

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

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National foreword

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Caractérisation des boues - Guide pour l'évaluation du
risque en relation avec l'usage et la 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.

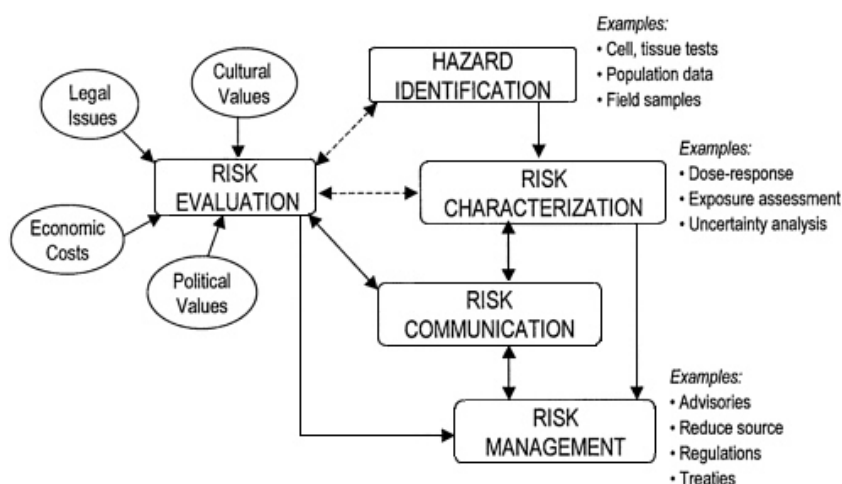


Figure 1 – The major components of the risk assessment and risk management process (from NAS, 2002)

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 ($t_{1/2} = 2$ 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).

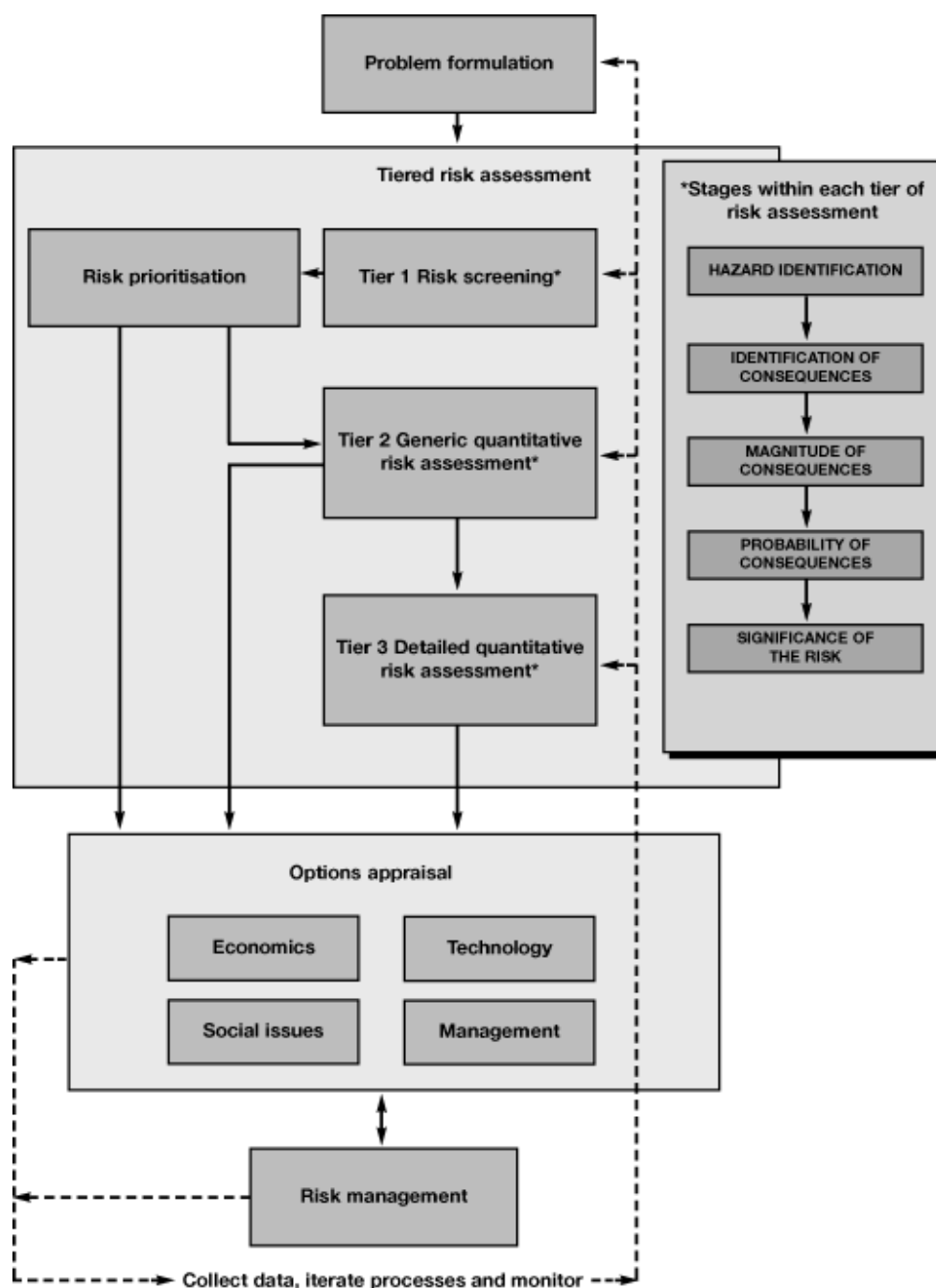


Figure 2 – An example of a framework for environmental risk assessment and risk management (from Anon, 2000)

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.

