

PEER REVIEW

**Standards for the Disposal of Sewage Sludge
U.S. EPA Proposed Rule 40 CFR Parts-257 and 503
(February 6, 1989 Federal Register pp. 5746-5902)**

Organized by

Cooperative State Research Service Technical Committee W-170

UNIVERSITY OF CALIFORNIA, RIVERSIDE

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COLLEGE OF NATURAL AND AGRICULTURAL SCIENCES
CITRUS RESEARCH CENTER AND
AGRICULTURAL EXPERIMENT STATION
DEPARTMENT OF SOIL AND ENVIRONMENTAL SCIENCES

RIVERSIDE, CALIFORNIA 92521

July 24, 1989

TO: William R. Diamond, Acting Director
Criteria and Standards Division
United States Environmental Protection Agency

FROM: A. L. Page and T. J. Logan
Co-Chairs, Peer Review Committee

RE: Environmental Protection Agency 40 CFR Parts 257 and 503 -
Standards for the Disposal of Sewage Sludge: Proposed Rule.

Subsequent to your request of January 13, 1989 the Cooperative State Research Service Regional Technical Committee W-170, with the assistance of experts from EPA, academia, environmental groups, and units of state and local government agencies, organized a Peer Review Committee (PRC) which has conducted a review of the above-referenced document. A copy of the review is attached.

The PRC convened its first meeting from April 12 through April 15, 1989 in Washington, D.C. and prepared a first rough draft of the review effort. The final document transmitted herein is the result of many long deliberation sessions, debates, and sometimes spirited discussions.

We commend EPA for their efforts to produce a comprehensive document on the use and disposal of municipal sewage sludge by using modern scientific and technological means. Our review in many respects is critical of the methods which the Agency has elected to use and interpret data. However, we believe our comments to be constructive and will serve to assist the Agency in producing a superior final product.

If we can clarify points made in our review, or be of assistance in the future, feel free to call upon us.

Sincerely,

Handwritten signature of A. L. Page in cursive.

A. L. Page
University of
California, Riverside
Committee Co-Chair

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T. J. Logan
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cc: A. C. Chang
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ACKNOWLEDGEMENTS

The Peer Review Committee gratefully acknowledges the sponsorship and financial support of the following agencies:

Association of Metropolitan Sewerage Agencies
Association of State and Interstate Water Pollution Control Administrators
National Association of Counties
National League of Cities
U.S. Conference of Mayors
Water Pollution Control Federation

Special thanks are due Mr. Kenneth Kirk, Executive Director, Association of Metropolitan Sewerage Agencies, for his untiring efforts in enlisting and coordinating the support of the above sponsoring agencies.

We wish to express our appreciation to those colleges, universities and agencies of government for donating the time of their faculties and professional staff to participate in the peer review process.

Arrangements for the meetings of the Peer Review Committee were made by Ms. Janet Hughes, Conference Coordinator, Association of Metropolitan Sewerage Agencies. We acknowledge with thanks her help in handling the many details associated with travel and accommodations for the committee meetings and for coordination of local arrangements at meeting locations.

The committee owes a special debt of gratitude to Ms. Mary Jacobs, The Ohio State University, Ms. Louise DeHayes, University of California, Riverside and Ms. Leslie Webster, University of California, Riverside, for enduring long hours typing working drafts and numerous revisions of drafts to the final copy.

PEER REVIEW

STANDARDS FOR THE DISPOSAL OF SEWAGE SLUDGE
U.S. EPA PROPOSED RULE 40 CFR PARTS-257 AND 503
(FEBRUARY 6, 1989 FEDERAL REGISTER PP. 5746-5902)

ORGANIZED BY

COOPERATIVE STATE RESEARCH SERVICE TECHNICAL COMMITTEE W-170

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BY:

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FOREWORD

FOREWORD

The U. S. Environmental Protection Agency (EPA), under authority of sections 405 (d) and (e) of the Clean Water Act (CWA) as amended (33 U.S.C.A. 1251, *et seq.*), proposed regulations to protect public health and the environment from any reasonably anticipated adverse effects of certain pollutants which may be present in sewage sludge. The proposed rules (40 CFR Parts 257 and 503, Standards for the Disposal of Sewage Sludge. Federal Register Vol. 54, No. 23 p 5746 - 5902) were published Monday February 6, 1989. They include standards for the final use or disposal of sewage sludge applied to agricultural and non-agricultural land, distributed and marketed, placed in monofills or surface disposal sites, or incinerated. In the proposed rules the Agency asks the U.S. Department of Agriculture (USDA) Cooperative States Research Service (CSRS), Regional Research Technical Committee (W-170) to review the scientific and technical bases of the proposed rule during the comment period. In response, W-170 formed a Peer Review Committee (PRC) with Drs. A. L. Page and T. J. Logan as Co-Chairs. The PRC, composed of 35 recognized experts from academia, government and private industry, met in Washington, DC from April 12 to April 15. They met in assigned workgroups (Monofills/Surface Disposal/ Nonagricultural Land Application, Agricultural Land Application, Distribution and Marketing, and Risk Assessment). Each workgroup was responsible for review and preparation of preliminary drafts of their particular area. During the meeting the whole PRC met numerous times to discuss progress and identify common areas. After the meeting, each workgroup reviewed and edited their section, and then the entire document was reviewed and edited by each of the PRC members. The Co-Chairs and Chairman of each Workgroup met July 8 to July 12, 1989 to revise and edit the complete draft report.

W-170

The W-170 committee and its predecessors, W-124 and NC-118, are CSRS committees formulated for the purpose of conducting regional research. Research projects must be regional in scope and are developed by researchers from land grant universities, agricultural experiment stations, and USDA laboratories within four regions throughout the United States (North East, North Central, Southern, and Western). Project approval involves preparation of a proposal, approval at the local, regional, and national levels. Funds for regional research are allocated under the provisions of the Hatch and MacIntire & Stennis Acts and each participating unit receives funds based upon a formula.

History

Regional research on land application of municipal sewage sludge was initiated in the North Central and Western regions in 1972. Chronology leading to formation of the W-170 committee follows:

-1972 NC-118 Project, "Utilization and Disposal of Municipal, Industrial and Agricultural Processing Waste on Land", and W-124 Project, "Soil as a Waste Treatment System", were approved for a 5-year duration. The projects involved researchers from Land Grant Universities, USDA laboratories, and EPA.

- 1977 Recognizing the similarity of interests and objectives between NC-118 and W-124, a national project was proposed that combined researchers from both projects and focused exclusively on land application of municipal sewage sludge. The project, designated W-124 and entitled "Optimum Utilization of Sewage Sludge on Land", was approved for a 5-year duration. The project involved 44 researchers from 15 Land Grant Universities, 3 USDA laboratories, 1 EPA laboratory, 2 municipal wastewater treatment agencies, and TVA.
- 1982 A two year extension of W-124 was requested and approved.
- 1984 Recognizing the continued need for national research on waste utilization on land, researchers within W-124 developed and submitted a new national project entitled "Chemistry and Bioavailability of Waste Constituents in Soils". The project was approved for a 5 year duration and designated W-170. The project involved 25 researchers from 13 Land Grant Universities, 2 USDA laboratories, 1 municipal wastewater treatment agency, 1 EPA laboratory, and TVA.

Involvement

In addition to the regional research projects, W-170 and its predecessor committees have been directly involved in a number of other activities dealing with land application of municipal sewage sludge:

- 1973 Organized and conducted with EPA, the Joint Conference on Recycling of Municipal Sludges and Effluents on Land, held at the University of Illinois. Publication of the proceedings of this early conference provided the stimulus for an extensive program of research conducted by federal, state, municipal, and private agencies.
- 1975 Published North Central Regional Research Bulletin No. 170, "Sampling and Analysis of Soils, Plants, Waste Waters, and Sludge: Suggested Standardization and Methodology". R. Ellis, J. J. Hanway, G. Holmgren, and D. R. Keeney, eds. Agr. Exp. Sta., Kansas State Univ.
- 1976 Published North Central Regional Research Pub. No. 235, "Application of Sludges and Wastewaters on Agricultural Land: A Planning and Educational Guide". B. D. Knezek and R. H. Miller, eds. OARDC, Wooster, OH.
- 1977 Published North Central Regional Extension Pub. No. 52, "Utilizing Municipal Sewage Wastewaters and Sludges on Land for Agricultural Production". 1977. L. W. Jacobs, ed. Coop. Ext. Serv., Michigan State Univ.
- 1979 At request of EPA, reviewed "U.S. EPA Criteria of Solid Waste Disposal Facilities - Proposed Classification Criteria", Federal Register, Feb. 6, 1979. Report submitted March 31, 1979.

- 1979 At request of EPA, reviewed "Interim Final Criteria", Federal Register, September 13, 1979. Report submitted January 25, 1980.
- 1983 Organized and conducted a workshop on "Utilization of Municipal Wastewater and Sludge on Land". This workshop was co-sponsored by EPA, USDA, CSRS, the University of California Kearney Foundation of Soil Science, the U.S. Army Corps of Engineers, and the National Science Foundation.
- 1985 Organized and conducted a workshop on "Land Application of Municipal Sewage Sludge". The purpose of the workshop was to bring together researchers involved in land application of sewage sludge to evaluate and summarize their most recent data. In light of this information, the workshop assessed the validity of assumptions made in the risk assessment process on fate of sludge contaminants. Findings of the workshop are contained in a book entitled "Land Application of Municipal Sewage Sludge", edited by A. L. Page, T. J. Logan, and J. A. Ryan, and published by Lewis Publishers, Inc., Chelsea, MI.

In addition to direct involvement in land application of sludge research, members of the W-170 committee have participated in sludge related activities sponsored by other agencies. Examples follow:

- 1976 CAST (Council for Agricultural Science and Technology) workshop, "Application of Sewage Sludge to Cropland: Appraisal of Potential Hazards of Heavy Metals to Plants and Animals". CAST Rep. No. 64.
- 1980 CAST workshop, "Effects of Sewage Sludge on Cd and Zn Content of Crops". CAST Rep. No. 83.
- 1987 EPA Science Advisory Board. Review of Technical Documents. Supporting Proposed Revisions to EPA Regulations for the Disposal/Reuse of Sewage Sludge under Sec. 405(d) of the Clean Water Act.
- 1988 Contributing authors and technical reviewers of "U.S. EPA Guidance for Writing Case-by-Case Permit Requirements for Municipal Sewage Sludge". Draft, September 1988.

PEER REVIEW PARTICIPANTS

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- (a) workgroup chair
- (b) committee co-chair
- (c) reviewed PRC report, did not attend PRC meeting

SUMMARY

SUMMARY

The PRC approached the review of the proposed rule by addressing specific components of the rule, questions raised by the Agency in the preamble, and the methodologies and technical databases given in the Technical Support Document (TSD).

At times in this review reference is made to the TSD upon which the rule is based. These TSDs are referenced in the Preamble of the proposed rule and are available through the EPA library in Washington, D.C.

The PRC attempted to be as comprehensive as possible in its review, but because of time limitations and the mix of technical expertise on the committee, we were unable to address all aspects of the rule. The PRC has drawn specific conclusions regarding the technical merits of the rule and its underlying assumptions, methodologies and databases, and has made specific recommendations to EPA for revision of the rule. We did not completely review and correct the TSDs. However, we found such extensive misinterpretation and errors in the TSDs that it is imperative that EPA review and revise them completely. We also recommend that review and revision of the rule and the TSDs be conducted in consultation with the PRC and other knowledgeable experts.

Beneficial Use of Sewage Sludge

Based on our knowledge of, and experience with, research results on sludge utilization in agriculture, the PRC strongly supports EPA's policy of beneficial use of sewage sludge. Also the committee is pleased to learn that "Prior to finalizing the rule, the Agency will carefully consider, and place heavy emphasis on, those comments and approaches that support the Agency's policy of beneficial reuse." If the Agency adheres to these policies, beneficial use should be achieved to the maximum extent possible.

EPA states that "the Agency's preference is for local communities to beneficially use their sewage sludge". However, the proposed rule is based on a series of worst case scenarios, which are so stringent and inflexible that local communities are precluded from beneficial use options considered protective of the public health and the environment under local conditions. Beneficial use is constrained because the proposed rule provides no allowances for local conditions within and among communities. The PRC is concerned that, in spite of the Agency's own findings that the aggregate risk for the land-based sludge utilization options are lower than that associated with other disposal options, the proposed regulations encourage non-utilization practices.

Separation of Science and Policy

It is evident from a review of the document that many of the conclusions reached by EPA are not driven by science, but rather by policy decisions. In view of the inherent uncertainties in risk assessment and the necessity for value judgements, the prominence of policy decisions is understandable. However,

instead of acknowledging these policy decisions and justifying them on legal, political and social grounds, EPA has, in many cases, tried to make it appear that the basis for these decisions was scientific. This problem permeates the proposed rule and technical support documents.

Again, with no desire to appear repetitive, we wish to emphasize that EPA has disguised policy decisions with the risk assessment assumptions and database, apparently to make it appear that the results were derived scientifically. Had they wished to do the effort correctly they should have, at the very least, clearly presented the underlying assumptions, data and models. Instead, these are scattered through numerous documents in a manner that is very difficult to access.

Another example of the attempt to gloss over uncertainties and to give an appearance of accuracy is a persistent use of more significant figures than can be justified. This problem leads to such absurdities as the use of 3.84×10^{-2} kg/ha as the maximum annual application rate for hexachlorobenzene when all the concentrations for such organics in the 40 City Survey were below the detection limit. Another example of this problem is the use of numbers such as 5976 for the baseline of lead risk in the case of incineration. The use of such numbers is dangerous in that it can give the impression that differences such as 5155 for Options II and III (see Table E of the Abt document (1989) and 5163 for Option III are meaningful. The uncertainties involved in the calculation are not only larger than the difference, but are likely to be larger than the difference between the highest value of 5976 and the lowest value of 4759 in the calculations. The same is certainly true for the differences in the annual cancer cases in the non-incineration options and probably true for all of the cases including incineration. Indeed, the extreme conservatism used, beginning with the plausible upper-bound nature of the carcinogen potency factors, means that there is no significant difference between the cancer cases calculated for incineration (about 12) and zero.

Aggregate Human Health Effects

The Agency has estimated aggregate human health effects for sewage sludge applied to agricultural lands and non-agricultural lands, distributed and marketed, placed in monofills, and incinerated. In the case of the aggregate effects analysis, the Agency used the common practice of upper-bound estimates of carcinogenicity. This makes the resulting postulated aggregate cancer cases likely upper-bound estimates. Even using this approach, the Agency determined the aggregate risk for all beneficial land effects-based options to be insignificant. In fact, by their own admission, "The actual incidence may be substantially less than predicted here and, in fact, may be zero" (p. 5779 proposed rule).

