A RISK ASSESSMENT APPROACH FOR SETTING CRITERIA FOR PATHOGENS IN BIOSOLIDS

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ABSTRACT

Risks associated with pathogens in biosolids are uncertain and are potentially of major concern in the marketing of biosolids products. At present there are no formal National biosolids guidelines in Australia. US EPA regulations require the monitoring of biosolids for pathogens or indicator bacteria but criteria have been based on detectable limits for pathogens. Two problems with this approach are firstly that detection limits in microbiology are constantly changing, and secondly that in some cases criteria based on detection limits may result in unacceptable risk. For this reason a risk assessment approach has been developed and is described here. This risk assessment approach has been applied to setting criteria for pathogens in biosolids. This involved the steps of hazard identification, development of acceptable risk criteria, dose-response assessment, exposure assessment and calculation of limits. Based on this risk assessment procedure a limit of less than 1 Salmonella in 50 g of biosolids product is proposed for biosolids which are to have unrestricted distribution. It is recommended that limits for Giardia and enteric viruses should not be included in guidelines until methods for their detection in biosolids are more developed.

KEYWORDS

Biosolids, criteria, Giardia, pathogens, risk assessment, Salmonella

1 INTRODUCTION

There is still a great deal of uncertainty about risks associated with pathogens in biosolids products. Biosolids material has the potential to contain human, animal and plant pathogens. It has been demonstrated that pathogens can be present in a variety of biosolids products (Gibbs et al., 1995). However, what level of risk this presents is still uncertain. There is also a climate in Australia where the water industry has to face the new and complex issues of 'liability, precautionary principles, due diligence and what constitutes reasonable care' (Chapman, 1995). Liability of individual directors may increase due to loss of immunity when water authorities are corporatised or privatised. This means insurance cover must be increased or risks reduced.

An outbreak of waterborne cryptosporidiosis in Milwaukee in 1993 illustrates the problems which can result from an outbreak of disease for which the water provider is held responsible. This outbreak resulted in over 400 000 cases of cryptosporidiosis (MacKenzie et al., 1994) with 50 to 100 deaths and accumulated approximately $25 000 000 in lawsuits (Chapman, 1995). Along with illustrating the responsibility that the water industry has for the products which they supply, the Milwaukee outbreak highlights the importance of adequate monitoring for appropriate pathogens or indicators. Traditionally the microbiological quality of drinking water has been assessed using the coliform and faecal coliform tests, and standards based on these are in place throughout the world. In Milwaukee these proved to be inadequate. In the case of biosolids products, monitoring is not routinely carried out. There is not a traditional framework for assessing the risks associated with pathogens in biosolids and one needs to be developed.

The philosophy endorsed in most biosolids guidelines is that for biosolids to be re-used they should have undergone significant treatment for stabilisation and reduction in pathogen concentrations. The most detailed information and guidelines have been produced by the United States Environmental Protection Agency (US EPA). Earlier US sludge regulations stipulated processes and process requirements for producing different grades of sludge (US EPA, 1989a). In more recent sludge guidelines, monitoring requirements have been introduced (US EPA, 1992). Monitoring is now mandatory for biosolids which are available for unrestricted marketing, and these are described in another support document (US EPA, 1992). The more recent document has introduced requirements to reduce pathogen densities below certain concentrations. These concentrations were selected on the basis of the limits of detection methodologies (US EPA, 1992). The major critique of this
approach is that if monitoring requirements are introduced in biosolids guidelines, then the limits should take into account an analysis of risks posed by the pathogens present in biosolids. The methodological limitations also need to be taken into account when setting standards. However, if requirements are only based on method limitations then requirements may be too severe if methods are very advanced, or not adequate if methods are not well developed. The purpose of this paper was to develop a risk assessment approach for setting criteria for pathogens in biosolids.

2 RISK ASSESSMENT APPROACH

Risk assessment has been defined in a number of ways but the definition which has been applied in risk assessments associated with biosolids is that provided by the US National Research Council (NRC, 1983). Their definition is that risk assessment is: “the characterization of the potential adverse health effects of human exposures to environmental hazards”. This risk approach consisted of four components. These were:

- Hazard identification
- Dose-response assessment
- Exposure assessment:
- Risk characterization:

This approach was used by the US EPA as the model for developing guidelines for sludge disposal (US EPA, 1989b). Although the risk assessment approach was defined for chemicals in biosolids (US EPA, 1989b) and used for setting criteria, it has not been as well developed for microbials. A risk assessment model was developed (US EPA, 1989c) but not used to set criteria. For this reason, before a risk approach could be used to develop criteria, some principles needed to be developed. These are introduced below.

