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Project Summary

Pathogen Risk Assessment Feasibility Study

This report evaluates the practicality of formulating guidelines to assess the risk associated with exposure to pathogens in sludge. Risk assessment may be used to determine the likelihood that an environmental agent may cause human disease (that is, potential to cause human cancer or toxicity). On the assumption that the agent causes a particular disease, given current and projected exposure levels, a quantitative evaluation can be made on the magnitude of the likely impact of the agent on public health. In this report, the feasibility of performing a microbiological risk assessment for pathogens in municipal wastewater sludge by various disposal options was evaluated.

This Project Summary was developed by EPA's Environmental Criteria and Assessment Office, Cincinnati, OH, to announce key findings of the research project that is fully documented in a separate report of the same title (see Project Report ordering information at back).

Introduction

Pathogen risk assessment involves an evaluation of the information available on representative species of microbes and their potential health effects, and modeling, which includes fate, persistence, and transport. The result of risk assessment is a focused output that addresses the potential for human health impacts. It permits a decision about the appropriate level of concern about existing sludge treatment and disposal options used to reduce the flow of pathogens from sludges to the human population, and whether other options should be considered.

Pathogenic organisms found in sludge of human origin include certain bacteria, viruses, fungi, protozoa, and helminths. After treatment by anaerobic, aerobic, composting, lime stabilization or other methods, the sludge and remaining pathogens are disposed of in one of five major ways: disposal of sludge in dedicated sanitary landfills; direct application of sludge to agricultural, pasture land, silviculture and reclamation areas; distribution and marketing by direct application of sludge to gardens and municipal areas such as roadsides, cemeteries and golf courses; dumping sludge into the ocean from a barge or tanker; and combustion of sludge in a multiple hearth or fluidized bed incinerator. Assessment of risk associated with incineration is not discussed because pathogens are destroyed by this method.

Mechanism of Pathogen Transmission

A number of possible pathways by which sludge pathogens and other constituents can be transferred through the environment to exert potentially adverse effects on humans have been identified. The pathways begin at the point where wastewater enters a municipal treatment plant. The first three stages represent wastewater treatment and sludge processing procedures necessary to dispose of sludge, or in the case of distribution and marketing, where a treatment plant, a retailer, or a broker can distribute and market sludge products.

Selection of Representative Pathogens for Risk Assessment Study

The number and types of microbes found in municipal wastewater sludges varies from community to community and depend on several factors. These include, but are not limited to, the degree of urbanization, population chemistry, sanitary habits, season of the year, and

rate of disease in the community. Microorganisms found in wastewater and sludges and their potential health effects are identified in the report.

Because of the limited data base on these and other species, and the lack of appropriate or simple measurement methods, specific representative species are tracked through the waste handling and disposal pathways. Thus, these representative pathogens may be used to assess risk and are, in fact, pathogenic surrogate organisms used for detection of human health hazards. This latter fact separates these organisms from "indicator organisms" that are used to monitor the microbiological quality of the environment, but may not be pathogenic or may only pose a minimal risk to humans.

The criteria used to select these representative pathogenic microbial species include:

- Known demonstrated occurrence in municipal sludge;
- Known pathogen in the general population;
- More adequate information base for the given species than for other species of the principal pathogen groups;
- Known infectious doses; and
- Relatively hardy species outside the host.

Thus, in practice, species are selected as examples from each of the principal pathogen groups. Many studies have used the following representative species: *Salmonella* as an example of enteric bacteria; enteroviruses as an example of human enteric viruses; *Entamoeba histolytica* (the cause of amoebiasis) or *Giardia lamblia* (the cause of Giardiasis) for protozoans; *Ascaris lumbricoides* for helminths; and *Aspergillus fumigatus* for fungi.

Because a model is an approximation of reality, decisions have to be made regarding which components of reality can be relaxed and which cannot. It is more feasible to model a few species as opposed to hundreds of species. Representative species are selected to be modeled and substitutes are used only when necessary The part of the model that must approximate reality to the greatest extent possible is the tracking of these pathogens through the treatment and disposal pathway to human exposure sites. The available data must describe the changes in viability and concentration that occur in pathogen populations along the pathways. The goal of the model is to provide reasonable predictions, within the constraints of data uncertainties, of the time-dependent concentrations and locations of pathogens. The concentrations of pathogens can provide a basis to assess the likelihood and consequences of infection, disease or fatality.

