verification activities should include actions to confirm the efficacy of all elements of the HACCP plan.

12. Establish Documentation and Record Keeping **(SEE PRINCIPLE 7)**

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Documentation examples are:

- Hazard analysis;
- CCP determination;
- Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Modifications to the HACCP system.

Figure B.8 is an example of a HACCP worksheet for recording the analysis.

Describe Product

Diagram Process Flow

Process step	Hazard(s)	Control Measures	CCP Question 1 2 3 4 CCP	Critical Limit	Monitoring Procedures	Corrective Actions	Records	Verification Comment

Figure B.8 – Example of HACCP Worksheet

B.9.2.4 Training

Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the people operating the process.

Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

Annex C
(informative)

Rio Declaration on Environment and Development

The United Nations Conference on Environment and Development, having met at Rio de Janeiro from 3 to 14 June 1992, reaffirming the Declaration of the United Nations Conference on the Human Environment, adopted at Stockholm on 16 June 1972, and seeking to build upon it, with the goal of establishing a new and equitable global partnership through the creation of new levels of cooperation among States, key sectors of societies and people, working towards international agreements which respect the interests of all and protect the integrity of the global environmental and developmental system, recognizing the integral and interdependent nature of the Earth, our home, proclaims that:

Principle 1 - Human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature.

Principle 2 - States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Principle 3 - The right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations.

Principle 4 - In order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it.

Principle 5 - All States and all people shall cooperate in the essential task of eradicating poverty as an indispensable requirement for sustainable development, in order to decrease the disparities in standards of living and better meet the needs of the majority of the people of the world.

Principle 6 - The special situation and needs of developing countries, particularly the least developed and those most environmentally vulnerable, shall be given special priority. International actions in the field of environment and development should also address the interests and needs of all countries.

Principle 7 - States shall cooperate in a spirit of global partnership to conserve, protect and restore the health and integrity of the Earth's ecosystem. In view of the different contributions to global environmental degradation, States have common but differentiated responsibilities. The developed countries acknowledge the responsibility that they bear in the international pursuit to sustainable development in view of the pressures their societies place on the global environment and of the technologies and financial resources they command.

Principle 8 - To achieve sustainable development and a higher quality of life for all people, States should reduce and eliminate unsustainable patterns of production and consumption and promote appropriate demographic policies.

Principle 9 - States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies.

Principle 10 - Environmental issues are best handled with participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.

Principle 11 - States shall enact effective environmental legislation. Environmental standards, management objectives and priorities should reflect the environmental and development context to which they apply. Standards applied by some countries may be inappropriate and of unwarranted economic and social cost to other countries, in particular developing countries.

Principle 12 - States should cooperate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries, to better address the problems of environmental degradation. Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided. Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus.

Principle 13 - States shall develop national law regarding liability and compensation for the victims of pollution and other environmental damage. States shall also cooperate in an expeditious and more determined manner to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control to areas beyond their jurisdiction.

Principle 14 - States should effectively cooperate to discourage or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health.

Principle 15 - In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Principle 16 - National authorities should endeavour to promote the internalization of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution, with due regard to the public interest and without distorting international trade and investment.

Principle 17 - Environmental impact assessment, as a national instrument, shall be undertaken for proposed activities that are likely to have a significant adverse impact on the environment and are subject to a decision of a competent national authority.

Principle 18 - States shall immediately notify other States of any natural disasters or other emergencies that are likely to produce sudden harmful effects on the environment of those States. Every effort shall be made by the international community to help States so afflicted.

Principle 19 - States shall provide prior and timely notification and relevant information to potentially affected States on activities that may have a significant adverse transboundary environmental effect and shall consult with those States at an early stage and in good faith.

Principle 20 - Women have a vital role in environmental management and development. Their full participation is therefore essential to achieve sustainable development.

Principle 21 - The creativity, ideals and courage of the youth of the world should be mobilized to forge a global partnership in order to achieve sustainable development and ensure a better future for all.