2.1 Microbial risk versus chemical risk

Many of the basic assumptions used for chemical risk assessments may not be directly transferable to assessing microbial risk. As outlined in the reference document to the development of US EPA sludge guidelines (US EPA, 1989b), determining acceptable concentrations for non carcinogenic chemicals involves determining the reference dose (RFD) which is the daily exposure that is likely to be without appreciable risk of deleterious effects during a lifetime. Similarly in draft Australian Drinking Water Guidelines (NHMRC and ARMCANZ, 1994) the guideline values for pesticides, organic and inorganic chemicals are the concentrations that, based on present knowledge, do not result in any significant risk to the health of the consumer over a lifetime of consumption (the no observable effect level, NOEL). There are a number of ways in which this approach is probably not appropriate for microbials and these are described below.

Firstly, the cumulative lifetime exposure model used for chemicals is probably not appropriate. Single hit exposure to microbials can result in adverse health effects and effects are generally not cumulative. Previous exposure may cause immune suppression which could increase the likelihood of infection. Conversely previous exposure may result in the development of immunity which will reduce the effect of repeated exposures. However, it was not considered possible at this stage to incorporate these effects into a risk assessment model, so a single hit exposure model is recommended.

Secondly, chemical exposure models do not take into account the very large variation in human host response, which is an important factor with microbial exposure. With microbials the large variation in susceptibility will significantly affect risk. For this reason, expressing risk in terms of general population risks is probably not appropriate for microbials. Risks need to be expressed for individuals within sub-groups of the population. As outlined in a discussion paper on risk assessment produced by the Western Australian EPA (1990), the principle that no individual should have to bear an unusually high risk can be expressed by individual risk criteria. The principle that no community should have to bear an unfairly high risk can be expressed by ‘community’, ‘societal’ or ‘population’ risk criteria. Although it may also be useful to investigate population risks, this paper focuses on individual risks. This is because, in the case of microbials in biosolids, individual risk criteria will need to be more stringent than population risk criteria.

Therefore the first suggested principle is that:

**Principle 1. Risk assessments for microbials in biosolids should be based on risks to the most at risk individuals.** Principle 1 should be applied in two areas of the risk assessment. Firstly, exposure levels should be based on most exposed individuals. Secondly, dose-response data should be calculated for the most
susceptible individuals.

The approach of calculating risk for most at risk individuals has been questioned by various sources because it can lead to an unrealistic amplification of risk. The US EPA (1989b) outlined a drawback of this approach and this was that the compounding of worst-case assumptions may lead to improbable results. They suggested that the key to the effective use of this methodology is careful and systematic examination of the effects of varying each of the input parameters, using estimates of central tendency and upper-limit values to gain an appreciation for the variability of the result. This has been illustrated by the application of their risk assessment model (US EPA, 1989c). Similarly Stevens et al. (1995) suggested that Monte Carlo simulation should be used to allow consideration of the variability of input parameters used in the risk assessment. With this approach, rather than assigning worst case or typical values, a probability distribution is assigned to each parameter. In the case of microbials the representation of uncertainty in estimates would be extremely valuable. However, it is still maintained that this should be carried out for individuals within different sub populations, rather than representing the whole population by one analysis. For the most at risk individuals within the sub population uncertainty of estimates could be expressed, and Monte Carlo type analysis for representing uncertainty may be appropriate.

The third way that chemical risk assessments are probably not appropriate for microbials is that most chemical risk assessments of health effects are based on the risk of death (mortality). However, it is suggested that risk assessments based on adverse health effects (morbidity) are more appropriate to microbial risk assessment. The risks of death from microbial exposure may be low for most infectious agents, but the adverse effects caused by disease are still unacceptable to the community. An added dimension with microbials is that exposure to a microbial agent may result in infection but not demonstrable illness. This may then impact on the general health of the community by providing a reservoir of disease for further infection. As this is very difficult to assess it is suggested that risks should be based on disease rather than infection. Therefore the second principle which is suggested is that:

Principle 2. Microbial risk assessments should be based on risks of demonstrable disease, rather than risks of death, or infection. As there is not an established history of assessing risk of disease rather than death, there are not well established practices, particularly with regard to risk management decisions.