Uncertainties and Major Data Gaps

Some uncertainties exist in the methodologies used to enumerate pathogens in sludges, soils, groundwater and surface water. The quantitative assumptions used to model risk exposure must take this into account Many of these uncertainties can be attributed to procedural differences among laboratories, even though the same "standard procedure" is followed. For example, in reviewing the literature on the efficiency of pathogen removal from wastewater during treatment processes, one may conclude that quantitative information should be compared on the basis of orders of magnitude. This may be true for detection of pathogens in general because of the laboratory-to-laboratory variability in methods, and the differences in pathogen recovery within a single laboratory depending on what methods were chosen. Also, as new methods are developed and older methods improved, the numbers of organisms typically isolated from wastewater and sludges will probably increase. Subsequent attempts to compare the new results with older results could be problematic.

Campylobacter sp., for example, can contaminate drinking water supplies and cause enteritis. With increased attention focused on *Campylobacter enteritis*, new methods resulting in greater recovery of the organism are being evaluated Recently, several methods were evaluated for recovery of *Campylobacter* from various specimens. Pretreatment, growth medium type, incubation time and temperature, and pre-enrichment techniques used, all affected the quantitative results. Results of standard tests, even for representative species, are subject to variability among different laboratories.

One way to evaluate the suitability of quantitative data among different laboratories is round-robin testing that involves simultaneous analyses of the same sample by several different laboratories. The results reported support the conclusion that quantitative detection of pathogens, especially viruses, is not highly precise. For modeling purpose the variabilities must be reported. An order of magnitude, plus or minus, may be the only reasonable starting point in lieu of rigorous interlaboratory development of standard methods for detecting pathogens in sludge.

Major data gaps for various components of a risk assessment exist The following are specific examples that must be dealt with:

- Microbes--population dynamics of important pathogen species are not completely understood especially in regard to interactions with other microbes or organisms in their ecosystem;
- Treatment and storage--the survival rate of sludge-bound pathogens needs to be more fully clarified along with the development of a better understanding of the importance of such survival to human health;
- Disposal, transport and fate--relationship of key environmental variables to pathogen survival and movement, especially as related to pathogens being bound to sludge and
- Human exposure--relationship of infection to disease (case histories) needs to be more fully explored.

These issues are among the most significant ones that warrant extensive research.

The dynamic nature of some pathogens bound to sludge pose questions of reduced die-off rate during treatment and the development of problems at the disposal or exposure site. The rate of pathogen movement may decrease and allow for longer retention at or in a given site. To date these processes are not quantified Finally, there is a lack of conclusive evidence (case histories) of disease resulting from pathogens in treated sludge disposed by any of the methods previously described.

Likelihood of Exposure

The probability of contact between sludge-originated pathogens and humans is never zero. Rather, certain likelihoods of exposure can be advanced for pathogens as they move from the various sludge treatment and disposal options through the exposure pathways Treatment, sludge management practices at the treatment site, sludge disposal methods, and pathogen survival and mobility in soil, water and air greatly affect pathogens and limit exposure to humans. For example, helminth eggs are

'arge, relative to viruses, and exhibit little ownward movement in a soil profile. Thus, helminth egg infiltration to groundwater is unlikely unless the water table is near the surface, the soil is very porous, or a fissure exists that connects the land surface with the saturated zone.

The likely contact between pathogens and humans is discussed in the report. Consideration is given to various exposure routes as they relate to sludge disposal options. This scoring of the various exposure routes is meant to guide and focus efforts for modeling and data collection that will allow consistent risk assessment of exposure to pathogens in sludge.