Principle 22 - Indigenous people and their communities and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. States should recognize and duly support their identity, culture and interests and enable their effective participation in the achievement of sustainable development.

Principle 23 - The environment and natural resources of people under oppression, domination and occupation shall be protected.

Principle 24 - Warfare is inherently destructive of sustainable development. States shall therefore respect international law providing protection for the environment in times of armed conflict and cooperate in its further development, as necessary.

Principle 25 - Peace, development and environmental protection are interdependent and indivisible.

Principle 26 - States shall resolve all their environmental disputes peacefully and by appropriate means in accordance with the Charter of the United Nations.

Principle 27 - States and people shall cooperate in good faith and in a spirit of partnership in the fulfilment of the principles embodied in this Declaration and in the further development of international law in the field of sustainable development.

Source: Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972 (United Nations publication, Sales No. E.73.II.A.14 and corrigendum), chap. I.

Annex D
(informative)

Fault Tree Analysis (FTA)

This is a graphical technique that provides a systematic description of the combinations of possible occurrences in a system, which can result in an undesirable outcome. This method can combine hardware failures and human failures.

The most serious outcome such as explosion, toxic release, etc. is selected as the Top Event. A fault tree is then constructed by relating the sequences of events, which individually or in combination, could lead to the Top Event. This may be illustrated by considering the probability of a crash at a road junction and constructing a tree with AND and OR logic gates. The tree is constructed by deducing in turn the preconditions for the top event and then successively for the next levels of events, until the basic causes are identified.