Appropriateness of the Exposure Assessment Models

The exposure models used by EPA to assess MEI sludge risks have five basic components: selection of appropriate environmental exposure pathways, selection of appropriate most-exposed individual (MEI) for each pathway, selection of

appropriate contaminant transport models, screening and selection of appropriate data for each contaminant and pathway, and selection of an allowable risk. There appear to be serious deficiencies in all of these components with the exception of pathway selection. The latter is appropriate for the disposal options considered.

The proposed Rule and supporting analyses, in many cases, have not provided the data generally considered necessary for the presentation of risk assessment results. At a minimum, the assumptions applied and the reasons for their selection should be clearly presented, with the associated uncertainties and their potential effect on risk considered.

For example, in its exposure assessments for the various pathways evaluated, the basis for the assumptions applied were often not clearly presented, and the methodologies for estimating the magnitude of exposures and the size of the populations exposed, were not always clearly provided. In its most complete form, an exposure assessment should describe the magnitude, duration, schedule and route of exposure; the size, nature and classes of the human populations exposed; and the uncertainties in all estimates. This information was often not clearly provided, or was provided inconsistently from pathway to pathway evaluated.

Most exposed individual (MEI)

Critical to the risk assessment models is identification of an MEI, who becomes the driving force of criteria setting. The MEI does not describe the total distribution of exposures and risks, even though such information is essential to predicting the range of risks of a disposal option. The exposures implied by the MEIs are grossly exaggerated, and it is impossible to know the probability that such an MEI exists. Because the assumptions underlying selection of the various MEIs differ, the extent of conservatism embodied in the various MEI exposure models also differs. Further, insufficient information is available to compare the relative degree of conservatism of one MEI with another. Consequently, it can be misleading to compare risks derived from one MEI with another because different premises were used within and among disposal options. The reliance on "worst-case" scenarios pervades these documents and needs to be reconsidered. The MEI is so rigidly defined that it completely overshadows other components of the risk assessment pathways, and even to the extent that it makes the issue of "inappropriate" technical data almost irrelevant.

The fundamental problem (mentioned repeatedly in this review) is that EPA attempts to define risk value by a layering of worst case assumptions. As a result, what is finally arrived at is unknown and unknowable. When worst case assumptions are made, do they lead to the 95th percentile, the 99th percentile, the 99.99999th percentile or what? At a certain point, which is a function of the size of the exposed population and other variables, there is a percentile which is ridiculous and not even defined because there are no individuals in the group (e.g., the 99.99 percentile of 100 people).

In our judgement, the definition of the "most exposed individual" used by the Agency is not consistent with the Agency's intent to protect the public

health and the environment from reasonably anticipated adverse effects associated with potential sewage sludge exposure. The scenario of exposure assessed for the MEI is unreasonable (overly conservative) for the vast majority of individuals in the general population, and substantially overestimates actual exposure for the sector(s) of the population with the highest potential exposures from sewage sludge.

Model selection

The models selected to simulate contaminant transport in surface runoff and landfill leachate were either overly simplistic (e.g., use of the USLE for runoff and erosion) or inappropriate (e.g., use of the CHAIN model for unsaturated flow landfill leachate). There was also poor documentation and use of the unvalidated saturated flow model, AT123D.

Screening and selection of data

A major flaw of the exposure assessment was the inappropriate and scientifically unsound approach used to select data for individual contaminants and pathways. Rather than accepting the existence of no-observed-adverse-effect data from valid field studies with sludge, data from pot studies or those with metal salts were selected if they were the only ones to show an effect. Researchers have emphasized on several occasions (Logan and Chaney, 1983; Page et al., 1987) that data from pot and metal salt experiments should not be extrapolated to results found in the field with sludge. This approach of data selection, for instance, led EPA to conclude that sludge-borne Cu, Ni and Zn would cause phytotoxicity in crops, a situation never observed in the field.


Definition of Sewage Sludge

The proposed rule includes sewage sludge products no matter how small the percentage of sewage sludge in the product or its quality to be regulated under the proposed rule as sewage sludge. This is counter productive to the Agency's stated policy of beneficial reuse. The proposed definition unfairly stigmatizes blended sewage sludge products, particularly those which contain only small percentages of sewage sludge, or "clean" sludge. This definition will discourage the development of privatization programs designed to utilize the uniquely high organic content of sewage sludge in the preparation of customized fertilizer blends.

We urge the Agency to develop the concept of a "clean sludge", i.e., a sludge that meets all criteria for unrestricted utilization. The Agency should exclude from regulation all products containing "clean" sludge.

98th Percentile Sludge Constituent Analysis

We question use of the 98th percentile constituent analysis from the "40 City Study" to regulate sludge disposal on non-agricultural land. The Agency



elected to use risk assessment analysis to develop standards for the disposal of sewage sludge. The results of this aggregate risk analysis showed no significant health or environmental constraints. Therefore, development of regulations for non-agricultural use based upon sludge constituent distribution (98th percentile) has no place in the proposed rule. Results of the on-going sludge quality study by EPA will not improve this approach.

The PRC fears that in spite of these "no-adverse-effects" findings, the Agency will promulgate regulations that discourage sludge reuse in low-risk, land-based options in favor of higher risk disposal by non-beneficial practices.

Distribution and Marketing

The PRC finds that the approach used by EPA in setting rules for D&M are unacceptable. Concerns include assumptions about loading rates, D&M MEIs, and the lack of a clear definition of D&M products. Errors in risk analysis for sludge constituents are so extensive and severe that the Agency needs to rewrite this section of the rule after re-evaluation of risks from sludge constituents using correct data.

Assumptions on Soil Background Levels

The risk assessment methodology assumes that the background level of organics in soils is zero, and that the background level of trace metals is that of uncontaminated soil. For many organics, particularly the chlorinated insecticides, i.e., dieldrin, chlordane and DDT, background levels in agricultural and even urban soils may approach those found in sewage sludges. Likewise, background levels of several of the trace elements, notably lead in urban soils, can be significantly higher than those for uncontaminated soil and present in many sludges. The Agency should utilize available data on background levels of these compounds.

Phytotoxicity

Based on: (1) evidence that phytotoxicity does not impact human health, (2) evidence that, even at very high application rates (>500 mt/ha), phytotoxicity rarely if ever occurs where municipal sludges have been used in field agricultural operations, and (3) the fact that if phytotoxicity occurs, it is easily corrected, the PRC rejects EPA's decision in the proposed rule to allow the issue of phytotoxicity (based upon worst-case scenarios and incorrect or incorrectly interpreted data) to essentially prohibit beneficial use of sewage sludge.

Sludge Application Rates

In Sections 503.12, p. 5799; 503.14, p. 5803; and 503.14, p.5880, the proposed rule limits sludge application to agricultural lands to a maximum of 50 metric tons per hectare on a dry weight basis. It is not clear if this is

an annual or cumulative rate of application. This limitation is based on the inability of the exposure assessment model to calculate pollutant limits above a 50 metric tons per hectare sludge rate and a belief by the Agency that land application at greater rates constitutes disposal rather than reuse. Only in the latter section (503.14, p. 5880) is the rate specified as an annual loading rate. If it is a cumulative rate in the other cases, agricultural utilization is limited without scientific basis. In fact, much greater rates have been utilized safely. Even if it is considered an annual limit, composted or lime-treated sewage sludges may have to be applied at rates greater than 50 metric tons per hectare for utilization at nitrogen fertilizer rates. Thus the only apparent rationale for the 50 metric ton per hectare rate is the inability of the Agency's exposure assessment model to calculate pollutant limits above the 50 metric tons for hectare rate. This being the case, the model should be corrected and annual application rates should be limited by the fertilizer value, and cumulative rates by pollutant limits. It is not clear why total sludge loading is limited to 50 metric tons per hectare because of model constraints, when in fact cumulative metal loadings are computed without a sludge loading limitation.

Management Practices

The PRC strongly recommends EPA allow for exceptions to all of the management practices on a case-by-case basis. It concludes that EPA should clearly state its assumptions on use of management practices as part of the regulations, and these assumptions should reflect the experimental conditions of the scientific data they utilize to develop their risk assessment. Further, a management practice should be permitted if site-specific considerations can be shown by the risk assessment calculation not to exceed EPA risk limits.

Pathogens

The PRC concludes there is no compelling risk assessment analysis to justify the scheme of classifying and regulating pathogen content of sludge in the proposed rule.

Analytical Detection Limits

The PRC concludes that, by lack of statements to the contrary, EPA has taken the position that, when sludge analytical data is reported as less than the detection limit, the reported limit of detection will be used to determine regulatory compliance. Because analytical methods and limits of detection for sludge constituents can vary widely, and because the Agency has established no mechanism for certifying sludge analytical methods, this position is unworkable. Certifiable analytical methods with appropriate limits of detection need to be established by EPA for all regulated pollutants in sludge. This is particularly important for the organics. Beyond this, the Agency needs to consider how to use data reported as less than the detection limit for regulatory sludge pollutants.

Dedicated Sites

The proposed rule assumes that local governmental utilities (POTWs) do not now own, nor are they interested in long term ownership of land application sites. This assumption is false. Many POTW entities, such as those in Seattle, WA., Sacramento, CA, Chicago, IL and Danville, IL already have acquired thousands of acres of land for long-term use as non-agricultural land application sites. This practice was encouraged under 40 CFR 257 as dedicated land application. It is unclear whether the proposed rule even recognizes this classification. In the absence of a clear recognition of this classification, the proposed rules pose many troubling problems for local governments such as:

1. The status of continued use of such lands
2. The status of current ownership
3. Transferability of ownership
4. The ability to convert dedicated land application sites to other uses.

Past experiences with local government ownership of dedicated land application sites suggest that this is a preferred mode of operation in many instances. Reasons may include local politics, public relations, and liability.

The proposed rule should offer clear directions on this issue to assist units of local government in their long term planning for beneficial use of sewage sludge.

RECOMMENDATIONS

RECOMMENDATIONS

The PRC recommends, at a minimum, that EPA revise and repropose the 503 regulations to correct their risk assessment methodology to consider different MEIs, models, clean sludge, site-specific considerations and data inputs, etc.. Specifically, EPA should:

- Revise the proposed rule to conform to their stated policy to encourage the beneficial use of municipal sewage sludge.
- Enlist working groups consisting of sludge experts, risk experts and modelling experts to review the data, revise the scenarios and obtain more realistic estimates of pollutant limits.
- Use risk assessment procedures which lead to best estimates and uncertainty bounds rather than calculating upper bound estimates. At a minimum, the MEI should be replaced with an approach which considers an exposure unit that is reasonably calculable.
- Use biokinetic models to obtain realistic estimates of absorption, translocation and excretion of pollutants.
- Use realistic dietary scenarios in calculating food chain inputs of pollutants to humans.
- Use sensitivity analysis to identify the most critical parameters in risk/exposure computation and make efforts to obtain reliable and realistic estimates for these parameters.
- Adhere to normal scientific practices in the use of the number of significant figures.
- Use field studies with municipal sludge instead of non-field studies with metal salts or pure organic compounds.
- Use field data to establish Lowest Observable Adverse Effect Levels (LOAELs) or No Observable Adverse Effect Levels (NOAELs) as a basis for calculating limits on pollutants.
- Expand the proposed rule to include consideration of potential Fe and F toxicity.
- Develop the concept of a "clean sludge" which allows minimal regulation.
- Not regulate all D&M products as sludge.
- Require labelling of D&M products to provide consumer information on proper use of the product.

- Drop MEI scenario for D&M that assumes a rural nonfarm family grows 60% of their fruit and vegetables in a D&M sludge-amended home garden.
- Prepare and address different categories for nonagricultural and D&M practices.
- Exempt from the rule banned compounds that have been shown to pose insignificant risk (such as lindane, chlordane, PCBs, hexachlorobutadiene). This action would be consistent with the screening approach used by EPA (i.e., Environmental Profile and Hazard Indices) to eliminate low priority pollutants from consideration.
- Develop more realistic data bases, assumptions and risk exposure models consistent with results from field studies using sludge applied PCB, and perform detailed re-evaluation and analyses of the PCB pathways.
- Use two distinct frameworks to assess risk for nonagricultural land:
 - a) exposure and significant future conversion very low,
 - b) exposure more likely or conversion more probable.
- Allow for exception to the five-year conversion period in nonagricultural land application on a case-by-case basis.
- Reject 98th percentile concept.
- Continue their approach of separating the vector attraction reduction requirements from the pathogen reduction requirements in the proposed regulations.
- Regulate pathogens on a risk based approach. In the interim the existing procedure in 40 CFR 257 should be maintained.
- Replace the air dispersion model in SLAPMAN and SLUDGEMAN with a more realistic model, such as that used for the EPA incineration program.
- Adopt a consistent approach for including volatile compounds (e.g., benzene and trichloroethylene) in models used to predict air and groundwater transport.
- Exclude from the rule the chemicals which the Agency assumes to be lost from the sludge during processing and are not present in the sludge in significant amounts.
- Discontinue use of the CHAIN model in SLAPMAN and SLUDGEMAN to model contaminant transport in the unsaturated zone and replace with a more appropriate model, such as PRZM, RUSTIC or LEACHM.

- Perform conversion of output from the unsaturated zone transport model to input for the AT123D saturated zone transport model in such a way as to satisfy conservation of mass.
- Use realistic, site-specific geologic, hydraulic and chemical parameters as input to computer simulations of contaminant transport.
- Differentiate between trench and area monofills because of the potential for leaching from these types of monofills.
- Modify the proposed definition of surface disposal to reflect the operational difference between storage with no intent for further management, and storage as an essential component in an overall sludge management scheme.
- Not require methane monitoring at surface disposal sites.
- Establish acceptable analytical methodologies and limits of detection for regulated sludge pollutants.
- Define the limit of detection (LOD) as the lowest concentration that can be determined to be significantly different from a blank for an analytical test method and sample matrix.
- Replace the sum of individual limits of detection for multiple pollutant categories (e.g., PCBs) with the highest level of detection for any individual parameter in the multiple parameter set.
- Develop a consistent method to use data that is reported as less than the limit of detection.
- Consider a POTW reporting a limit of detection less than or equal to the acceptable limit of detection to be in compliance with any EPA concentration-based regulatory limit derived from that limit of detection.
- Allow the use of zero concentrations from sludge pollutant data below the limit of detection for laboratories meeting the Agency's analytical standards.