Most infections from pathogens follow a dose-response relationship. Therefore, as the concentration of consumed or inhaled pathogens increases, there is a greater likelihood of a population becoming infected. The number of cases of the disease that result is eventually expressed as an incidence rate. The measured response in humans to a microbial challenge could be in the form of no infection, infection without illness (such as subclinical, in apparent infection), or infection with illness (such as infectious disease in an increasing proportion of test subjects). Whether or not a response is noted depends on the dose of the pathogen the human is exposed to, the susceptibility of the individual, and the virulence of the pathogenic organisms. Infection is detected by identifying progeny bacteria in body products, such as nasal or oral secretions, blood, urine and feces, or by host response such as antibody formation that results from infection.

Host response to an infectious agent has also been measured in terms of disease production, that is, visible signs of illness. However, this is a much less objective measure of response and does not include infections in which no clinical disease is produced. In this "carrier" state the agent is still shed in body products in a viable, communicable form.

Viral infectivity can be measured in ways similar to those described for bacteria. However, viruses are also measured in cell cultures. Cell culture methods require that the virus replicate and kill the infected cell, and that progeny virus, in turn, replicate and kill other cells in the culture. The presence of the infectious virus is detected by its ability to cause destruction throughout the cell monolayer (cytopathic effect) or to cause cell destruction in restricted egions of the monolayer (plaque formation).

Infectivity of protozoans is measured by the detection of cysts in feces of the host. Depending on the strain, 1 to 10 cysts can produce an infection and many of these infections are asymptomatic. Similarly, single eggs (ova) of helminths produce human infections, as measured by the identification of the eggs in the host's feces.

The terms "infective dose" (ID) and "minimal infectious dose" (MID) are actually a discrete part of the dose-response. Generally, the MID is the dose required to infect 50% of the population (ID_{50}) though infectious doses such as ID_1 could be used for worst-case scenarios.

Minimum infectious doses for bacteria are on the order of 10^2 to 10^6. Even though these doses are high, such concentrations can be found in some sludges. In contrast, a single viral unit may initiate an infection. In this particular case it was considered that about 1% of the human population would become infected from exposure to one viral unit. If 50% of the population were to respond to an infection, the MID would be 5 to 30 viral units. Similarly, for helminths and protozoa, the MIDs are lower than for bacteria. A single egg is considered infectious to man, although some researchers assume 10 cells or cysts to be an infective dose. Much less is known about infectious doses for fungi Individuals predisposed to lung problems may be at high risk from inhalation of *Aspergillus* spores from composting sludge. The actual infective dose for *Aspergillus* is not known,but exposure to the fungus seems to be much less important than levels of abnormal human susceptibility.

The information on minimal infectious dose can be systematically integrated with information on the number of pathogens that are likely to be present in the various exposure pathways. In this matrix, consideration was given to the survival and transport capabilities of each of the principal pathogen groups as they relate to the various exposure pathways. For example, helminths move very little in soil and their contamination of groundwater is unlikely. In contrast, however, viruses can move through a soil profile and contaminate groundwater. The infectious dose for viruses is also very low. The integration of these facts produces a high likelihood of occurrence relative to the previously described example with a helminth.

Relative to helminths and protozoa, bacteria and viruses are more likely to penetrate and move along exposure pathways, and finally come in contact with humans. This information, when coupled with infectious doses for viruses and bacteria directs risk assessment efforts toward viruses because of the large number of viruses in sludge, their relative ease of mobility, and their low infectious dose.

Conclusions

Pathogens in sludge, especially pathogenic bacteria, viruses, protozoa, helminths and fungi, have been studied for many years. Studies range from enumeration of microorganisms before and after various treatments to epidemiological documentation of the role of aerosol pathogens in human infection and disease. Priorities can be set for what exposure situations should be recognized and examined first.

Data available for microbiological risk assessment for sludge pathogens varies in quality and quantity for all parts of the process for a limited number of pathogen species. Uncertainties can be identified and rational assumptions justified to augment the evaluation. Risk assessment of pathogens in sludge is a reasonable activity to undertake at this time. Although the models can be improved, sufficient data are available that should approximate reality

This Project Summary was prepared by staff of the Environmental Criteria and Assessment Office-Cincinnati, Cincinnati, OH 45268.
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The complete report, entitled "Pathogen Risk Assessment Feasibility Study," (Order No. PB 88-191 440/AS; Cost: $25.95, subject to change) will be available only from:

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