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Project Summary

Development of Methodology for Determining Risk Assessment When Sludge is Applied to Land

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This project explored the feasibility of developing a risk assessment methodology that could be applied to sludge management decision making. It examined cadmium, since this substance is one of the best studied and most extensively reported contaminants.

The methodology developed allows determination of the proportion of the population experiencing given levels of exposure to a toxic substance under specified management strategies. In addition, it provides for the evaluation of the damage caused by such exposure. When both the dosage-response analysis and the exposure population analysis are joined, the distribution of population into levels of response can be established. Each requires separate categories of data. The first is the result of controlled experiments and carefully designed epidemiological statistical studies. The second consists of ongoing data bases on a national scale, including both measurements of background levels of the toxic substance and data on the actual levels at the various stages of the disposal and dispersal procedures. This report establishes that these data bases are required. The problems associated with both categories of data are considered and discussed.

To determine feasibility of risk assessment, the study began an exploratory analysis of modeling, data bases and transfer characteristics needed for an actual risk assessment. Existing data bases were reanalyzed on a single systematic basis in a form which was suitable for undertaking the exercise. This study used nonparametric, robust and resistant statistics for determining empirical distributions characterizing the desired transfer characteristics.

On the basis of the study, it appears feasible to use risk assessment for decision making on toxic substance disposal. Much of the required data is being gathered currently, but in an inefficient fashion not appropriate for risk assessment. It will be necessary to formulate appropriate data gathering and record keeping protocols. This will eventually happen as regulators and industry realize that the only way to defend their decisions is through such risk analysis using the best current data and techniques.

This Project Summary was developed by EPA's Health Effects Research Laboratory, 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).

Discussion

The purpose of this project was to determine the feasibility of applying risk assessment methodology to sludge management decisions. The results might be used as a possible model for the larger problem of environmental risk assessment. The latter was the subject of two National Academy of Sciences reports on chemicals in the environment, which suggested directions for risk assessment methodology

The risk assessment problem for environmental decision making became more prominent after the appearance of Lowrance's *Of Acceptable Risk*. It was intended to delineate the distinction between risk and safety, where risk analysis was a quantitative assessment of consequences of decisions, and safety analysis was the assessment of level of risk acceptable to society. This report accepts that distinction, and is confined to risk, not safety.

One approach to risk assessment evaluates the fundamental quantity in determining risk to the populace (in the case of effects of toxic substances and in some other situations) by the degree of exposure of the populace, determined by the summing of all exposures along alternate pathways by which the toxic substance reaches the populace.

This approach is refined to give a methodology which, in principle, would determine what proportion of the population experiences each level of exposure to the toxic substance under some specified management strategy for handling the substance. Ideally, this would consist of charting the movements of the substance from source to final human exposure along the principle exposure paths followed by the substance, allowing summation of all exposure to obtain total exposure. This is an ideal aim, but in the presence of limited empirical data, ingenuity is required to establish approximate total exposure.

A second part to risk analysis, assuming that the first approach was empirically determined, concerns the *damage* such an exposure may cause in terms of societal or individual losses. This is substantially the question of both: (1) establishing dose-response relations, in which the dose is the exposure level, and (2) measuring the response either in physiological terms (e g., organ load of a toxic substance), or in epidemiological terms (such as excess morbidity and mortality). It is only when *both* exposure population analysis and dosage response or epidemiological analysis are joined that the distribution of population into levels of response can be established. Safety analysis can then be undertaken determining whether the population response does or does not represent acceptable damage. Also, whether an alternative management strategy is called for, which reduces the fraction of the population with damaging response above a certain level.

Two separate categories of data requirements are involved The first consists of results of carefully controlled experiments and carefully designed epidemiological statistical studies. In the case of land application of sludge, such results and others are required for plant uptake data from cadmium in sludge, human uptake data from cadmium in food, animal uptake data from cadmium in grain, physiological response data for ingestion of cadmium in food, etc. The second category of data consists of ongoing data bases which are on a national scale. These include both measurements of background levels of the toxic substances in the medium involved, and data on the actual levels persistent throughout the country at the many stages of the disposal and dispersal procedures. This is a massive data base requirement. Many of the results, however, would be invaluable for many risk assessment efforts other than sludge management.

Concerning the first category of data, one reason that the dosage response data has not been sufficiently emphasized in assessing damage is an assumption that the response is either proportional to the total dose received, or given by an a priori function of dose, independent of the circumstances. Two reasons that epidemiological studies of health effects have not been used extensively are the possibility of confounding causes for observed phenomena other than those that are apparent in an uncontrolled "experiment," and the immense size of the data bases and processing effort required. It is important to stress that, very often, only the *relative* risks of alternate disposal plans can be estimated well, and not the absolute risks of any one. Thus, one may determine that one route will lead to many times the exposure of another, without being able to specify any one's exposure consequences accurately.