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RISK ASSESSMENT METHODOLOGY

RISK ASSESSMENT METHODOLOGY

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SUMMARY

While we commend EPA for using a multimedia, risk assessment approach for developing the rule, we believe the effort has been severely compromised by a piece-meal, policy-driven effort. The use of upper bounds and worst case estimates is not new. But, usually there are not multiple layers of conservative assumptions as there are in the development of the presently proposed rule. We believe that this situation is a striking example of the need to attempt best estimates and uncertainty calculations. There is no question that this is a more difficult approach. It is certainly easier to develop a scenario so bizarre that no person will ever have that much exposure and then to protect that nonexistent person and thereby all existing persons. But, as pointed out numerous times in this review, that approach leads to results that can not only be unrealistic, but where the degree of unreality can not even be estimated. The regulation of sludge disposal options based on multi-media risk assessments should not be driven by these bizarre scenarios.

We believe that the aggregate risk analysis is reasonable with regard to the relative impacts of the technologies. However, any reasonable analysis of the uncertainties in these calculations make the cost/benefit analysis questionable.

We realize that EPA is under time pressures from the courts and that limited options are available regarding the proposed Rule. The best of all choices would be to put together a task force including risk and sludge experts that could develop consistent and realistic values using best estimates and uncertainties to arrive at exposure numbers representing some appropriate percentile of the exposed population. If one group were to develop the framework this would also help with some of the problems involving inconsistencies between different disposal options. While such an effort would not be trivial, it would not require going back to ground zero. Many of the calculational aspects are in place and simply need to be rerun with more appropriate numbers.

Another choice, recognizing the time constraints, is to make the best use of the proposed regulatory approach, based on the MEI calculational algorithms. In this case, we recommend using the data and calculational corrections mentioned in this report plus a modified approach to establishing a "more reasonable MEI". This approach would replace the "most exposed individual" with a Reasonably Calculable Exposed Unit (RCEU). The RCEU would use explicit safety factors, defined in a policy statement, to account for extremes. The RCEUs would be formulated by an interdisciplinary committee including sludge technology, environmental, health, and risk experts along with EPA, contractor and NRDC staff. The specific steps in this approach are as follows:

- 1) List the basic methodology assumptions and data inputs for the calculational algorithm for each disposal technology,
- 2) Convene a working group for each technology. The working group will include a modeler, sludge technologists, and risk experts using the best judgement of the group to reach a set of appropriate assumptions, models and data sets. The methodology and data base for each technology will be reviewed for consistency among the technologies. A main focus of the group will be to establish RCEUs to replace the MEIs.
- 3) The RCEUs for each technology will be reviewed for consistency among the technologies. The RCEUs will be used to generate the disposal option limits for the Rule.
- 4) The RCEU algorithms will be applied to several sites to test the impact on the disposal technology. The impact on "well managed" technology as well as a hypothetical poorly managed technology will be calculated to observe the ability to achieve risk management objectives. If time permits, the aggregate risk impacts of the Rules for these examples could be estimated. As necessary, the RCEUs will be modified to reflect desired risk management objectives. This step will include the addition and/or modification of policy decisions (e.g., safety factors) for the RCEUs.
- 5) The ability of sludge practices to deviate from the RCEU algorithms based on a site-dependent risk assessment resulting in de minimus risks will be established. This will allow "good practices" that may be unfairly impacted by the RCEU to continue their practice by demonstration of insignificant risk.
- 6) The RCEU algorithms will allow to update and/or modification based on new models and data, as appropriate.

As the least attractive option, it is possible to patch up the documents and the rule in a piecemeal fashion, but this would not help with the lack of consistency between options and other problems. It would not be a very satisfactory approach. Nevertheless, we have made several specific suggestions concerning various issues, and many of these do not involve great efforts to correct.

INTRODUCTION

The charge to the group was to review the methodologies and details of the risk assessments performed by EPA in preparing the proposed rule for sewage sludge disposal. Unfortunately, the group only had access to the rule itself in advance of the meeting. At the meeting and shortly following the meeting, several other documents were obtained. The most important of these were the Technical Support Documents, the Science Advisory Board (SAB) Review, the document by Abt (1989) describing the aggregate risk assessment and documents describing the 40 City Survey. Also, during the meeting in Washington, D.C., the subgroup was fortunate in receiving an informative briefing on the aggregate risk analysis from representatives of Abt and EPA.

Because of the relatively limited time available to the Risk Assessment subgroup, this review will focus mostly on the deficiencies in methodology and philosophy of EPA's approach rather than on specifics. Where we do become specific it will generally be to give an example of methodological deficiencies.

We recognize that the EPA has put a great deal of effort and resources into these documents. Some, indeed many, of our concerns were raised by the SAB. EPA gave consideration to some of the SAB comments, but decided not to change their analysis in many cases. We feel that in many cases the SAB comments should have been taken more seriously. Thus, if some of our comments seem repetitious and/or already addressed by the SAB, it is because we, like the SAB, feel that there are deficiencies yet to be corrected. At the same time, we recognize that EPA was operating under severe time constraints that limited the ability to do a rigorous analysis.

BACKGROUND AND OVERVIEW

The EPA Approach

EPA is "proposing regulations to protect public health and the environment from any reasonable anticipated adverse effects of certain pollutants which may be present in sewage".

EPA is constrained by certain Acts and Court decisions in its approaches. These include the Vinyl Chloride decision in which the court ruled that under the Clean Air Act the Agency must use a two step process in making regulatory decisions for air emission standards. The first step is to define an acceptable risk based on health factors alone. The second step is to define a regulatory limit in which the Agency may consider non-health related issues, such as cost, as long as the limit does not exceed the acceptable level of risk. Various other acts such as TSCA, RCRA and CERCLA address the issue of acceptable risk and establish excess lifetime cancer risk levels in the general range of 10^{-4} to 10^{-6} . EPA considered various approaches and adopted the one that involves the use of a mixture of methods involving the most-exposed-individual (MEI) risk, the 98th percentile pollutant concentrations in sludge and aggregate risk.

In general, the driving factors in their analysis are the MEIs. An MEI can be human, plant or animal. This is essentially a model that is supposed to represent a living organism that, because of individual circumstances, has the maximum exposure to a given pollutant for a particular disposal practice. While this concept seems simple, it presents severe methodological problems to a risk assessment. Risk assessment is fundamentally a probabilistic analysis dealing with a random variable. It is possible to discuss the upper 99th percentile (or 90th or 95th), but the individual with the greatest exposure is a concept without statistical relevance. EPA can improve the MEI approach by attempting to define the risk value that corresponds to a very small, but statistically meaningful, percentage of the population.

The MEI approach also presents a potential conflict with the basic aim of the proposed Rules to protect public health and the environment from any

reasonably anticipated adverse effects. Sludge will be generated, and all the disposal options have risks. (There is no zero risk option.) These options should not be constrained based on MEI algorithms to disposal practices that result in increased aggregate population risks. The MEI is the result of specific scenarios that include appropriate exposure pathways. The MEI concept is difficult to correlate to aggregate risks for the different practices. The extreme nature of the current MEI makes it inappropriate to create algorithms to "protect" the MEI. The disagreement over the extreme nature of the MEI and the level MEI risk can be moot because of lack of correlation to the relevant public health and environmental risk. A reasonable alternative approach to the MEI is to look at "high percentile" fractions of exposure groups.

The fundamental problem (mentioned repeatedly in this review) is that EPA attempts to define this risk value by a layering of worst case assumptions. As a result, what is finally arrived at is unknown and unknowable. When worst case assumptions are made, do they lead to the 95th percentile, the 99th percentile, the 99.99999th percentile or what? At a certain point, which is a function of the size of the exposed population and other variables, there is a percentile which is ridiculous and not even defined because there are no individuals in the group (e.g., the 99.99 percentile of 100 people).

Definitions and Risk Assessment

There has been difficulty in defining risk (Gratt, 1989a). The definition we will use is:

Risk is the potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the expected consequence of the event given that it has occurred.

Thus, risk is a random variable with a corresponding distribution function which implies an uncertainty associated with the risk.

Uncertainty in risk assessments is usually considered near the end of the analysis, if at all. Uncertainty analysis as used herein refers to methods by which the inexactness of the knowledge and description of events and processes can be translated into probabilistic statements about the resulting consequences. Sensitivity refers to the impact of a change in a given value on the overall risk assessment result (such as a partial derivative).

A risk assessment usually involves the estimation of components of the risk. In many cases, assumptions must be made to quantify a risk estimate. The components are often based on assumptions that differ in degree of conservatism. The use of "conservative bounding estimates" for some of the risk components and "best estimates" (most probable, average, etc.) for others severely complicates the understanding of the uncertainty of the final risk estimate. Unfortunately, many risk analysis processes use risk estimates from several different sources and management quickly becomes confused by the enormous range of risks. Furthermore, because inconsistent assumptions are applied, it

is impossible to make reasonable comparisons between different options (although this is not always recognized). As a result, regulators and policy makers will often select extremes in the name of conservatism. But, they have no idea of the degree (i.e., the event probability) of extremeness represented by the final result.

In the context of the EPA analysis, the definition of the MEI specifies an extreme event. For example, a person staying on the edge of a monofill for 70 years, with the wind always in the same direction, etc. These events have associated with them certain probabilities. Given that the event occurs, there is some consequence (e.g. a 10^{-4} chance of cancer).

Having made these definitions, we can point out what we believe is the fundamental problem with the MEI analysis as it presently stands. Traditionally, risk assessment has dealt with two extreme ends of the risk scale. One is the low probability-high consequence risk (e.g., nuclear reactor meltdown). The other is the high probability-low consequence risk (e.g., car accidents). The EPA approach is yet another extreme, namely a low probability-low consequence risk. That is, the probability that an MEI as defined actually exists is certainly very small, and in many cases zero, and the health consequence, given that this hypothetical person does exist, is 10^{-4} , or less. We believe that this problem has arisen because of a confusion of policy and science.

Policy Versus Science

The effort by EPA has clearly been driven by policy decisions rather than science. In view of the inherent uncertainties in risk assessment and the necessity for value judgements, the prominence of policy decisions is understandable. However, instead of acknowledging these policy decisions and justifying them on legal, political and social grounds, EPA has, in many cases, tried to make it appear that the basis for decisions was scientific. This problem permeates the entire effort. For example, on pages 6-3 to 6-5 of the Technical Support Document on Incineration, EPA "derived" a value for the percentage of total chromium which is hexavalent (the carcinogenic form) by averaging data from tests on two sludge incinerators. One test found Cr^{+6} at less than the detection limit of 10 mg/kg. The other test yielded a value of 130,000 mg/kg. A difference of at least four orders of magnitude! EPA assumed the lower value was the detection limit, calculated the geometric mean of 10 mg/kg and 130,000 mg/kg and multiplied by an uncertainty factor of 10 to give a value of 1% that was used to calculate the cancer risk. There is no scientific basis for this approach, but it looks scientific! It appears that for some reason EPA decided that 1% was a reasonable number and simply tried to find a way to generate it.

Another example of the attempt to gloss over uncertainties and to give an appearance of accuracy is a persistent use of more significant figures than can be justified. This problem leads to such absurdities as the use of 3.84×10^{-2} kg/ha as the maximum annual application rate for hexachlorobenzene when all the concentrations for such organics in the 40 City Survey were below the detection limit. Another example of this problem is the use of numbers such as 5976 for the baseline of lead risk in the case of incineration. The use of such numbers is dangerous in that it can give the impression that differences such as 5155

for Options II and III (see Table E of the Abt document (1989) and 5163 for Option III are meaningful. The uncertainties involved in the calculation are not only larger than the difference, but are likely to be larger than the difference between the highest value of 5976 and the lowest value of 4759 in the calculations. The same is certainly true for the differences in the annual cancer cases in the non-incineration options and probably true for all of the cases including incineration. Indeed, the extreme conservatism used, beginning with the plausible upper-bound nature of the carcinogen potency factors, means that there is no significant difference between the cancer cases calculated for incineration (about 12) and zero.

Part of the problem mentioned above arises from a failure to attempt a best estimate and a calculation of uncertainties. We feel this was a mistake. EPA did do some sensitivity analyses for certain parameters such as the distance to aquifers and the stack height of incinerators. These calculations showed that in some cases the risk was 2 or 3 orders of magnitude less than the default value used. Similarly, in view of the extraordinary values allowed for lindane, it would appear possible to have a sludge that is 100% lindane presenting little or no risk. Furthermore, these "uncertainties" do not include a consideration of the uncertainties involved in the cancer potency factors which are known to be as much as six orders of magnitude (Cothorn et al., 1986).

The uncertainties in the calculations are of particular concern when evaluating the significance of the costs and benefits estimated in Table XI-1 in the proposed Rules. For example, the estimated human health benefits for land application are 0.06 cancer cases avoided and a reduction of approximately 20 lead cases. Any reasonable evaluation of uncertainties would lead to the conclusion that the uncertainties are much larger than the calculated benefits.

Again, with some fear of appearing repetitive, we wish to emphasize that EPA has disguised policy decisions with the risk assessment assumptions and database, apparently to make it appear that the results were derived scientifically. Had they wished to do the effort correctly they should have, at the very least, clearly presented the underlying assumptions, data and models. Instead, these are scattered among numerous documents in a manner that is very difficult to access.

The apparent policy decisions that emerge are that incineration is not a favored option because it potentially exposes larger numbers of people leading to greater aggregate risk and that monofills are not favored because of the potential for high exposure to a few individuals. These considerations resulted from the application of a 10^{-5} lifetime risk for incinerators and an unreasonable MEI for monofills. But when the proposed rules are applied, inconsistencies inevitably result and the risks of the various options can not be fairly compared with one another. EPA states that it prefers beneficial use to incineration and yet the result may be to drive some municipalities toward incineration because of the apparent technical fix (i.e. electrostatic precipitator control technology) and the severe restrictions for land application. EPA's failure to include ash disposal and fly ash deposition risks of incineration (e.g., oxidation of Cr compounds, dioxin formation, and soluble As and Se) in the risk assessment will further contribute to this possibility.

Improvements

Instead of attempting to force numbers to justify policy decisions, EPA should be straightforward and clearly state policy decisions as they occur in the process. If, on the other hand, legal aspects require a risk-based approach, then EPA needs to do the assessment correctly, which means the assessment has to be scientifically based and complete.