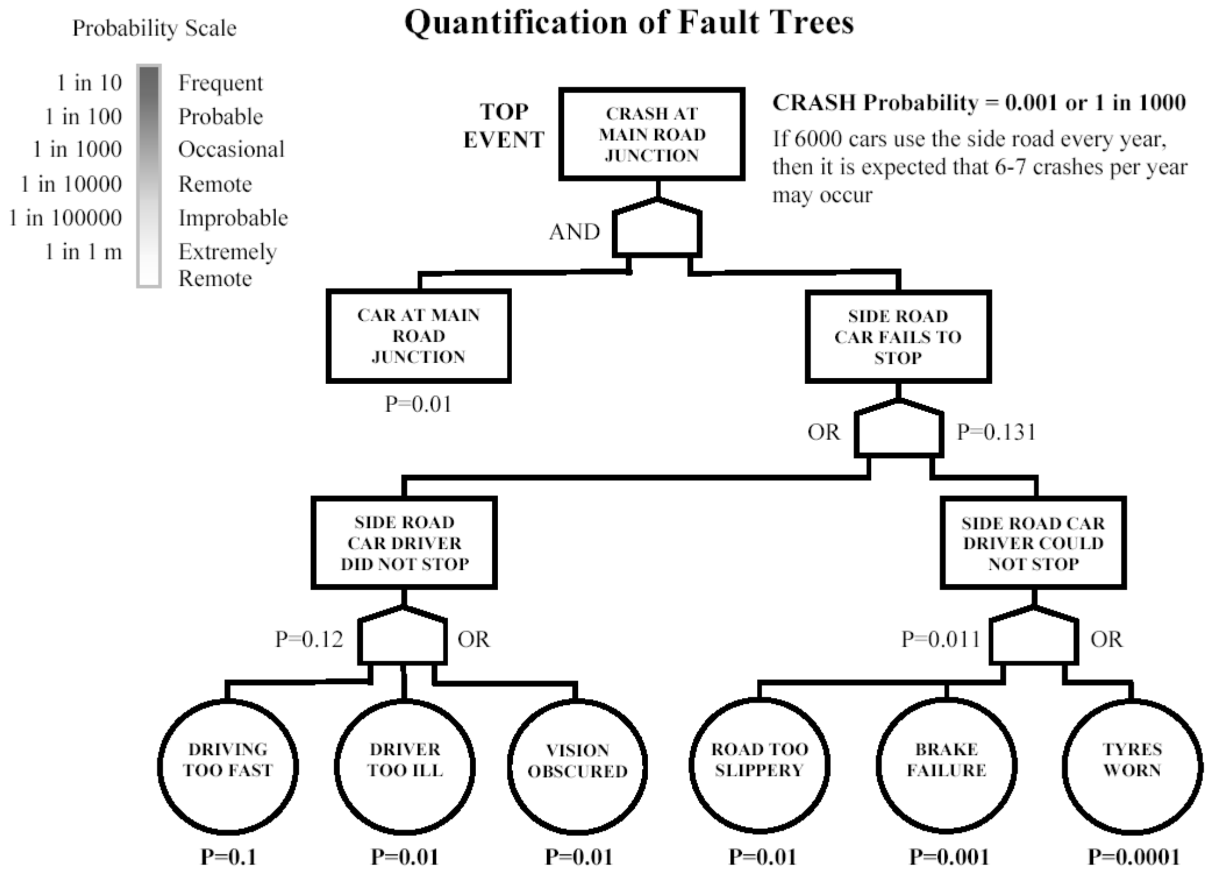

Figure D.1

By ascribing probabilities to each event, the probability of a Top Event can be calculated. This requires knowledge of probable failure rates.

At an OR gate the probabilities must be added to give the probability of the next event, whereas at an AND gate, the probabilities are multiplied. This is a powerful technique for identifying the failures that have the greatest influence on bringing about the End Event.

Human Error and FTA

The human error contribution to overall system failure can be included in a Fault Tree Analysis, if human error probabilities are described in the same terms as component and hardware failures.

To include human error, a detailed Task Analysis is first required, breaking down the detail of the actions to be done, taking account of conditions, speed of operation and the correct sequencing of individual actions. Possible deviations can then be identified. After allowing for shaping factors, which influence individual performance, (such as skill, stress etc.), and recovery factors, (most human errors are recoverable), the contribution of human error can be estimated, by using data on human error rates.

Bibliography

[1] Anon (2000) *Guidelines for Environmental Risk Assessment and Management* HMSO, London http://www.defra.gov.uk/environment/risk/eramguide/index.htm

[2] Bouder, F. (2005) *Social Dialogue and the Tolerability of Risk Framework*. ITPS Report vol. 82 http://www.jrc.es/home/report/english/articles/vol82/SCI6E826.htm

[3] BS 8555:2003 "*Environmental management systems – Guide to the phased implementation of an environmental management system including the use of environmental performance evaluation".* BSi, London

[4] CEC (2000) *Communication from The Commission On The Precautionary Principle* COM(2000) 1 final http://europa.eu.int/eur-lex/en/com/cnc/2000/com2000_0001en01.pdf Brussels, 2.2.2000

[5] CEC (2001) Directive 2001/42/EC of the European Parliament and of the Council on the assessment of the effects of certain plans and programmes on the environment. Luxembourg, 27 June 2001

[6] Codex (1997) *Basic Texts On Food Hygiene* Codex Alimentarius, FAO, Rome. June 1997 http://www.fao.org/DOCREP/005/Y1579E/y1579e03.htm#bm3

[7] Composting Association (2003) Evans, T.D. *Hazard Analysis and Critical Control Point (HACCP) for Composters.* ISBN 0-9532546-6-6 The Composting Association, Wellingborough, England

[8] CR 13455 : 1999 *Soil improvers and growing media – Guidelines for the safety of users, the environment and plants*

[9] Crompton, S. (2005) *A risky business.* The Times, 26 February 2005, London http://www.timesonline.co.uk/article/0,,589-1499162,00.html

[10] Covello, V. and P. Sandman. (2001) "*Risk communication: Evolution and Revolution*," in Wolbarst A. (ed.) Solutions to an Environment in Peril. Baltimore, MD: John Hopkins University Press (2001): 164-178 (available at www.psandman.com)

[11] Department of Health (1999), *Economic Appraisal of the Health Effects of Air Pollution*, Ad-Hoc Group on Economic Appraisal of the Health Effects of Air Pollution, The Stationery Office: London. www.dh.gov.uk/assetRoot/04/07/99/60/04079960.pdf

[12] European Commission Environmental economics homepage http://europa.eu.int/comm/environment/enveco/

[13] FWR (2002) *Endocrine Disrupters in the Environment*. Review Of Current Knowledge FR/R0003, November 2000, Revised and Updated July 2002, FWR, Marlow, England http://www.fwr.org/

[14] HSE (1992) *The Tolerability of Risk from Nuclear Power Stations (TOR)* Health and Safety Executive (London: HMSO).