Since there is interest in simultaneously controlling at acceptable levels all toxic substances in the environment, it is necessary to keep records for many substances at once in the national data bases. This makes the whole problem multivariate and vector, rather than univariate and scalar. It complicates decision making, since a strategy which will lower exposure to one toxic substance may very well raise exposure to another. For this reason, no rules for safety based on risk analysis (e.g., population exposure, dosage-response, epidemiological response) are likely to be forthcoming. The principal purpose of such analyses is to show the probable consequences in the form of response and damage that each alternative strategy will entail. Then comes the problem of deciding among the competing alternatives. Each alternative entails resulting population exposure and population response distributions of *each* of 'n' toxic substances This results in a vector of exposure distributions and a vector of response distributions. When specifically applied to sludge management decisions, each proposed strategy for sludge disposal leads to both a population exposure and a population response distribution for each toxic substance in sludge.

The disposal alternatives for sludge are: pyrolysis or incineration, water disposal (e.g., ocean dumping), and land application (including both agricultural use and simple land storage and disposal). Each alternative has well-known general advantages and disadvantages. Incinerated sludge yields air pollution byproducts which impact the environment, enter the food chain, and produce health effects directly through lung respiration. Ocean dumping disturbes ocean ecosystems, the marine environment and the sea animal food chain to man. Land application and land disposal result in increased plant uptake of substances which enter the food chain to man directly through human ingestion and indirectly through use as animal fodder. It also causes toxic substances to leave application areas, in runoff, entering lakes, rivers and groundwater. Each alternative yields deleterious effects to man, due to breathing, eating, or drinking toxic substances, and each alternative has its own health effects. The purpose of risk analysis in sludge management, therefore, is to assess the relative effects of toxic substances on human health in the alternative disposal schemes.

This requires the establishment of population exposure distributions for each toxic substance in sludge for each disposal alternative. It requires establishment of dose-response and epidemiological results to determine the population response distributions for each health effect dependent upon each toxic substance for each alternative disposal scheme. Since population exposure depends on some kind of summing over all pathways leading to man, and each pathway involves different transport mechanisms, different transformations of form for the contaminants, different ingestion routes in man with differing efficiencies, and different physiological systems exposed to the contaminants, this is a very complicated endeavor

This report is restricted to what can be obtained from current data bases in both the literature and in computer storage systems. It was decided to examine one important substance on which a great mass of literature has currently been assembled, cadmium in sludge The reasoning is that if risk assessment is feasible for any contaminant in sludge, it should be feasible for cadmium. This, therefore, is a "best possible" case for risk assessment. If it is infeasible for cadmium in sludge, it is very likely to be infeasible altogether The only drawback is that although cadmium is very harmful on general chemical grounds in the forms that might be ingested from sludge, very little has been done for dosage-response studies to demonstrate adverse health effects In addition, the epidemiological approach for demonstrating increased mortality, morbidity and chronic effects has not been systematically applied.

The best way to determine feasibility of risk assessment for cadmium in sludge was to begin an exploratory analysis of modeling, data bases, and transfer characteristics needed for an actual risk assessment. This did not include evaluation of data bases needed for all subsystems which enter into population exposure calculations, or for the epidemiological approach to determining health effects

The evaluation of the effects of sludge, independent of which disposal alternative or combination of alternatives is evaluated, include sources of sludge, measurement of cadmium content as a function of sewage plant characteristics, and output variability

The risk of any one disposal method can only be evaluated after establishment of a large reliable data base for each stage of translocation and transformation of the sludge cadmium. Since systematic risk evaluation as a subject is in its infancy, some necessary data bases do not currently exist. Those that do exist, having been accumulated for other purposes in existing measurement programs, may not be adequate to describe the transfer features from stage to stage of the disposal process. What can be done at present is to reanalyze the existing data bases on a single systematic basis. This would be in a form suitable for establishing the desired transfer characteristic for each stage and combining them to obtain a final population exposure analysis. Also to see if it is feasible to upgrade these measurement programs and to introduce new ones to fill in the present gaps, so as to demonstrate the feasibility of at least population exposure analysis for each disposal method

This study used non-parametric, robust and resistant statistics, with the purpose of determining empirical distribution characterizing the desired transfer characteristics The data bases used are as follows For land application, there is information on soil uptake of cadmium from applied sludge and applied cadmium salts under a variety of conditions, and on plant uptake, both as a function of soil cadmium and as a function of applied cadmium in sludge or salt form. Some literature is available on animal and human food uptake of cadmium from cadmium-containing food, and on distribution of cadmium in human diets (market basket, institutional diets). There is an extremely amorphous literature on the health effects of dietary ingested cadmium

This information was accumulated neither on a common statistical basis nor on a transfer characteristics basis It was necessary to reanalyze all this literature data from its raw form to obtain an insight as to whether further experiments designed to fit into transfer form for risk assessment would lead to a reliable population exposure analysis. Even the proper indicators (measurements of appropriate observable quantities) have not been standardized; these are such quantities as cadmium content of sludge, available soil cadmium, standard soils, standard definition of plant load or exposure, and standard definition of human load or exposure through dietary ingestion. This is partially due to what exact forms the cadmium takes, and the strong association of their effects with those of other heavy metals Another problem concerns the lack of human and animal *in vivo* non-destructive testing for which there are methodologies not yet used at this time. A non-parametric reanalysis of the available data in this area was done.