The overall risk methodology that looks at the aggregate risks (Abt, 1989) indicates that incineration is the least preferred option compared to all land disposal options if one compares the results for lead. The reviewers believe that these results would be consistent for the other sludge constituents. These aggregate results are not, however, used in the application of the rules to determine the sludge management practices. Instead, policy decisions have been used, with apparent inconsistencies, to establish algorithms for disposal practices based on the MEI. It is apparent that the analysis methodology for the aggregate risks could be applied at each site to determine disposal practices allowed under a revised set of rules. Although this would entail a larger effort for EPA initially, the result would be more appropriate to achieve the desired results.

The proper application of risk assessment techniques should include the attempt to get a "best estimate" and the associated uncertainty band about this point estimate. Policy decisions can then be made to set a given degree of protection for a level of confidence or specific percentile. The selection of upper bounds leads to very improbable results where the application of the rules are driven by pure policy decisions in selecting the degree of conservatism versus trying to obtain a true understanding of the risk. The risk of the MEI is not meaningful if it is for a vanishingly small fraction of persons. The nature of risk assessment in using probabilistic models means the population at risk and pollutants of concern for the critical pathways must be properly defined. This is equivalent to obtaining the proper sample space in probability theory. The population at risk is the entire US population. The pollutants must be considered with conservation of mass and properly tracked in the environment including their pathways to target organisms. The results can use intermediate distributions (as opposed to single point estimates as an upper bound or worst case values) to represent possible outcomes. These distributions can be used to estimate the final distributions of the risk for each option. The appropriate policy decision can then be made based on the aggregate risks for the different disposal options. The policy decisions can now be reduced to algorithms for risk management and incorporation into the Rules. The critical factors for each decision, along with the potential need for research to resolve important uncertainties can also be identified for future modifications of the rules.

Because of the shortness of time involved in this review, we could not fully develop examples or alternative calculations to illustrate how to calculate uncertainties and estimate distributions. A brief example is given later. A general description of the process is given Gratt (1989b), and an example for an entire industry (oil shale) is given in Gratt et al. (1984).

We note that there has been a recent effort at EPA to do some of the analyses we are recommending. We have had a short time to review a July, 1988 draft report entitled "Feasibility of a Novel Approach Using Most Exposed Populations (MEP) as a Basis for Assessing and Comparing Risks of Sewage Sludge Disposal Options." While we are not in agreement with all of the methods being examined, we do think this effort is commendable and should have been an early step instead of an afterthought. At various points in this report, we illustrate ways in which we believe uncertainty could have been estimated. One example is given below.

The MEI for Land Application (Agricultural) Pathways 1, 3 and 4 analyses is an example of the problem of piling conservative assumption on top of conservative assumption. While one might argue that there are people who receive 2.5% of plant groups grown on sludge-amended land, etc., it is impossible for such a person to have the highest consumption of all the key food groups for 70 years from birth to death. Nor is it necessary to do so. Various food consumption surveys give data on consumption by age, sex, income, geographical region and other variables (Pennington, 1983). There is no need to take such a simplistic and erroneous approach.

Food consumption data can be used to choose variables such as income which maximize intake but at the same time use a food intake appropriate to the age and sex of the individual (Tsongas et al., 1980; Pennington, 1983). This approach could then lead to a best estimate and an uncertainty range. An additional discussion of dietary intake is given by the Land Application Workgroup.

The choice of 2.5% of plants from sludge-amended soils was, of course, arbitrary. It simply represents 100 times the average value. Whether that value is realistic or not, is virtually impossible to verify. But no one is going to (nor would want to) eat the diet of a 20 year old for 70 years.

REVIEW OF RISK ASSESSMENT

Approach and Presentation

EPA's proposed Rule aim to protect public health and the environment from any reasonably anticipated adverse effects of certain pollutants which may be present in sewage sludge. Heavy emphasis was placed upon the application of risk assessment methodologies. In developing its proposed limits, EPA made numerous decisions related to ultimate risk determinations including: Selection of pollutants to be evaluated; determination of which media (air, water, soil) transport the pollutants from sewage sludge into and through the environment; selection of target organisms (i.e., individuals or groups of humans, plants or animals) most likely to be effected by exposures to sludge; selection of mathematical models to simulate the movement of sludge components into the environment and ultimately to selected target organisms; definition of an effect of concern; and judgements about levels of risk that are adequate to protect human health and the environment.

In reviewing the approach that EPA has taken in this proposal, one could question almost any of the hundreds of data points and assumptions that have been applied and evaluate the strength of the scientific data upon which they are based. Indeed, this is done in the other sections of this report. The approach of the Risk Assessment Workgroup to this review, however, has been to focus on the major areas and assumptions that appear to drive the ultimate risk-associated decisions, and to de-emphasize in-depth evaluation of those for which the approach is consistent with general EPA and U.S. regulatory agency policy.

The proposed rule has been primarily based on the application of risk assessment methodologies to determine acceptable concentrations of pollutants to protect public health and the environment from any "reasonably anticipated adverse effects."

The proposed rule and supporting analyses, in many cases, have not provided the data generally considered necessary for the presentation of risk assessment results. At a minimum, the assumptions applied and the reasons for their selection should be clearly presented, with the associated uncertainties and their potential effect on risk considered.

For example, in its exposure assessments for the various pathways evaluated, the basis for the assumptions applied were often not clearly presented, and the methodologies for estimating the magnitude of exposures and the size of the populations exposed, were not always clearly provided. In its most complete form, an exposure assessment should describe the magnitude, duration, schedule and route of exposure; the size, nature and classes of the human populations exposed; and the uncertainties in all estimates. This information was often not clearly provided, or was provided inconsistently from pathway to pathway evaluated.

In estimating exposures, the risk assessor generally has several options available that will yield more or less conservative estimates of exposure. Among the options are different assumptions about the frequency and duration of exposure, rates of intake or contact, and rates of absorption or uptake. The reason for the selection of a particular option was not always provided and its effect on risk and ultimate allowable concentration not clearly presented.

In its presentation of ultimate risk information, the proposed Rule often did not provide the appropriate units necessary to fully characterize risk. For example, risk levels are presented as " 1×10^{-4} " without an indication of whether this applies to a lifetime or to an annual risk. Such units should be more clearly presented in the final document.

A convenient way to present the major risk assessment-related issues is to divide them into the appropriate category of the 4-step risk assessment process, as defined by the National Academy of Sciences (1983):

1. Hazard Identification: The evaluation of the data on the types of health injury or disease that may be produced by a chemical and on the conditions of exposure under which injury or disease is produced.

2. Dose-Response Evaluation: The evaluation of the quantitative relationship between the amount of exposure to a substance and the extent of toxic injury or disease.

3. Exposure Assessment: The estimation of the nature and size of the population exposed to a substance and the extent of toxic injury or disease.

4. Risk Characterization: The integration of the analysis from the previous three components to determine the likelihood that humans or other organisms will experience an effect of concern.

As a general comment, we feel that the citations in the various EPA documents can be improved. We recommend:

1) References should be to the original source, not a review or a government document, e.g., "U.S.EPA".

2) If "U.S.EPA" is appropriate (e.g. extracting a net conclusion from literature sources) the relevant page number(s) should be included in the reference. Otherwise, the citation is almost useless.

The above are standard practices for good reason, but are not adhered to in the technical support documents.

Hazard Identification

The Risk Assessment group did not address the completeness of the list of chemicals considered.

Blood lead and blood pressure

The Agency chose to use a two-pronged attack to calculate the effects of lead. Approach A used a threshold and estimated the number of individuals raised above thresholds for blood leads which were 7 $\mu\text{g}/\text{dl}$ for elevating blood pressure in middle-aged white males and 12.5 $\mu\text{g}/\text{dl}$ for women and young children. These respective values are not firmly established as either significant effect levels or thresholds, but their use for this purpose seems reasonable at this time. However, Approach B attempts to estimate the number of middle-aged males above the blood lead thresholds who would be expected to develop disease because of the elevated blood pressure. The scientific basis for this latter extrapolation is subject to question. Sharp et al. (1987) reviewed the data on lead and blood pressure and noted that while "These data suggest an association between past occupational lead exposure and hypertensive heart disease," the mediating link is "circumstantial." We believe that it is a leap of faith to attempt to calculate cases by Approach B and that only Approach A should be used for that aspect. We have no problems with Approach B for women (i.e., calculating the

percentage of women pregnant with blood leads over the threshold) or for children where every child above the threshold is a potential case.

Cadmium toxicity

The weight of evidence suggests that elderly women are the most sensitive population to cadmium toxicity as a result of their cumulative body burden resulting from longer life spans. Attention is called, however, to the fact that recent evidence points to the fetus as a possible candidate for the "most sensitive individual." Thus, there is a high negative correlation between placental cadmium exposure and physical development (Ward et al., 1987). It is well-known that smoking has a similar depressive effect on fetal development. Smoking also results in a substantial increase in the body burden of Cd and may depress fetal development due to factors other than Cd, e.g., CO and nicotine. The Cd correlation, however, was present even in the non-smokers. One other study also shows a relationship of Cd to birthweight, at least among smokers (Kuhnert et al., 1987). Maternal blood Cd accounted for 7.1% of the variance in fetal birth weight. Animal studies suggest a plausible mechanism for the Cd effect, reduction in placental blood flow (Levin and Miller, 1981). On the other hand, the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1989) recently considered these issues and decided to retain the kidney as the primary target organ of concern (JECFA, 1989). Their recommendation was that dietary Cd be less than or equal to 1 $\mu\text{g}/\text{kg}$ body weight for adults.

Dose - Response Evaluation

Reliance on data generated under artificial conditions

Biological systems are complex and behave differently from simple models. Thus, it is difficult to extrapolate greenhouse data to the field (in the case of phytotoxicity) or animal data to humans (in the case of human toxicology). Consequently, risk assessors dealing with human risk always look for human data (epidemiological studies of occupational or population groups) to corroborate animal data. When the results from animal studies disagree with those from human studies, there is a natural presumption that the results from the human studies are more reliable than those from animal studies, given equal study quality. This presumption is based on the fact that the target organism is a human and the uncertainties inherent in extrapolation from animals to humans, and from high to low dose (as is generally the case) are avoided.

A similar choice often occurs between in vivo versus in vitro data. Because of the complexity of biological systems, in vivo data is preferable because it reflects the entire organism, with all its homeostatic mechanisms intact. Similarly, it is reasonable to be skeptical of data on phytotoxicity that is obtained from pot studies as opposed to field studies. There are numerous factors that differ between the pot and field environments such as the molecular form of the toxin under consideration.

One behavior that is particularly difficult to model is the no effect level. Most low-dose extrapolation models are linear and assume a response to

any stimulus, no matter how small. However, thresholds are often observed in nature. If there are field or epidemiological data that indicate the existence of a no effect level or there is reason to believe there is a threshold, then instead of relying on linear models, EPA should examine the database to see if it can establish a NOAEL (No Observed Adverse Effect Level) or LOAEL (Lowest Observed Adverse Effect Level) as a means of deriving a maximum allowed concentration or loading.

Inappropriate choices of data

Good scientific judgement should be used in choosing data for development of limits on pollutants. An example of an inappropriate choice of data is found in the consideration of lead toxicity to avian species. The lead toxicity data cited by EPA on chickens, quail and ducks are all relatively consistent except for the one study used by EPA to select a threshold feed concentration of 39.6 $\mu\text{g Pb/g DW}$ (another glaring example of too many significant figures). Table 4-60 in the Technical Document on Land Application and Distribution and Marketing lists the studies considered by EPA and the doses and responses found in each study. Three studies showed no adverse effect at 100 $\mu\text{g/g DW}$ over periods of 28-56 days. Five studies showed mild toxicity, such as decreased weight gain and feed use at 500-2000 $\mu\text{g/g DW}$ over 28-56 days. Four studies found 10-50% mortality at 2000 to 10,000 $\mu\text{g/g DW}$ over 11-42 days. One study showed "mortality" (no mention of how much) at 200 $\mu\text{g/g DW}$ for "subacute" durations. Another study showed "death in 19-27 days" at 60 $\mu\text{g/g DW}$, while another (by the same author) showed death in "24-41 days" at 46 $\mu\text{g/g DW}$. It was the latter study that EPA chose to use. That study was the oldest of those considered (the paper appeared in 1951) by 15 years. In view of the advances in toxicology and analytical chemistry that occurred between 1951 and the 1970's when most of the papers appeared, it is peculiar that EPA made this choice. This would appear to be another example of the science being dictated by policy choices.

The Coburn et. al. (1951) study used by EPA is an outlier. The methods used by EPA can be used to develop a threshold from the other studies. These other studies consistently give a NOAEL of 100 $\mu\text{g Pb/g DW}$ and a LOAEL of 200-500 $\mu\text{g Pb/g DW}$. Using EPA's approach of taking the geometric mean of the NOAEL and LOAEL would give a value of 140-225 $\mu\text{g Pb/g DW}$ instead of 46.

The Land Application Workgroup report contains more detailed analysis of EPA's discussion of this pathway. Their analysis indicates other, more serious, errors than that presented here. But this use of "outlier" data is indicative of serious problems in the EPA analysis.

Pathogens

There is some concern regarding EPA's treatment of pathogens. While it was stated that the state-of-the-art was such that a risk assessment for pathogens was not possible, we feel that this point was glossed over rather quickly and needs greater justification.

Indeed, another office of EPA, the Office of Drinking Water, in a recently published document entitled "Comparative Health Effects Assessment of Drinking

infection from echovirus-6 exposure due to consumption of water containing one viral infectious unit per 1000 liters to be 10^{-3} and the annual risk of mortality for the same exposure to be less than 10^{-5} . Risk estimates were also obtained for exposure to hepatitis and other pathogens. These estimates were apparently based in part on a paper by Gerba and Hass (1986).

Use of nondetectable concentration

In the proposed rule, EPA has consistently chosen to deal with the problem of values below the detection limit by assuming them to be at the detection limit. This can lead to cascading errors. In particular, there is a problem with organics and pathways from the sludge to soil and plants.

Exposure pathways 1, 2, 5, and 7 deal with transfer of pollutants from the sludge to soil and to plants; from the plants they may be transferred to animals and to people, either through eating the plants or the animals. These pathways consider toxicity to the plants, to herbivores, and to people. Pathway 9 considers uptake of pollutants from the sludge by soil biota, and then by animals that feed on the biota.