[15] ICON (2001) *Pollutants in urban waste water and sewage sludge*. Final report of IC Consultants Ltd., London for European Commission, DG Environment. ISBN 92-894-1735-8 http://europa.eu.int/comm/environment/waste/sludge/sludge_pollutants_xsum.pdf

[16] ISO/IEC Guide 51:1999 Safety aspects -- Guidelines for their inclusion in standards and revised Draft January 1998.

[17] Montforts, M.H.M.M. (2003) *Environmental risk assessment for veterinary medicinal products Part 1. Non-immunological drug substances Second update RIVM report* 320202001/2003 www.rivm.nl/bibliotheek/rapporten/320202001.pdf

[18] NRC (2002) *Biosolids Applied to Land: Advancing Standards and Practices*. National Research Council. National Academy Press, 2101 Constitution Avenue, N.W., Washington, DC http://www.nap.edu/books/0309084865/html/

[19] Pollard, S. and Guy, J. (2001) *Risk Assessment for Environmental Professionals.* ISBN 1 870752 71 6 CIWEM, London

[20] Powell, D. (1996) *An Introduction to Risk Communication and the Perception of Risk* http://www.foodsafetynetwork.ca/risk/risk-review/risk-review.htm

[21] RiskWorld internet site - www.riskworld.com/

[22] SAS (2004) A green blue-print for sewage sludge disposal. www.sas.org.uk

[23] Smith, S. R. (2000) *Are controls on organic contaminants necessary to protect the environment when sewage sludge is used in agriculture?* Progress in Environmental Science **2** 129-146

[24] Smith, S.R. (1996) *Agricultural recycling of sewage sludge and the environment*. CAB International, Wallingford, England.

[25] UKWIR (2003) Gale, P. *Pathogens in Biosolids - Microbiological Risk Assessment*. Report ref. 03/SL/06/7. ISBN: 1 84057 294 9 UKWIR, London http://www.defra.gov.uk/environment/water/quality/sewage/sludge-research.htm

[26] USEPA (1992) *Technical Support Document for Land Application of Sewage Sludge*, Volume I and II (Appendices). US Environmental Protection Agency, Eastern Research Group, Lexington. http://www.biosolids.org/docs/1index.PDF

[27] USEPA (1993). *Standards for the Use and Disposal of Sewage Sludge. 40 CFR Part 503*. Federal Register 58 (32), 9248-9415. (19 February 1993). http://www.biosolids.org/docs/1index.PDF

[28] USEPA (2001) *Risk Assessment Guidance for Superfund Volume 3 Part A: Process for Conducting Probabilistic Risk Assessment*. (U.S. Environmental Protection Agency). http://www.epa.gov/superfund/programs/risk/rags3adt/

[29] USEPA (2002a) *A Guide to the Biosolids Risk Assessments for the EPA Part 503 Rule* http://www.epa.gov/owm/mtb/biosolids/503rule/index.htm

[30] USEPA (2002b) *Exposure Analysis for Dioxins, Dibenzofurans, and Coplanar Polychlorinated Biphenyls in Sewage Sludge- Technical Background Document Including Appendices* http://www.epa.gov/ost/biosolids/support.html

[31] WERF (2003) *Public Perception of Biosolids Recycling. Literature Review, Case Studies, and Survey*. WATER ENVIRONMENT RESEARCH FOUNDATION PROJECT #00-PUM-5 http://www.nebiosolids.org/werf/

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