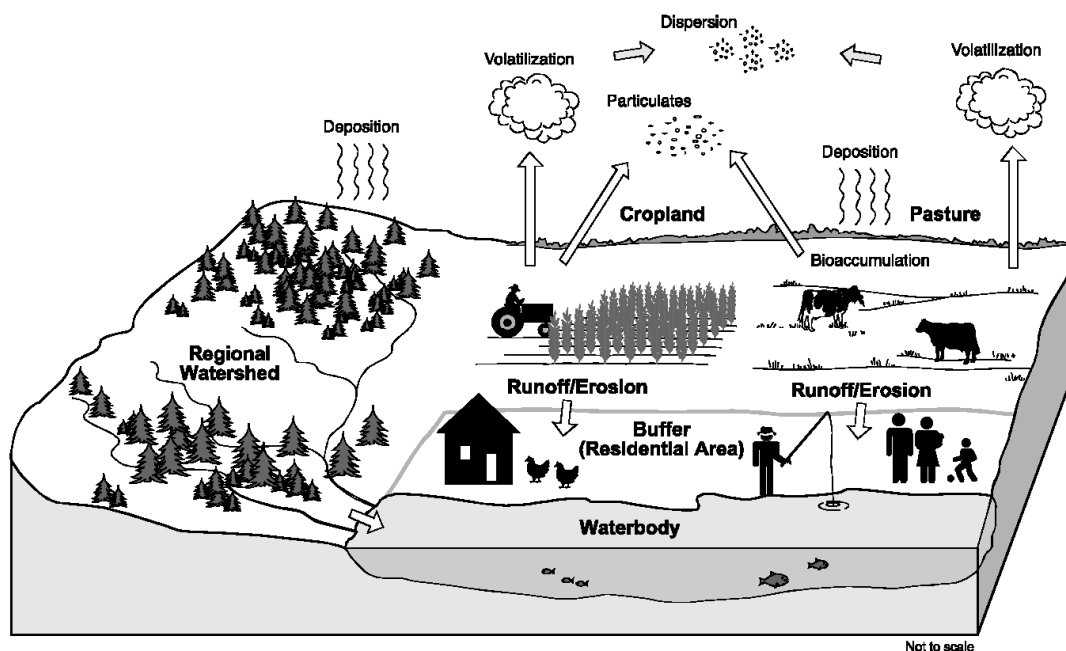


Figure 3 – Conceptual site model of sludge use in agriculture (from USEPA, 2002b)

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 determinants 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](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 bypassed 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 CFR Part 503 (USEPA, 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 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 than protecting the whole population at $1:10^6$.

40 CFR 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.

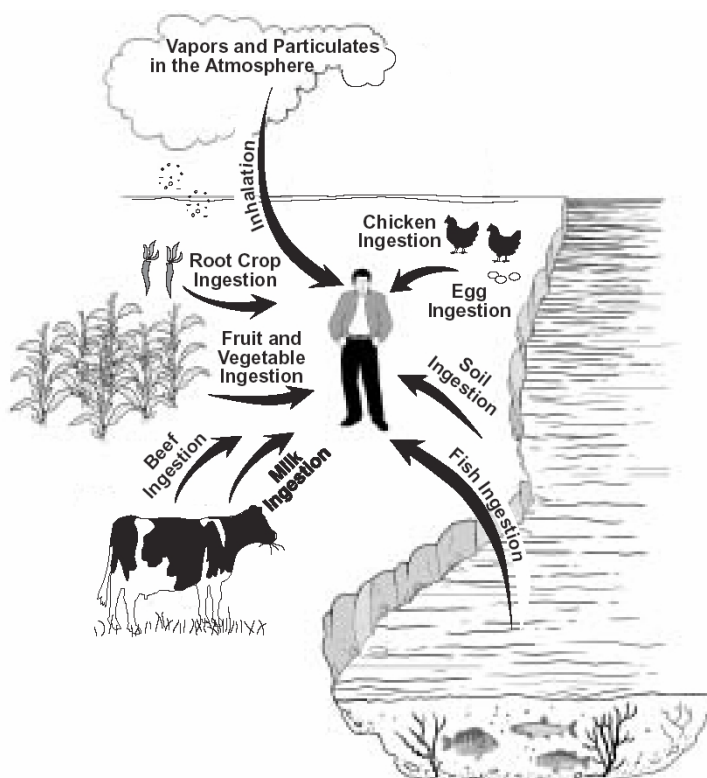


Figure 4 – Integrated human exposure pathways used in the USEPA, 2002b fully integrated assessment, all pathways were considered simultaneously in each iteration

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. coli* [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 *Cryptosporidium* 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.ilsa.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

Watanabe, T.; Sano, D.; Omura, T.

Dept. Civil Engineering, Tohoku University, Sendai 980-8579, Japan

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.