3 APPLICATION OF RISK ASSESSMENT APPROACH TO SETTING CRITERIA FOR UNRESTRICTED MARKETING OF BIOSOLIDS

When the four steps of risk assessment outlined in Section 2 above are carried out, a hazard is defined, and the risks then quantified through dose-response and exposure assessment. To use the risk assessment approach for developing monitoring criteria the same process needs to be carried out but acceptable risks also need to be defined. Following hazard identification, the next step in using risk assessment to develop criteria is to define an allowable or acceptable exposure. The dose-response and exposure level then need to be combined with the acceptable risk to set standards. The steps involved in developing criteria for microbials in biosolids therefore are:

- Hazard Identification
- Development of Criteria for Acceptable Risk
- Dose-Response Assessment
- Exposure Assessment
- Calculation of Limits.

The rest of this paper focuses on developing microbial criteria for unrestricted marketing of biosolids, as monitoring criteria are not so important for other biosolids disposal routes.

3.1 Hazard identification

A qualitative risk assessment for biosolids was carried out previously in which the relative health risks represented by different groups of pathogens were grouped on the basis of the number of reported cases, the excreted load, the persistence, and infectious dose (Gibbs and Ho, 1993). On the basis of this assessment the highest risk group of pathogens consisted of enteric viruses, and the second highest risk group of Salmonella, Giardia and Trichuris. As the people infected with Trichuris were mainly recent immigrants and travellers, it
appeared that the number of excreting individuals in the resident population was low. In lower risks groups were organisms such as Campylobacter, Shigella, Cryptosporidium and other helminths. Further studies were therefore conducted on the pathogens considered to present the most risk in biosolids, the enteric viruses, Salmonella and Giardia (Gibbs et al., 1995). It is suggested that these three types of organisms should be of primary concern in considerations of setting criteria for monitoring biosolids.

3.2 Acceptable Risk

The meaning of acceptable risk can be expressed in various ways. Commonly it is expressed as the question: 'how safe is safe enough'? How safe is safe enough has not been defined previously for the area of microbial risk and is still a contentious issue for most areas of risk. Acceptable risks have generally been defined in terms of risk of death and this approach is described below. However, the principle recommended above is that with microbial risk, acceptable risk as it relates to disease should be used as an alternative approach, so this is also discussed below.

The approach taken by a Royal Society Study Group (1983) to defining the concept of acceptable risk was to divide the risks to the individual into three broad zones. In category one were risks higher than a certain level which were unacceptable whatever the benefits. In category two were risks that were between upper and lower limits and for which it was necessary to consider the interrelationship of level of risk, detriment, costs and benefits. In the third category were risks of a frequency so low that the manager or regulator of risk could reasonably regard them as negligible in their overall impact on society, even though the consequences to the rare individual might be serious.

This negligible or 'de minimis' risk approach comes from the legal principle that the law does not concern itself with trifles. With risk this means that there is a threshold of concern below which we would be indifferent to changes in the level of risk (Fiksel, 1987). It is an acceptance that zero risk is neither achievable or desirable. There have been a variety of suggested means of setting acceptable risks on the basis of 'de minimis' risk. These include setting levels at natural background levels, such as for radiation, and alternatively basing acceptable risks on the risk levels of various hazards that are commonly encountered in daily life (Menkes and Fray, 1987). The assumption is that these levels of risk are acceptable to the population.

An acceptable limit for risk of infection from microbials was set for the first time when a 'de minimis' type approach was used for drinking water standards. A landmark decision was that by the US EPA in the Drinking Water Act (US EPA, 1989d) when it was stated that drinking water should create no more than 1 extra gastrointestinal case per 10 000 people per year. Discussion which went into forming this decision was reported by Regli et al. (1988). The basis of this limit was that the risk limit of 1 in 10 000 people per year was similar to that currently being experienced in the US and Canada through drinking water exposure, and was not out of proportion with other common microbial risks.