One of the critical parameters in the equation for calculating the upper limit on the rate of application of sludge to agricultural land is the quantity transferred from the soil to the plant or to the soil biota. This quantity is expressed by the slope, VC, which is defined as

$$VC = \frac{\text{concentration in tissue (of the plant or soil biota)}}{\text{concentration in soil}}$$

where the relationship may, in fact, be non-linear e.g.

$$VC = \frac{(\text{concentration in tissue})^{1/2}}{\text{concentration in soil}}$$

When the concentration of the pollutant in either the tissue or the soil is less than the analytical detection limit, the lower limit of detection of the analytical method is assigned as the concentration. If both the tissue and the soil concentrations are below the lower limit of detection, the value of the slope is one. This arbitrary value of one (for which there is no basis in fact), has a profound effect on the calculated maximum rate of application of sludge, and introduces a large degree of uncertainty in the calculated results.

Surrogates

Another approach is to consider a surrogate (for example, benzo-a-pyrene is often used as a surrogate for polycyclic aromatic hydrocarbons) as opposed to performing numerous individual calculations for individual chemicals as part of the Rules. Rules can be developed by using sludge measurement data to select a single (or a few) relevant value for sludge application management. If the available data are insufficient to calculate risk with a reasonable degree of

a single (or a few) relevant value for sludge application management. If the available data are insufficient to calculate risk with a reasonable degree of certainty on the large number of chemicals and pathways considered, it would be more appropriate to base the proposed limits upon surrogate chemicals and scenarios for which data are relatively complete.

EXPOSURE ASSESSMENT

Most Exposed Individual (MEI)

EPA is proposing Rules to "protect public health and the environment from any reasonably anticipated adverse effects of certain pollutants which may be present in sewage sludge. To establish standards for the disposal of sewage sludge, the Agency evaluated the effect of a pollutant on the MEI, and on the population as a whole (aggregate risk analysis).

In our judgement, the definition of the "most exposed individual" used by the Agency is not consistent with the Agency's intent to protect the public health and the environment from reasonably anticipated adverse effects associated with potential sewage sludge exposure. The scenario of exposure assessed for the MEI is unreasonable (overly conservative) for the vast majority of individuals in the general population, and substantially overestimates actual exposure for the sector(s) of the population with the highest potential exposures from sewage sludge.

As an example of the unrealistic nature of the MEIs used, in the case of non-carcinogens, the 25-30 year old man is the MEI in pathways leading to man. This is so in all cases except for direct soil ingestion, in which case the child < 6 years is used. This seems overly simplistic. The MEI for human ingestion of food derived from sludge-amended soil varies from one non-carcinogenic metal to another. As an example, as discussed earlier, if nephrotoxicity is used as the critical endpoint for the toxicity of cadmium in humans, the MEI is probably the elderly woman. If, on the other hand, one agrees with recent information suggesting that the MEI is the fetus, the appropriate MEI is the pregnant woman. Need to consult appropriate biologists also is evident in the case of identification of the duck as the MEI for lead. Ducks apparently do not tend to forage in fields for earthworms. A Canadian Goose or some other species may be a more appropriate MEI. For further discussion regarding problems with this MEI, see the section on Lead: Pathway 9 of the Land Application report.

Regardless of which human MEI is used, dietary intake of pollutants should take into account the shifting relative and total consumption of dietary constituents as a function of sex and age, as was mentioned earlier.

Relevant expertise which takes into account all readily available data was not used as an integral part of the risk assessment in the development of these scenarios. It is unreasonable to create a scenario that results in a 10^{-2} individual life time cancer risk if the probability of this scenario occurring is of the order of 10^{-4} per lifetime. It appears that the MEI is a set of unreasonable scenarios (of low probability of occurrence).

The MEI can be developed from consideration of exposures over a lifetime that results in an individual risk distribution (e.g. lognormal). This allows selection of a certain point in the distribution (e.g. 90th or 98th percentile) to represent the MEI for development of calculational algorithms for regulatory purposes. This approach should use the databases consistent with the relevant expertise on the pathways under consideration. Policy, or lack of positive findings, should not cloud this process. The estimates of relevant parameters and variables can include some of the assumptions applied in the current proposal, but those features considered "extreme" estimates should be identifiable as such in the development of a revised and more realistic MEI. The concept of MEI (which implies a least upper bound) should be replaced by an exposure unit which is reasonably calculable (RCEU).

Exposure Models

Biokinetic models are often used as surrogates for real data on real people. A number of different models, of varying degree of complexity are in use. For example, in determining the limits for airborne concentrations of radioactive particulates, use is made of the multi-compartment lung model published by the International Commission on Radiological Protection (ICRP). This model considers particle size distribution and solubility of the aerosol. These considerations lead to realistic estimates of the quantity and site of deposited particulates and to the translocation kinetics of the deposited particulates. In contrast to this relatively sophisticated - yet practically useful - lung model, the proposed Rule is based simply on daily deposition and retention of all the particulates suspended in 20 cubic meters of air. This leads to a highly unrealistic overestimate of the risk from airborne particulates. The same oversimplifications and consequent overestimation of risk characterize the assumptions applied to gastrointestinal absorption from ingestion of pollutants in the EPA risk analyses.

We recommend that scientific data for intake and absorption of specific chemicals be used to determine maximum acceptable inhaled or ingested quantities. In the absence of chemical-specific data, biokinetic models that realistically describe the intake, uptake, deposition, and elimination of the pollutants of concern should be applied.

A good example of model application, and perhaps the most critical one here, involves the uptake of lead from soil by young children. The considerations for the child ingesting soil/sludge mixtures lead to a cumulative loading limit of 195 kg/ha, or an additional 97.5 mg/kg. These values, totaling 73.5 mg/kg and 108.5 mg/kg when background is included, are unrealistically low, and are well within the range found in relatively non-sludged soils in most urban areas.

The problem of finding a protective concentration of lead in sludge/soil mixtures is divisible into two general questions 1) how much soil do children ingest? and 2) how readily absorbed are sludge-derived pollutants in soil? EPA has developed a biokinetic model for lead uptake from multiple sources (U.S.-EPA, 1986). This model includes soil and dust as sources. Blood lead

concentration (PbB) is used as the surrogate for internal dose. This is for two reasons: 1) the model can be validated because data sets are available relating soil Pb to PbB and 2) the toxicological consequences of Pb exposure can be readily assessed using PbB as the dose component of "dose-effect."

We suggest that EPA consult its staff paper (U.S.-EPA, 1986) and Hoffnagle and Decesar (1987). The latter report is essentially a validation exercise, using actual PbB and soil Pb data from three major field studies. From these two documents, a scientifically-derived estimate of the impact of sludge-amended soil on lead exposure in children can be achieved. A recent EPA study for the Bunker Hill Superfund Site (U.S.-EPA, 1988) used this approach. The conclusion reached was that "maximum protection (in the absence of an intervention program) is expected to be at soil/dust lead concentrations of approximately 250 mg/kg (to yield blood lead levels of approximately 10 μ g/dl for < 3% of the population)." Such a level would allow a cumulative loading of approximately 500 kg/ha by sludge application. This number is not significantly different from the 300 mg/kg or 600 kg/ha recommendation that is discussed in great detail in the Land Application Section of this report. The Risk Assessment Subcommittee agrees that 300 mg/kg or 600 kg/ha presents a low risk to the highly improbable event of a pica child chronically consuming sludge/soil mixtures.

EPA apparently has several groups working on lead-related risks. The Agency should consider trying to pull together these efforts to develop a consistent approach.

RISK CHARACTERIZATION

Best Estimates and Uncertainties

Using risk assessment to develop acceptable concentrations for various sludge disposal practices is admirable. Unfortunately, the application of the risk assessment methodology is inconsistent between the disposal practices in terms of both the assumptions and data. Examples of data inconsistencies are readily apparent in EPA's use of medians, means, and 98th percentile. Where upper bounds and safety factors are applied they should be clearly described and justified as policy rather than scientific decisions.

The key criticism of the approach is the use of maximum or upper bound estimates when data to support realistic estimate are available. This criticism is important because the inconsistent treatment of relevant data may force choosing a disposal option that results in higher risk than that based on a more consistent (or fairer) treatment of the data. When EPA scientists were asked why best estimates were not provided with the associated ranges of uncertainty, the answer was "we don't know how." In our judgement, worst case risk assessment may be useful for screening, but not for management of the sludge disposal options. A best estimate of the risk with a probable upper bound and a probable lower bound should be presented for policy decisions and development of regulations.

The aggregate risk assessment applied for lead and cadmium appears to be an initial attempt at a meaningful best estimate. For carcinogens, presentation

of the results based on the maximum likelihood estimate in addition to the 95% upper bound Q_1^* results should be considered. For both carcinogens and noncarcinogens, the analysis should use more realistic assumptions with an appropriate uncertainty bound on the result. The bounds would not necessarily be used in the ultimate regulatory decisions, but would aid assessment of the differences between use of the individual risk and the true impact of the rule on the overall populations-at-risk.

Incineration

The incineration analysis considered the sensitivity of the ambient air concentrations around the incinerator as a function of meteorology, stack height and gas temperature (Abt, 1989). Using the sensitivity analysis, EPA calculates allowable sludge pollutant concentrations using a simplified air model based on stack height and pollutant control efficiency for a risk specific dose (RSD). Under the proposed Rule, the facility can demonstrate compliance at any of three levels of increasing complexity: 1) using the EPA dispersion factor and control efficiencies contained in the proposed Rule, based on a simplified air dispersion analysis technique, 2) using the site-specific values for dispersion factors while using the control efficiencies provided in the Rule, and 3) using site-specific dispersion factors and control efficiencies (requires performance tests and stack sampling of incinerator emissions to compute control efficiencies).

The question is why site-specific modeling with POTW-specific data that allows use of the modeling feature available (e.g. particle-size distributions and dispersion-by-size class) should not be allowed? The development of simplified techniques presents problems that would be avoided by site-specific analyses, which may be in reality easier (especially if air quality results are needed for other regulatory concerns). As an example, the measured metal content of the sludge and the sludge incineration rate can be used as the source term calibration with measured particle-size distributions at the stack exit for particle-size class dispersion. Appropriate settling velocity and deposition partitions can be used to calculate the ambient concentrations in particle-size classes available for inhalation and the deposited particles available for human exposure via other pathways. The particles below $0.1 \mu\text{m}$ mean aerodynamic diameter can be assumed to be re-respired and those greater than $10 \mu\text{m}$ to be stopped in the nasal passages. Thus, only a fraction of the emissions will be available for inhalation and pollutant dose in the human lung. In the case of oil combustion, two distinct particle-size classes have been observed with a break at about $10 \mu\text{m}$. Only 50% of the pollutant available for the "lung exposure." If this result were typical, and a 50% deposition were considered, the RSD could be increased by a factor of 4.

Other concerns also arise from the risk assessment review of incineration. One of these is the grid used. Why use a 50 km polar grid when most of the exposure is within the first km? It is predicted that closer spacing will result in higher maximum ground level concentrations than the current methodology.

The primary concern should not be the MEI but the amount of pollutant released that enters a human. The total amount of pollutant that is calculated to be inhaled represents only a small fraction of the total amount released. This fraction can be estimated using a representative mixing height and

concentration for the entire area. Much of the pollutant leaves the 50 km circle and represents a potential health impact in populations from long range transport of the pollutants. The use of Carcinogen Assessment Group (CAG) risk and potency factors means that even low levels in very large populations may result in significant numbers for aggregate health impacts.

Methods are available to estimate these risks. Treatment of each known carcinogen for which factors are known represents a large uncertainty. The small number of carcinogens that are considered in this analysis makes one wonder how many have been omitted. If it is a few, the results are relevant. But if it is tens of thousands, the risks may be drastically understated. An approach to this problem would be to use a "sludge surrogate" for all causes of premature death. Fine particulates emitted from an incinerator stack may be a more appropriate measure all health impacts resulting in premature death. The application of such a surrogate would illustrate the risk management preference for "land related" forms of sludge disposal.

The Technical Support Document had some inconsistencies and/or typographical errors that need to be addressed. On page 1-2, the MEI is stated to "absorb 100% of all pollutants inhaled" but on page 5-8 the statement about the dose received by the MEI is "with 75% of the contaminant mass being absorbed into the body."

Another picky comment concerns the example calculation to determine the sludge concentrations on page 5-12. The control efficiency (FE) is assumed to be 95% but the equation used is $FE = (1 - 0.96) = 0.04$ with a further confusing reference to Table 7-2 (which is 96% for chromium).

Numerical Example

A numerical example was constructed to illustrate some of the proposed methodology improvements. The example is related to metal ingestion as considered in pathway 2F. The example concerns the estimate of change in the concentration of pollutant X (e.g., Pb) in the blood of young children due to ingestion of soil/sludge mixtures. The calculation is:

$$XB = A \cdot B \cdot C \cdot D \cdot k \cdot (\mu\text{g}/\text{dL})$$

where XB is the blood concentration of pollutant X, A is the concentration of X in the sludge/soil mixture (in $\mu\text{g X/g}$ sludge/soil), B is the soil ingestion rate for children (mg soil/day), C is the percentage of total soil ingested that is soil/sludge (%), D is the change in blood X ($\mu\text{g}/\text{dL}$) per $\mu\text{g}/\text{day}$ ingested and k is a constant for adjustment of the units ($k = 10^{-3} \text{ mg}/\mu\text{g} \times 10^{-2}/\% = 10^{-5}$). (Note that the EPA Rule is based on using A as an unknown with C as 100% and solving for the change in blood level with respect to a threshold.)

Instead of single values, a set of three values for each variable are considered in Table 1 where the middle value is a "best estimate" and the low and high represent "liberal and "conservative" estimates.

There are a myriad of methods to analyze the tabulated data. It appears the EPA approach is to construct a "worst case" type of scenario. This implies that all high values would be used. That is, the "MEI" value is

$$XB_{\max} = 1000 \times 500 \times 70 \times 0.15 \times 10^{-5} = 52.5 \mu\text{g/dL}$$

If a "policy decision" is made by using more representative values, say 50 mg/day ingested (the median value for soil ingestion [Calabrese et al., 1988]), 50% of the soil ingested as sludge instead of 70% and 0.1 as the change in blood lead per $\mu\text{g X/day}$ instead of 0.15, the result is

$$XB = 1000 \times 50 \times 50 \times 0.1 \times 10^{-5} = 2.5 \mu\text{g/dL}.$$

This new value then has a result with policy decision in the data selection imbedded into the estimation process.