The purpose of these reanalyses was to determine whether natural refinements of present day experimental measurement practice would lead to a coherent set of transfer characteristics. These would yield, for each relevant form of cadmium, the proportion of the population with a given incremental exposure due to a given regimen of land application of sludge Failing this, if enough identification of transfer characteristics would result to identify the feasibility of controlling certain stages of the sludge disposal system, the analysis of the proportion of population with a given exposure level might result in a predetermined way at specifiable cost.

The remaining problem concerns the determination of the human health effects at a given exposure level. This would be the result of clinical trials, of extrapolation from animal experiments, or of epidemiological studies of correlation of ingestion levels with likely mortality and morbidity and chronic symptoms on a population basis. The former is preferable to the latter, but often the epidemiological route is the only one available in exploratory data analysis, due to the lack of suitable clinical experiments. In the present case, the information on dietary distribution of cadmium available through regional market basket surveys is so inadequate in method and sample, that correlation with regional health effects is simply not possible, even on an exploratory basis. This is due to the chosen sampling technique. For the health effects of given exposure level to dietary cadmium, therefore, there is no easy solution. Current technology may be adequate to supply some dose-response information on an *in vivo* basis once the usefulness has been emphasized. Past measurements of cadmium level in cadavers with given symptoms apparently does not contribute much information for the transfer characteristics of dose-response needed for exposure-health effect analysis for risk assessment, since the corresponding exposure levels of the cadavers are unknown.

Recommendations

(1) Risk assessment of sludge management should assess

comparative population exposure and health effects obtained for each of the main sludge management alternatives: land application, incineration, and ocean dumping

(2) Risk assessment of these alternatives in sludge management is best carried out in the context of a general risk assessment program for heavy metals and probably for toxic substances. The many necessary data bases for each risk assessment for sludge management are certain to be used as subsystem descriptions for risk assessments for other toxic substance management problems not involving sludge management.

(3) The empirical distribution of the nation's sludge output, characterized by heavy metal levels, needs to be collected on an ongoing basis. A record keeping and reporting system should be mandated. Exploratory data analysis on preliminary data indicates that the monitoring resources should be utilized to maximize the number of sludge plants sampled, rather than the number of times a single plant is sampled.

(4) The distribution of land area by yearly application rate of sludge needs to be evaluated by sampling, together with descriptions of land type and crop The result is the cadmium loading pattern Exploratory data analysis reveals that cadmium availability for plant uptake depends on recency of application. This possibility should be investigated as a potential control point in the land use strategy; it should certainly be incorporated as a design element in any future studies of plant uptake following sludge application.

(5) For a variety of plants (corn, soybeans, etc) the relative proportion that each one accounts for in the mix of crops that will be grown on sludge-amended soil should be ascertained, as should the distribution of cultivars within species The analysis should be separated at this point by plant type.

(6) From existing data and from new work, as required, the response (uptake and translocation) of these cultivars and species needs to be found, or a plausible distribution of such responses needs to be estimated, and the resulting distribution convolved with the one described in recommendation 4, the cadmium loading pattern. One may imagine that the problem has been refined to that proportion of the whole cadmium problem that is represented by the fraction of the total acreage that is devoted to the particular cultivar.

(7) The distribution should then be refined further by plant part, and the task here is simply to keep track of the separated distributions of uptake in leaf, grain, and stover.

(8) Population physiological and epidemiological response to dietary cadmium exposure has not been established by current research. This is a necessary component of risk assessment if the latter is to be based on population response, rather than population exposure

(9) The measurements needed for the forms of cadmium at each level of the risk analysis process have not been standardized. This is essential for uniformity and reliability of results. This is the problem of validating the indicators of risk.

(10) The data bases are not organized nationally so as to facilitate population exposure analysis, i.e., exposure to cadmium via air, food and water. Thus, programs for accumulating the missing bases and programs for rationally storing the bases in compatible form need to be developed

(11) It is desirable to collect the bivariate distributions expressing the dependencies of pairs of variables (assuming to be independent in the stage diagrams) as well as the marginals of these distributions described above, at least for all heavy metals.

(12) The statistical methodology for estimating distributions that result from the combinations used for population exposure analysis from sampled data for the component distributions should be developed further The non-parametric approach appears to be best suited mathematically for this purpose

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The complete report, entitled "Development of Methodology for Determining Risk Assessment When Sludge is Applied to Land," (Order No. PB 81-240 012; Cost: $15.50, subject to change) will be available only from:

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