Earlier discussion of acceptable risks from microbials has pointed towards this kind of approach. In discussion of the risks of sludge disposal to land Akin et al. (1977) concluded that it would be unrealistic to require all domestic wastes that are applied to land to be pathogen free. They highlighted the point that this could not be guaranteed without the complete testing of all waste with methods that were 100 percent efficient for all pathogens, which would be economically impractical and technically unattainable. The goal should therefore be to achieve and maintain the microbial hazard from waste disposal on land at an acceptable risk level. They concluded that for the health scientist, acceptable could be defined as when disease transmission through a single source could be demonstrated by epidemiology to occur below the background transmission rate of disease from all other sources.

In the absence of epidemiological information concerning the unrestricted marketing of biosolids, the use of a risk assessment approach is proposed. Risk assessment could be used to determine pathogen concentrations in biosolids which would raise the potential transmission rate above reported transmission rates. Following on from this discussion the following principle for setting acceptable risks is proposed:

Principle 3. The risk of disease transmission through the re-use of biosolids products should be less than background transmission rates for that disease from other sources. In the case of biosolids re-use, the major limitation of this approach is that present biosolids re-use practices may contribute to background transmission rates of diseases. However, in the absence of epidemiological information it is not possible to know what this impact is. It is also difficult to determine how much less than background transmission rates is
acceptable. For the risk of mortality from individuals located near nuclear power plants it was considered that the risk should be 0.1% of the sum of prompt fatality risk resulting from other accidents to which members of the US population were generally exposed (Spangler, 1987). Similarly, it was considered that the risk of cancer fatalities to the population in the area near a nuclear power plant that might result from nuclear power plant operation should not exceed 0.1% of the sum of cancer fatality risks resulting from all other causes. It is suggested that the rates of reported disease are a good baseline for setting criteria. However, 0.1% of risk from other sources as suggested by Spangler (1987) appears to be too conservative when applied to risk of disease, rather than risk of mortality. It is suggested that the criteria for biosolids should be based somewhere in the region of 1% to 10% of present infection rates, rather than 0.1%.

3.3 Exposure assessment

Exposure assessment should be based on most exposed individuals. It is suggested that the most exposed and at risk individual in the unrestricted marketing of biosolids would be a child ingesting biosolids while playing in the home garden. The number of children in the 1 to 3 years age group in Australia is approximately 520,000 (Castles, 1994). This at risk group therefore represents 3% of the total population of Australia. It was considered that adults handling biosolids were likely to ingest smaller amounts than children, and therefore be at less risk. The exposure assessment was therefore based on soil ingestion by children.

The amount of soil which young children ingest has not been clearly established from published studies. Some early estimates were prepared by Lepow et al. (1974) who measured the amount of soil on children's hands. By multiplying this figure by 10 they estimated the amount that would be ingested in one day as 100 mg. More recently soil ingestion studies have been carried out using soil tracer methods. Soil ingestion estimates from these studies varied depending on the study technique and tracer used. Calabrese et al. (1989) calculated a median soil ingestion value of 29 mg/day using aluminium as a tracer. In contrast Binder et al. (1986) reported a daily soil ingestion value of 1834 mg/day using titanium as a tracer. Based on a critique of soil ingestion studies by Calabrese and Stanek (1991) the two studies of Davis et al. (1990) and Calabrese et al. (1989) appear to be the most reliable, particularly with the two tracers aluminium and silicon. The average soil ingestion value from these two studies and two tracers is approximately 50 mg/day. Data from two soil ingestion studies showed that some children consume much more soil than 'average' children and these are termed pica children. Of the sixty five children studied by Calabrese et al. (1989) one had pica behaviour and ingested somewhere in the region of 5 to 8 g of soil per day. In the study of van Wijnen et al. (1990) nine out of 557 daily soil ingestion values were greater than 1 g/day. In a study of 18 children by Clausing et al. (1987) none appeared to have exceptionally high soil ingestion values for all three tracers. From the three studies for which data was available it was calculated that approximately 1 in 60 or 1.7% of children ingested abnormally high levels of soil. This is similar to an analysis of pica children by Calabrese and Stanek (1994) who suggested that 1.9% of children in the 1 to 6 age group exhibit pica behaviour. Abnormally high ingestion rates were considered to be greater than 1 g per day. On the basis of these studies it was estimated that a pica child could be ingesting 5 g of soil/day.