Table 1 Example Case Values for Variables

Variable:	Value			
	A	B	C	D
Low	10	10	5	0.07
Middle	100	50	10	0.10
High	1000	500	70	0.15

The example data set represented by Table 1 allows for $3^4 = 81$ individual outcomes that can be calculated. The relation of the values of 52.5 $\mu\text{g/dL}$ and 2.5 $\mu\text{g/dL}$ can be related to these possible outcomes or a distribution function for the change in blood lead based on distributions for the individual variables. As an illustration, a distribution function assuming these outcomes are equally likely results in 2.5 $\mu\text{g/dL}$ as the 88th percentile and 52.5 $\mu\text{g/dL}$ as the 98.8 percentile (80/81). The 50th percentile is 0.05 $\mu\text{g/dL}$. This value is a factor of 10^3 less than the "MEI" value.

The appropriate method for the estimate is to provide a reasonable set of values for each estimate, estimate the distribution of the desired quantity and then make the policy decision on the final (e.g., risk) distribution. This method could avoid generation of MEIs based on unreasonable scenarios.

To continue the example, the probabilities of the individual high and low values can be varied. The other cases to be considered are the case where middle values are twice as likely as either the high or low, which are of equal probability, and the case where the middle value has a probability of 80% and the high and low are of equal probability (10%). The numerical results describing the resulting discrete probability and cumulative distribution

functions are shown in Table 2. Figure 1 illustrates the resulting probability density functions. For the case of the high and low at half of the middle probability, 2.5 $\mu\text{g}/\text{dL}$ corresponds to the 91.3th percentile and 52.5 $\mu\text{g}/\text{dL}$ to the 99.6th percentile. The case where the high and low are at 10% probability, 2.5 $\mu\text{g}/\text{dL}$ is the 98.1th percentile and 52.5 is the 99.99th percentile. In all three cases the 50th percentile is 0.05 $\mu\text{g}/\text{dL}$. The cumulative distribution can then use a stated policy decision to regulate based on the 90th percentile by selecting a value of either 3.5, 1.75, or 0.245 $\mu\text{g}/\text{dL}$ depending on which case is selected to be representative.

The impact of the assumption on the individual distributions can be studied using a sensitivity analysis. Actually, log normal fits to the data are often appropriate and would obviate the need for selection among the cases. The use of continuous distributions using nonparametric methods to obtain estimates for an assumed log normal fit for the calculated result (e.g., risk) is recommended. Further effort on this type of analysis may help reveal the difficulties with the MEI approach as now used (e.g., how extreme the percentile of the scenario becomes even though the techniques used have difficulties at the "tails" of the distribution).

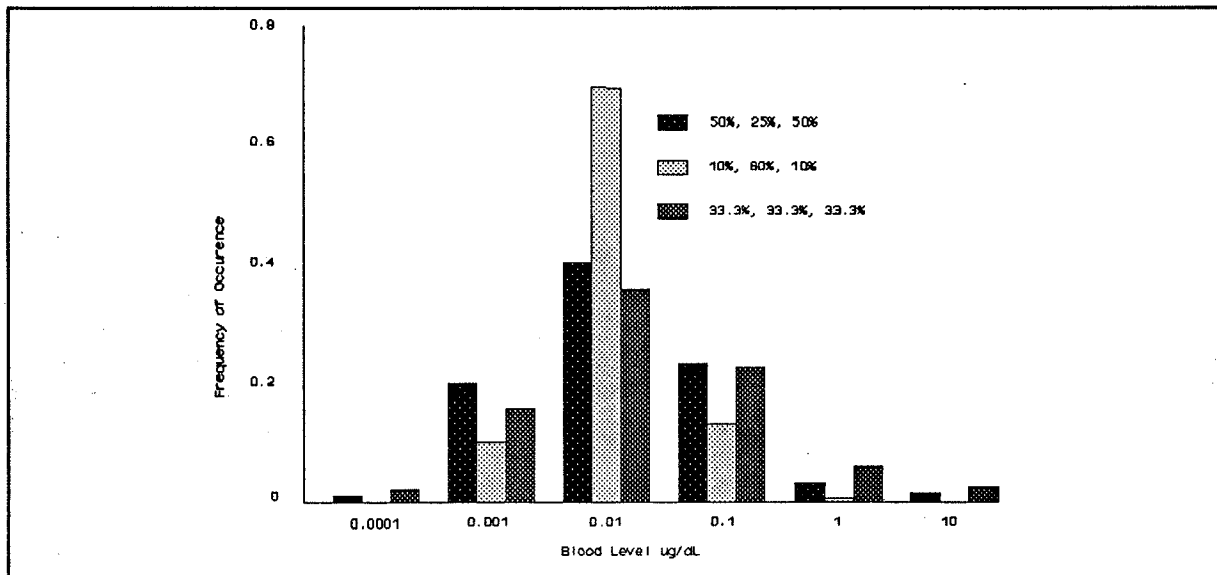


Figure 1. Example Probability Density Function

Table 2 Example Case Calculated Probabilities

Number	Change in X Lead	Case A: High, Middle and Low Values Equally Likely		Case B: High & Low at Half of Middle Value Probability		Case C: High & Low Values at Probability of One-tenth	
		Frequency	Cumulative Frequency	Frequency	Cumulative Frequency	Frequency	Cumulative Frequency
1	0.0004	0.0123	0.0123	0.0042	0.0042	0.0001	0.0001
2	0.0005	0.0123	0.0247	0.0083	0.0125	0.0069	0.0070
3	0.0007	0.0123	0.0370	0.0083	0.0208	0.0001	0.0071
4	0.00075	0.0123	0.0494	0.0042	0.0250	0.0009	0.0080
5	0.001	0.0123	0.0617	0.0167	0.0417	0.0001	0.0081
6	0.0015	0.0123	0.0741	0.0083	0.0500	0.0009	0.0089
7	0.0018	0.0123	0.0864	0.0083	0.0583	0.0001	0.0090
8	0.0025	0.0123	0.0988	0.0167	0.0750	0.0009	0.0099
9	0.0035	0.0123	0.1111	0.0167	0.0917	0.0001	0.0100
10	0.0035	0.0123	0.1235	0.0083	0.1000	0.0009	0.0109
11	0.00375	0.0123	0.1358	0.0083	0.1083	0.0551	0.0659
12	0.0049	0.0123	0.1481	0.0042	0.1125	0.0009	0.0668
13	0.005	0.0123	0.1605	0.0333	0.1458	0.0069	0.0737
14	0.005	0.0123	0.1728	0.0167	0.1625	0.0009	0.0745
15	0.007	0.0123	0.1852	0.0167	0.1792	0.0069	0.0814
16	0.007	0.0123	0.1975	0.0083	0.1875	0.0009	0.0823
17	0.0075	0.0123	0.2099	0.0083	0.1958	0.0069	0.0891
18	0.0075	0.0123	0.2222	0.0167	0.2125	0.0009	0.0900
19	0.01	0.0123	0.2346	0.0333	0.2458	0.0001	0.0901
20	0.0105	0.0123	0.2469	0.0042	0.2500	0.0069	0.0970
21	0.015	0.0123	0.2593	0.0167	0.2667	0.0001	0.0971
22	0.0175	0.0123	0.2716	0.0042	0.2708	0.0009	0.0980
23	0.0175	0.0123	0.2840	0.0042	0.2750	0.0001	0.0981
24	0.0175	0.0123	0.2963	0.0167	0.2917	0.0009	0.0989
25	0.0245	0.0123	0.3086	0.0083	0.3000	0.0001	0.0990
26	0.025	0.0123	0.3210	0.0333	0.3333	0.0009	0.0999
27	0.025	0.0123	0.3333	0.0083	0.3417	0.0001	0.1000
28	0.025	0.0123	0.3457	0.0083	0.3500	0.0009	0.1009
29	0.035	0.0123	0.3580	0.0333	0.3833	0.0551	0.1559
30	0.035	0.0123	0.3704	0.0083	0.3917	0.0009	0.1568
31	0.035	0.0123	0.3827	0.0167	0.4083	0.0069	0.1637
32	0.035	0.0123	0.3951	0.0042	0.4125	0.0009	0.1645
33	0.035	0.0123	0.4074	0.0083	0.4208	0.0069	0.1714
34	0.0375	0.0123	0.4198	0.0042	0.4250	0.0009	0.1723
35	0.0375	0.0123	0.4321	0.0042	0.4292	0.0069	0.1791
36	0.0375	0.0123	0.4444	0.0167	0.4458	0.0009	0.1800
37	0.049	0.0123	0.4568	0.0083	0.4542	0.0069	0.1869
38	0.05	0.0123	0.4691	0.0167	0.4708	0.4404	0.6273
39	0.05	0.0123	0.4815	0.0083	0.4792	0.0069	0.6342
40	0.05	0.0123	0.4938	0.0667	0.5458	0.0551	0.6892
41	0.05	0.0123	0.5062	0.0167	0.5625	0.0069	0.6961
42	0.0525	0.0123	0.5185	0.0083	0.5708	0.0551	0.7512
43	0.07	0.0123	0.5309	0.0083	0.5792	0.0069	0.7581
44	0.07	0.0123	0.5432	0.0167	0.5958	0.0551	0.8131

Table 2. Continued

Number	Change in X Lead	Case A: High, Middle and Low Values Equally Likely		Case B: High & Low at Half of Middle Value Probability		Case C: High & Low Values at Probability of One-tenth	
		Frequency	Cumulative Frequency	Frequency	Cumulative Frequency	Frequency	Cumulative Frequency
45	0.075	0.0123	0.5556	0.0083	0.6042	0.0069	0.8200
46	0.075	0.0123	0.5679	0.0083	0.6125	0.0009	0.8209
47	0.075	0.0123	0.5802	0.0333	0.6458	0.0551	0.8759
48	0.075	0.0123	0.5926	0.0042	0.6500	0.0009	0.8768
49	0.1	0.0123	0.6049	0.0167	0.6667	0.0069	0.8837
50	0.105	0.0123	0.6173	0.0083	0.6750	0.0009	0.8845
51	0.15	0.0123	0.6296	0.0083	0.6833	0.0069	0.8914
52	0.175	0.0123	0.6420	0.0083	0.6917	0.0009	0.8923
53	0.245	0.0123	0.6543	0.0042	0.6958	0.0069	0.8991
54	0.245	0.0123	0.6667	0.0042	0.7000	0.0009	0.9000
55	0.245	0.0123	0.6790	0.0167	0.7167	0.0001	0.9001
56	0.25	0.0123	0.6914	0.0167	0.7333	0.0069	0.9070
57	0.35	0.0123	0.7037	0.0083	0.7417	0.0001	0.9071
58	0.35	0.0123	0.7160	0.0167	0.7583	0.0009	0.9080
59	0.35	0.0123	0.7284	0.0083	0.7667	0.0001	0.9081
60	0.35	0.0123	0.7407	0.0333	0.8000	0.0009	0.9089
61	0.375	0.0123	0.7531	0.0083	0.8083	0.0001	0.9090
62	0.49	0.0123	0.7654	0.0042	0.8125	0.0009	0.9099
63	0.5	0.0123	0.7778	0.0333	0.8458	0.0001	0.9100
64	0.525	0.0123	0.7901	0.0042	0.8500	0.0009	0.9109
65	0.525	0.0123	0.8025	0.0167	0.8667	0.0551	0.9659
66	0.525	0.0123	0.8148	0.0042	0.8708	0.0009	0.9668
67	0.7	0.0123	0.8272	0.0083	0.8792	0.0069	0.9737
68	0.75	0.0123	0.8395	0.0167	0.8958	0.0009	0.9745
69	1.05	0.0123	0.8519	0.0042	0.9000	0.0069	0.9814
70	1.75	0.0123	0.8642	0.0042	0.9042	0.0009	0.9823
71	2.45	0.0123	0.8765	0.0083	0.9125	0.0069	0.9891
72	2.5	0.0123	0.8889	0.0083	0.9208	0.0009	0.9900
73	3.5	0.0123	0.9012	0.0167	0.9375	0.0001	0.9901
74	3.5	0.0123	0.9136	0.0083	0.9458	0.0069	0.9970
75	3.75	0.0123	0.9259	0.0042	0.9500	0.0001	0.9971
76	5	0.0123	0.9383	0.0167	0.9667	0.0009	0.9980
77	5.25	0.0123	0.9506	0.0083	0.9750	0.0001	0.9981
78	7.5	0.0123	0.9630	0.0083	0.9833	0.0009	0.9989
79	24.5	0.0123	0.9753	0.0042	0.9875	0.0001	0.9990
80	35	0.0123	0.9877	0.0083	0.9958	0.0009	0.9999
81	52.5	0.0123	1.0000	0.0042	1.0000	0.0001	1.0000
Totals		1.0000		1.0000		1.0000	

Values for individual components of calculation for change in BI Level of pollutant X (XB = A B C D) are in Table 1.

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LAND APPLICATION - AGRICULTURE

LAND APPLICATION - AGRICULTURE

George O'Connor, Rufus Chaney, James Ryan, Dale Baker, Ken Barbarick, Andrew Chang, Richard Corey, Robert Dowdy, Paul Fitzgerald, and Thomas Hinesly (Primary Authors) with assistance from Herman Cember, George Woods, David Taylor, and John Walker

SUMMARY

1. The EPA documents (Proposed Rule and Technical Support Document) suffered from serious scientific deficiencies. Corrections of these deficiencies showed that application of median sludges at agronomic rates comprised little risk to humans, livestock, wildlife, or the environment when utilized on agricultural land.
 - a. Only data from field studies of sludge-applied metals should be used to derive pollutant transfer coefficients. Such data are readily available, including important "No-Adverse-Effect" data that should not be ignored in preparation of this Rule.
 - b. Data misinterpretation and misuse was common in the TSD. Scientists knowledgeable about the fate and effects of sludge-applied pollutants should be enlisted to assure correct interpretation of research data. During the present evaluation, only part of the data in the TSD were reviewed.
2. The risk assessment components of the EPA Proposed Rule and TSD need considerable improvement.
 - a. The Most Exposed Individual definition and use are unrealistic and cause false estimations of risk.
 - b. Diet scenarios are inappropriate.
 - c. Relative effectiveness of Dose coefficients were assumed by EPA to be 1 in nearly all cases, but appropriate data indicate that they should have been $\ll 1$ in many cases significant to the proposed Rule.
3. Computer models of risk assessment from sludge-applied pollutants are inadequate. Conceptualization is poor, and validation with field results was missing.
4. The Proposed Rule suffers from problems in analysis of pollutants in sludges. Proposed techniques should be verified in sludge matrices. Further, limits of detection in analytical techniques were misused in estimating pollutant transfer coefficients.

5. Additional sludge constituents need consideration in the Proposed Rule. Sludge F and Fe can cause toxicity to livestock and wildlife by direct ingestion of some sludges.
6. Those sludges ("Clean Sludges") which contain low enough concentrations of pollutants that they can be used on agricultural land with no significant risk to humans, livestock, wildlife, or the environment should be placed in a separate category and constrained by labeling.