4 CRITERIA FOR SALMONELLA

4.1 Acceptable limit for salmonella

For devising acceptable limits for salmonellae in biosolids products it was decided to make the assumption that background rates of transmission for Salmonella are acceptable to the public. What impact present biosolids disposal practices have on reported cases has not been assessed, these may contribute to present background transmission rates. In 1991 the annual reported Salmonella infection rate for children in Australia in the 0 to 4 year age group was approximately 400 per 100,000 (Anura and Hall, 1992). This means that the probability of infection was $4 \times 10^{-5}$. The average notification rate for the whole population was 31 in 100,000 with a probability of infection of $3 \times 10^{-4}$. As described in Section 3, it was decided that risks of infection from Salmonella in biosolids should be at most in the region of 1% to 10% of reported infection rates. Therefore the probability of a child becoming infected with Salmonella from ingesting biosolids in the home garden should be at most in the region of $4 \times 10^{-4}$ to $4 \times 10^{-5}$.

4.2 Infectious dose for salmonella

The number of organisms which need to be ingested to cause an infection (infectious dose) is not a constant number. It varies with factors such as the species of Salmonella, the status of the individual and the vehicle in
which Salmonella is administered. For this reason it is not possible to say what the infectious dose for Salmonella will be in individual cases.

The range within which the infectious dose for Salmonella is likely to fall can be derived from two sources. These are human volunteer studies and outbreaks. Both types of studies suggest that higher doses of Salmonella appear to cause a higher rate of attack and quicker onset of infection. However, there appears to be some discrepancies between results from the two types of studies. As summarised by Blaser and Newman (1982) the lowest dose of ingested Salmonella reported to cause infection in human volunteer studies was $10^5$ Salmonella per mL, which resulted in attack rates ranging from 17 to 35%. Infectious dose information from outbreaks, as opposed to human dosing studies, appears to provide a different picture (Gibbs and Ho, 1995) with half of the 13 reported outbreaks appearing to be caused by doses of less than 1000 organisms. However, the data are not sufficient to generate a probability distribution model. The beta distributed probability model generated by Rose and Gerba (1991) from human volunteer data appears to be the best available method of calculating probability of infection based on dose. For Salmonella the model therefore is:

$$p = 1 - \left(1 + \frac{N}{139.9}\right)^{-0.33}$$

where $p$ = probability of infection and $N$ = exposure.

Unfortunately this model was generated using human volunteers who are generally healthy adults (Haas, 1983). Therefore it is not representative of more immunologically susceptible individuals.

### 4.3 Risk characterisation

Equation 1 (above) was expressed in terms of $N$ so that acceptable exposure levels could be calculated from acceptable probabilities, as shown below.

$$N = 139.9\left(\left(1-p\right)^{3.03} - 1\right)$$

The acceptable exposure was then calculated for the range of acceptable probabilities of infection derived in Section 3. This was then expressed as a limit for Salmonella in biosolids material, for a normal child and a pica child, as shown in Table 1.

<table>
<thead>
<tr>
<th>Acceptable Risk (percentage of reported infection rate)</th>
<th>Acceptable Probability of Infection ($p$)</th>
<th>Acceptable Exposure (No. of Organisms) ($N$)</th>
<th>Amount Ingested</th>
<th>Limits for Salmonella in Composted Biosolids</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>$4 \times 10^{-4}$</td>
<td>0.169</td>
<td>0.05 g (normal child)</td>
<td>1 in 0.3 g</td>
</tr>
<tr>
<td>10%</td>
<td>$4 \times 10^{-4}$</td>
<td>0.169</td>
<td>5 g (pica child)</td>
<td>1 in 30 g</td>
</tr>
<tr>
<td>1%</td>
<td>$4 \times 10^{-5}$</td>
<td>0.0169</td>
<td>0.05 g</td>
<td>1 in 3 g</td>
</tr>
<tr>
<td>1%</td>
<td>$4 \times 10^{-5}$</td>
<td>0.0169</td>
<td>5 g</td>
<td>1 in 300 g</td>
</tr>
</tbody>
</table>

### 4.4 Risk criteria

Table 1 shows that the acceptable limit for Salmonella in biosolids products ranges from 1 in 0.3 g to 1 in 300 g depending on which parameters are chosen. For determining which of these criteria would be acceptable the first suggested principle is that the pica child should be protected. Although the number of exposed individuals in this group may be low, it is felt that these most at risk individuals should be protected.

It is difficult to say what is an acceptable probability of infection. However, it is proposed that a criteria of less than 1 Salmonella detected in 50 g of biosolids products is acceptable. This is partially an acknowledgment of the limitations of methodology, and financial limitations on analysing larger quantities of biosolids material. The limit of less than 1 Salmonella in 50 g of biosolids would result in a probability of infection of less than $2 \times 10^{-4}$ for a pica child, which is less than 6% of present reported infection rates for children in the 0 to 5 years age group.
This suggested limit of less than 1 Salmonella detected in 50 g of biosolids product differs from that in US EPA sludge guidelines (US EPA, 1992). US EPA guidelines specify that sewage sludge which is sold or given away must contain less that 3 Salmonella sp. per 4 grams total solids sewage sludge (US EPA, 1992). These two limits differ in a number of ways. Firstly, US guidelines specify a limit for Salmonella per total solids, which refers to dry weight. The suggested limit in this paper is per gram of biosolids product as produced, or wet weight. The reason for setting a limit per gram of wet weight is that it is conceptually easier to apply and less analysis is required than for dry weight. US guidelines have specified limits per gram dry weight in the past because there can be an apparent increase in concentrations through treatment such as dewatering if wet weights are used. However, for routine monitoring of one type of product this is not an important issue.

Secondly, the two limits differ in the actual acceptable concentrations specified. The US guidelines are therefore less stringent than suggested in this risk assessment paper, as the US guide value would equate to a limit of less than 5 Salmonella per 50 g of biosolids product. The reason for the difference is that US guidelines are based on detectable limits whereas this paper uses a risk assessment approach. However, lower concentrations of Salmonella can be detected than the detectable limit specified in US guidelines. The limit of less than 1 Salmonella in 50 g of product which is suggested on the basis of risk assessment is methodologically achievable.

The third difference is that US guidelines specify a most probable number (MPN) or quantitative method whereas this paper recommends a presence/absence test. In both US guidelines and this paper it is suggested that Salmonella concentrations should be below a certain concentration. This can be shown by a presence/absence test. A presence/absence test will be more cost effective than an MPN test. A suggested method for carrying out a presence/absence test for Salmonella in 50 g of composted biosolids product is that described by Hu et al. (1995).

5 CRITERIA FOR GIARDIA

Using the risk assessment procedure described for Salmonella, criteria for Giardia can be calculated (Gibbs and Ho, 1995). However, as the viability of Giardia cysts detected in biosolids is at present unknown, it is recommend that criteria for Giardia should not be included in biosolids guidelines. It is highly recommended that further research should be carried out to evaluate Giardia cyst viability.

6 ENTERIC VIRUSES

At this point in time it is felt that reasonable criteria for acceptable concentrations of enteric viruses in biosolids products could not be set. Methods for monitoring viable enteric virus concentrations in biosolids are not developed enough to justify any method involving routine monitoring of biosolids for viruses. It is suggested that more work should be carried out on methods for detecting enteric viruses in biosolids, and research carried out on the effect of treatments on virus concentrations in biosolids.

7 CONCLUSIONS

- A risk assessment approach should be used to develop criteria for acceptable concentrations of pathogens in biosolids products.
- The application of risk assessment techniques to developing pathogen standards for biosolids re-use is difficult, because principles for risk assessment are not well developed for microbials and data is limited.
- A suggested principle is that the risk of disease transmission through the re-use of biosolids products should be less than background transmission rates for that disease from other sources.
- Risks should be calculated for the most at risk sub population, which was suggested to be children accidentally ingesting biosolids in the home garden.
- Biosolids products should be monitored for the presence of Salmonella, but not for Giardia or enteric viruses at this stage. Methods for Giardia and enteric viruses are not sufficiently developed to justify the inclusion of monitoring requirements for these pathogens.

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