INTRODUCTION

Land application is an efficient, cost-effective method of sludge disposal that also recycles plant essential nutrients in the sludge to the soil-plant system. Sludge additions can also improve soil physical and chemical properties. Thus, land application of sludge in the agricultural sector is responsive to EPA's policy of promoting beneficial use of sludge.

Balanced against these well-documented benefits of agricultural utilization of sludge are environmental concerns based on potential risks arising from heavy metals, toxic organics, and pathogens in the sludge. Excessively high rates of sludge application can also cause excessive levels of soluble salts that can reduce plant yields, or excessive leaching of $\text{NO}_3\text{-N}$. Straightforward management procedures can solve the salinity problem and prevent excessive nitrate leaching. These issues will, therefore, not be considered further.

The EPA has proposed a Rule (Federal Register 54:5746-5902, 1989) for the disposal of sewage sludge when sludge is applied in various land use scenarios. This discussion centers on various aspects of the Rule as it applies to agricultural use.

The Rule, as proposed, threaten to severely limit agricultural use of sludge based on risk assessment associated with various pathways of transfer of sludge constituents to humans, animals, and biota, and with environmental damage. We believe the analysis to be flawed on several counts and attempt to document them below. Our approach was to address several issues associated with the analysis generically, and to provide specific examples of critical review for the most-limiting pathways and constituents. As time and resources permitted, we suggested alternative approaches to protect against identified risks, indicated data representing a more appropriate basis to compute the transfer coefficients, relative effectiveness, and other estimates needed to compute each pathway. Where possible, we estimated the more appropriate limits of application for a reviewed pathway/constituent after correcting identified errors in the Technical Support Document (TSD). The reader should note that for clarity, we used the abbreviation mt = metric ton where the TSD used Mg = megagram = 1000 kilograms. Further, abbreviations which are not defined in this document are those of EPA from the TSD.

We did not regard it as our responsibility nor did time permit us to correct every error in the Proposed Rule or in the TSD. We trust that EPA will accept the examples given as impetus to review the entire process with input from sludge experts.

GENERIC ISSUES

Metals

Use of data from studies of soluble metal salt additions to pots in place of sludge-applied metals in the field to estimate slopes of plant uptake: Metals in sludges occur in many different forms, some of which have very limited solubility. As a result, the metal activity and soil solution concentrations supported by a given soil-sludge mixture will often be orders of magnitude lower than those supported by the same amount of metal added to soil as soluble salts. Thus, the plant uptake slopes for metal salt additions are much higher than with sludge borne metals. Additionally, the predicted phytotoxic soil metal levels, so important in certain pathways of the risk assessment, are much lower with soluble metal salts than with sludge-metals. This effect is illustrated dramatically by the data of Hinesly et al., 1984 (Figure 1). In their study, Cd additions were made as CdCl₂ or as sludge-borne Cd, at various soil Cd loadings. There is a clear difference in plant response (uptake, tissue concentration) between the two Cd sources. Sludge-borne Cd data suggest a plateauing in plant responses with increasing Cd additions. Similar data are available for other sludge-borne cationic metals (Corey et al. 1987). Both curves could be extrapolated to tissue Cd contents associated with phytotoxicity (200 mg/kg DW leafy vegetable; Mahler et al. 1978). The difference is that the Cd application corresponding to this tissue Cd level would undoubtedly be greater with sludge-borne Cd than CdCl₂ (if indeed the sludge Cd line ever reached 200 mg Cd/kg DW). The difference in plant uptake of metals applied as metal salts vs. as sludge is probably similar for Zn, and even greater for the more strongly bound metals such as Cr, Ni, and Cu. Results such as these are the basis for the strong recommendation of Page et al. (1987) that data derived from soils treated with metal salts should never be used as surrogates for sludge-metal studies.

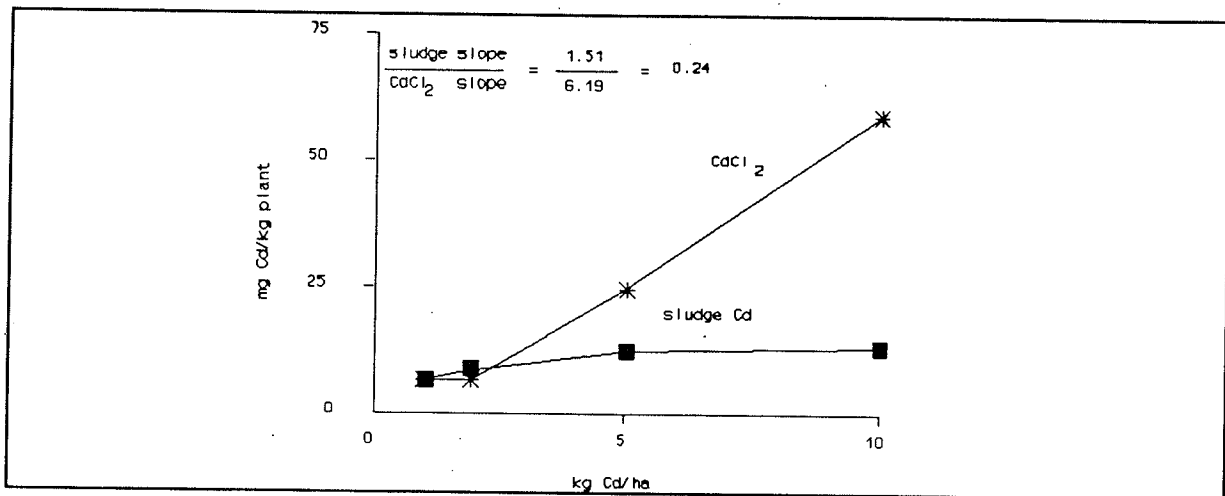


Figure 1. Comparison of crop uptake of Cd from a soil with additions of CdCl₂ vs. sewage sludge.

Lowest "no-adverse-effect" sludge rate data should not be ignored: Research has shown that data from sludge-borne metals used in field studies after 1 or more years, with biologically-processed sludges, are the only valid data for evaluating plant responses. Such studies often result in plant tissues with metal levels insignificantly different from controls. Such "no-adverse-effect" data were ignored by EPA in evaluating phytotoxicities, often in favor of data from metal salt studies, where the level of metal additions were not as high. We maintain that the "no-adverse-effect" data are, in fact, of prime importance in a meaningful evaluation of potential for risk. The highest metal application rate which causes no significant yield reduction of sensitive crops grown in acidic sludge-amended fields is a valid number in estimating phytotoxicity limits. This number is even more critical where no valid field study demonstrating phytotoxicity from sludge-applied metals exists.

Use of yield depression as an indicator of individual metal phytotoxicity: Yield depressions can result from many factors, particularly when very high sludge rates are used, and when data are collected the first or second year after sludge application. High sludge additions can result in excessive accumulation of soluble salts in soils. The problem can be severe in greenhouse pot studies, but can also occur in the field, particularly on fine-textured soils. High single applications of sludge almost always produce excessive amounts of mineral N which can create nutrient imbalances in plants. Excess N generally favors vegetative growth at the expense of tuber, edible root or seed production (or causes lodgings of grain plants). Thus, decreases in edible product yield may temporarily be associated with N imbalance, not metal toxicity. High microbial activity associated with large sludge additions increase the probability of anaerobic conditions following rainy periods, particularly during the first year after application. This can reduce yields and change relative uptake rates of metals. Further, these conditions increase metal diffusion rates to roots, increasing the soil to plant transfer during the first year. The only way a yield reduction can be reasonably attributed to a phytotoxic level of a specific sludge-borne metal is if the metal concentration in plant leaves (tissue concentration) exceeds a level generally recognized to indicate specific metal phytotoxicity. Even this approach can be compromised if the metabolic processes of the plant have been perturbed by a nutrient imbalance, by soluble salt accumulation, or by toxicity of another element.

Significant figure errors: In many cases, the TSD overstates the number of significant figures for the slopes, etc., obtained by their calculations. The TSD shows three significant figures regardless of the original data from which the indicated numbers were obtained. This is not appropriate, and should be carefully examined during revision of the TSD.

Sludge definition: Careful attention should be given to the definition of sludge when selecting data to estimate pollutant transfer coefficients. Metals in sludges highly polluted by industrial discharges may have received no or ineffective biological treatment; also, metals in these sludges often behave more like metal salts than metals in sludges of typical (median) concentrations. Thus, studies conducted with these materials overestimate the bioavailability of metal in typical municipal sludges.

Appropriateness of references: Critical references were frequently found to be inappropriate for the intended use (see metal salt phytotoxicity discussion above). In a few cases, even these references were misinterpreted. For example, an error in reference interpretation relative to Pb (Pathway 9) reported the data as mg Pb/kg diet when the data were for mg/kg body weight. In other pathways, the TSD recorded metal applications as kg/ha when the actual data were mg DTPA-extractable metals/kg soil. These misinterpretations identified incorrect critical pathways.

Inconsistent application of results: For example, Pathway 8 for Cu utilized data from a study of applied metal salts because sludge-metal studies showed "no-adverse-effect" (see above). With other metals, however, no data of any kind could be found, so no limits were calculated.

Another example is in the Cr risk analysis. Studies of Cr applied in sludges were overlooked in favor of studies of applied Cr salt or Cr-containing industrial wastes. There are several studies of Cr toxicity and plant uptake from serpentine soils. Such soils naturally contain very high Cr levels ($\geq 10,000$ mg/kg), but exhibit no Cr toxicity and do not cause significant true Cr uptake (see Cr section below). Additional examples are given under the specific pathways studies for "Group I and II" metals (below).

Organics

Toxic organics in sludges present special problems because of analysis complexities, scarce data bases and contamination problems not shared by metals. Investigators have taken several "short cuts" to minimize analytical difficulties and have only learned over long periods the shortfalls of methodic errors. The unsuspecting reader of the literature may be lead into several errors as exemplified in the EPA TSD.

Use of ^{14}C data: ^{14}C -labeling of compounds can greatly simplify analytical efforts and is much more widely used by researchers than, for example, GC/MS analysis at trace levels. Radioisotope labeling and assay, however, is only appropriately used as a surrogate for the target chemical (parent compound) when the ^{14}C -tag is known to remain with the intact parent compound. If the ^{14}C -compound is degraded in the soil, or is metabolized within the plant, ^{14}C assay is no longer a valid indication of the concentration of the parent compound. The error may be small, or large, depending upon the compound's behavior in soils and plants. In general, ^{14}C -based data (uptake, degradation, etc) must be considered unreliable unless confirmational analysis for intact compound is also available. Unfortunately, unconfirmed ^{14}C data abound in the literature.

Use of data derived from studies that added pure organic compounds, or spiked sludges in studies of organics: Nonpolar organics (PCBs, DEHP, PAHs) are strongly adsorbed by organic matter. If these compounds exist in sludge, their bioavailability can be expected to be different than pure compounds. Much of the early literature on the fate of organics utilized high application rates of reagent grade chemicals. Plant response ("uptake") to such PCB additions (Strek & Weber, 1980) were significantly greater than to sludge-borne PCBs (O'Connor, 1988).

Use of chemical concentrations and/or unique soils not appropriate for evaluation of sludge-amended soils: Early researchers often used very high concentrations of chemicals to facilitate soil and plant analyses. These concentrations (e.g. 20, 100, or even 1000 mg PCBs/kg soil) are totally unrealistic with respect to permissible applications of sludge-borne PCBs. Lower concentrations (0.01 to 1 mg PCBs/kg soil) expected in sludge-amended soils promote very strong adsorption by the amended soil (Fairbanks and O'Connor, 1984), and thus reduced bioavailability. The very limited plant uptake data available are insufficient to demonstrate a linear response to organic loading; in fact, some studies (O'Connor et al., 1989) suggest that plant contamination with PCBs approaches a plateau, similar to the pattern observed for Cd, Cu, Zn, and other metals in sludge-amended soils. Besides use of high concentrations of added compounds, researchers often deliberately used unique soils [sands with extremely low organic carbon (OC) contents] to maximize plant uptake and for analytical ease (e.g., Iwata and Gunther, 1976). Dramatic reductions occur in plant uptake of PCBs when sludge, charcoal, or clay are added to the soils studied (Weber and Mrozek, Jr., 1979; O'Connor, 1988). Unfortunately, some of the more highly cited studies (Iwata and Gunther, 1976) involve high pure chemical concentrations added to "sand" soils. These data are unrepresentative of agronomic applications of organic amendments to agricultural soils.

Insufficient attention given to chemical forms (isomers, congeners, compounds): PCBs and PAHs refer to families of compounds. The term PCBs refers to a family of compounds with the same basic chemical structure but with different degrees of chlorination and isomers thereof. PCBs may consist of a mixture of several congeners, each with different properties. On the other hand, the term PAHs (polycyclic aromatic hydrocarbons) is a much broader term that refers to several different families of compounds with somewhat similar characteristics, but with different basic structures. Studies that do not clearly identify the specific PCBs or PAHs studied have limited usefulness in risk evaluation. Studies with more polar and labile forms of PCBs (Moza et al., 1979) usually exhibit much different plant uptake characteristics than PCBs representative of sludges (much less polar, nonlabile) (Sawhney and Hankin, 1984). Similar data are available (Harms and Sauerbeck, 1983) that demonstrate that the various PAHs have different bioavailabilities.

No distinction between contamination caused by foliar absorption of vapor vs. root uptake: PCBs, in particular, are known to volatilize from surface deposits (or shallow soil) and to be sorbed from the vapor phase by plant tissues closer to the soil (Fries and Marrow, 1981). Little or no PCB is absorbed by plant roots and moved to the leaves in the transpiration stream (Fries and Marrow, 1981; Sawhney and Hankin, 1984). Sludge additions significantly reduce PCB volatilization from soil (Fairbanks et. al, 1987) and thereby likely reduce plant contamination compared to PCBs added as pure compounds. Reagent grade chemical, at high concentrations applied to sands (low OC), would be much less strongly retained by the soil and more likely to contaminate plants.

Errors resulting from assuming that background soils contain no toxic organic compound: Many soils contain residues of pesticides, industrial xenobiotics, and even naturally formed compounds (PAHs) considered toxic (Jones et al., 1989). The literature (eg. Gould, 1966; Edwards, 1973) would suggest

that there are probably no land areas in agriculturally important regions that have not suffered some level of pesticide contamination. The bioavailability of the soil residues may be very low (Frink and Bugbee, 1989), but the residues may be extractable. Assuming zero background levels may cause substantial error.

Further error results when a slope is calculated by using the zero background assumption for control soil, and a result in which plant concentration is below the detection limit at all sludge or chemical application rates including zero (Fig. 2). If the bioconcentration factor (tissue concentration/soil concentration) is calculated from the slope of line A, the slope will be zero. If the control is treated as having zero background, and the detection limit used as a real value for the sludge treatment, the slope of line B could be erroneously estimated. Clearly, estimates of chemical bioavailability can be affected by background soil levels and they should not be ignored a priori.

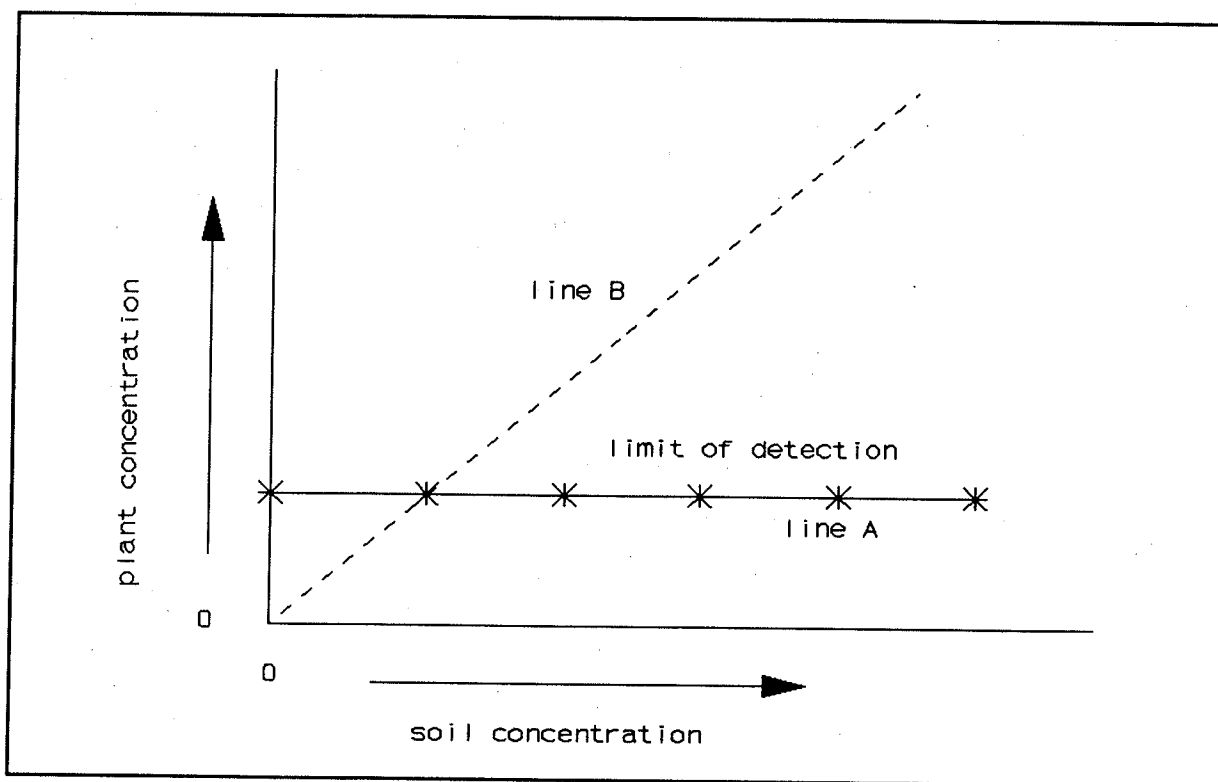


Figure 2. Effect of using different methods to deal with results which are not above the detection limit, and of the zero addition treatment as zero vs. non-detected.

All Chemicals

The Technical Support Document (TSD) lists figures used in the calculations throughout the document. However, it was sometimes difficult for us to locate the numbers for evaluation. Reviews of EPA documents would be facilitated if the final, complete calculation for each pathway and constituent were shown in the TSD, with all units indicated. Reviewers could then follow the calculation method and more easily evaluate impacts of data from reliable field studies.

MEI Discussion (See also Risk Assessment Subgroup Report):

Many of the risk assessment pathways involved a Most Exposed Individual (MEI). Obviously, identification of the ultimate human receptor of the toxicants originating from municipal sludge-amended land is critical. We are, nevertheless, deeply troubled by the MEI used in this risk assessment. The assumptions (life style, diet habit, age, etc.) used to define the target individual do not appear unreasonable when examined separately. When aggregated, however, they produce a purely hypothetical individual. We appreciate EPA's concern to protect all humans. Risk free environmental protection practices, however, do not exist. In public health and environmental protection regulations, the high risk group intended for protection (diabetics, drug addicts, etc.) is clearly identifiable, and risks imposed on them are calculable. We have difficulty identifying any population group which meets all the criteria for Pathway 1F, the garden scenario. It requires the rural farm family to consume 60% of their garden foods grown on a poorly managed (low pH; maximum sludge application) sludge amended soil for 70 years, during which they remain in a metabolic condition which promotes retention of metals and organics in their bodies.

Enacting Rules to protect such hypothetical individuals is scientifically misleading. The stated level of protection is 1 in 10^4 (10^{-4}), but the actual effective level of protection is more likely 10^{-9} .

Critical to the risk assessment models is identification of a MEI for each pathway. Various assumptions are made relative to types of food in diet, amounts of food consumed daily, and, in some cases, the probability of occurrence. In the interest of protection (safety), some of the risk analysis scenarios appear to be extreme, such that we question whether the MEI actually exists in the U.S. population. Further, the MEI definition varies with pathway within a particular sludge use, making comparisons between pathways difficult. MEI also varies across intended sludge uses. The latter variance may be necessary, but consistency in MEI definition within an intended sludge use seems necessary.

Diet Scenarios

Diet scenario inappropriate: For example, one scenario has the farm family consuming 40% of their lifetime meat consumption from livestock exclusively fed crops grown on their own land, all of which was presumed to have been sludge-amended. Data from states with long-term utilization of sludge in agriculture indicate that no more than about one-third of the land in a farm is amended in any one crop year if the farm is large enough to provide all the meat supply of

the farm family (D.S. Taylor, personal communication). Thus, a factor of about 1/3 could be incorporated into the annual loading rate calculations. In contrast, the scenario for general agricultural use estimates 0.025% of the diet is impacted, and then multiplies this times a 100-fold safety factor (= 2.5% of diet). In the farm family example, the MEI has a low probability of occurrence. The general population case describes a more reasonable scenario.

Another example deals with constructing artificial trophic scenarios. The lack of specific data for the various soil biota-predator trophic schemes understandably forces EPA to use possibly unconnected biological systems (e.g., ducks eating earthworms.) If such a pathway is found to be critical in regulating applications of a constituent, however, the trophic scheme should be revisited and carefully examined (both for appropriateness, and for availability of alternate data for observed trophic transfers). Data may have to be generated for a trophic transfer appropriate to the pathway if this substitute evaluation becomes a significant limitation in sludge utilization.

Relative effectiveness of dose: In almost all cases, the relative effectiveness of dose has been assumed to be equal to one. Lack of data suggesting otherwise is usually cited as justification for this assumption. A more extensive literature search, however, is necessary to identify the correct RE values. We believe such a search will show $RE < 1$ in most cases. Hinesly et al. (1985) fed female chickens diets formulated from corn grain and soybean meal containing three levels of biologically incorporated Cd. After 80 weeks, the hens retained only 1.3, 0.98, and 0.87% of the total ingested Cd. Similar results were obtained from studies with pheasant (Hinesly et al., 1976) and sows (Hansen and Hinesly, 1979).

Models

There is clear consensus among the peer review committee that models used in several scenarios are inappropriate. More detailed discussion is given in other sections of the report. The land application-agriculture group identified problems with the use of MINTEQ (no adsorption considered), USLE (data suggest poor predictive abilities), and ground water models (too simplistic, many ridiculous assumptions). A general feature of the entire modeling effort is the lack of model documentation available for peer review and use of non-validated models.

OTHER ISSUES

Analytical Methods

New methods: New analytical methods are part of the Proposed rule. Our understanding is that these methods have been tested in the laboratory with aqueous standards. Verification of the method, especially the purported new lower limits of detection (LOD), must be done on sludge matrix samples. We also strongly recommend "round-robin" lab testing of the method to realistically assess method success. Consideration should also be given to the economic impact of the methods on sludge users relative to the real benefit of lower LODs that might result.

Limits of detection > regulated application limits: Some pathways dictate loading rates lower than the limits of detection from existing or new analytical methods. It is unclear how a sludge user is supposed to address this situation.

Limiting Banned Chemicals

The Proposed Rule include limits for chemicals banned by EPA (DDT, chlordane, aldrin/dieldrin, etc.). Some of these chemicals have been banned since the early 1970s. Even if the new National Sludge Survey shows these chemicals to be absent (or more likely, at vanishingly small levels) can we expect the chemicals to be removed from the Rule?

Pathogens or Vector Reduction

In general, the Proposed Rule appear to be adequate based upon current knowledge relating to viruses, bacteria, protozoa and helminths, and vectors. However, there are some other factors that should be considered. Generally, we favor continued use of the present requirements in 40 CFR 257.

Methodology: The presence or absence of viable Ascaris (helminth) ova is used as an indicator of potential pathogen content of sludges. Thus, proper identification and evaluation is critical. No information is given in the Proposed Rule as to the necessity of identifying only viable Ascaris ova. Information should be included to insure that laboratory technicians understand the need for, and will be able to determine the viability of the ova. Ova viability is usually substantially reduced as a result of adequate sludge treatment. Simple observation of ova presence is not enough. "Free-living" soil or plant-living helminths are the most frequently observed helminths in waste water and sludges, but are not a health hazard to man or animals (Fitzgerald, 1982).

Class B treatment concerns: The Proposed Rule for Class B sludges for application to soil suggest Ascaris sp. ova survive for an upper limit of 5 years after their application to control soils. Literature suggests longer survival times of 7+ (Fox et al. 1981) or even 12 years (Krasnonos, 1978). However, no problems have been reported with the present 30 day waiting period before grazing after sludge application, or 18 month waiting period before culture of crops marketed without a process which would reduce pathogens. Both waiting periods are part of the present recommendations of U.S.-EPA, U.S.-FDA, and USDA (1981).

Beef tapeworm: Pathogens such as beef tapeworm (Taenia saginata) are probably adequately controlled, relative to potential human infections, by USDA meat inspection regulations and programs. Thus, the Proposed Rule seem to over-predict danger of tapeworm infection. Potential sources of infection of animals, and eventually humans, exist most commonly as infected recent immigrants. Control of beef tapeworm and other pathogens in sludge can be controlled by heat treatment (composting) and/or time, etc.

SPECIFIC SLUDGE CONSTITUENTS--PATHWAY CONSIDERATIONS

The various constituents of sludge considered in pathways pertinent to Land Application-Agriculture use are addressed in more detail below. Constituents are grouped to facilitate discussion.

Metals: Group I (Cu, Zn, Ni and Cr)

These metals are found in all municipal sludges in the U.S. Whereas their concentrations in sludge vary with the level of industrial waste contribution to POTWs, significant amounts are inherent to domestic wastewater. The agricultural-land sludge utilization assessments reported in the TSD identified inputs of these four metals to be limited by Pathway 7 (sludge→soil→plant).

Phytotoxicities due to Cu, Zn, Ni, and Cr have been reported in the literature. Data documenting phytotoxic responses, however, were primarily generated from studies of metal salts additions in solution culture or pot studies, or used very high metal concentration sludges or metal salt-spiked sludges in pot studies or even occasionally in fields (e.g., Williams, 1980 used sludges containing 11,400 mg Zn/kg or 5100 mg Ni/kg). On the other hand, Cu, Zn, Ni, and Cr toxicities to even very sensitive plants have not been observed in any municipal sludge land application experiment with $\text{pH} \geq 5.5$. Exceptions are when the metals were predominantly inorganic forms (resulting from massive contamination of sludge from industrial sources), or soil pH was $\ll \text{pH} 5.5$. In fact, plant tissue concentrations of Cu and Cr are rarely affected by sludge applications. Thus, no data are available to directly compute the threshold phytotoxic soil metal concentrations for sludge-amended field soils. Municipal sludge land application experiments have generally not been designed to determine phytotoxic threshold soil concentrations in sludge-amended soils. However, even at relatively high sludge application rates (>100 mt/ha), typical municipal sludges (Cu < 1000 , Zn < 2500 , Cr < 1000 , and Ni < 250 mg metal/kg sludge) have not produced any phytotoxic symptoms, or reduced crop yields (Logan and Chaney, 1983). Further studies of long term high annual rates of application have not produced phytotoxic symptoms (Hinesly et al., 1984).

In the absence of a phytotoxic crop response specifically due to the pollutant being evaluated, the pollutant input and plant tissue pollutant concentration corresponding to the highest No-Adverse-Effect case should be used to calculate the soil phytotoxic threshold from the plant response curve slope. This approach seems the only scientifically justifiable approach.

If the "no-adverse-effect" approach is not acceptable, we propose an alternative approach which has substantially better justification than resorting to metal salt experiments. Determine the plant uptake slope using data for a sensitive plant species (eg. lettuce, snap-bean, etc.) grown under the highest no-negative-effect sludge loading. Based on the calculated uptake slope and phytotoxic foliar concentration derived from field soil experiments which exhibited phytotoxicities from metal salt additions, the phytotoxic threshold concentrations in sludge-amended soils may be estimated. However, in no case should results of metal salt additions to pots of soil in a greenhouse, or

solution culture experiments be used to compute metal uptake slopes of plants (see Fig. 1).

Based on this reasoning, we reevaluated parameters used in the TSD to assess potential effects of, and to set limits on, application of Cr, Cu, Ni, and Zn in Pathway 7. The correction of parameters in one pathway often led to readjustments in other pathways, and a change in the limiting pathway for a given pollutant. We then evaluated the next most limiting pathways, element by element, until all necessary adjustments for that element were completed, or until the cumulative application rate for a median quality sludge approached or exceeded 1000 mt/ha.

Copper

Pathway 7 (sludge→soil→plant): The TSD assessment selected $42 \mu\text{g Cu/g}$ soil as the soil's phytotoxic threshold concentration (RLC) and $0.15 \mu\text{g Cu/g plant shoot DW} \cdot [\text{mg/kg soil DW}]^{-1}$ as the plant's uptake slope. Both parameters were derived from studies of metal salt additions to sludge-treated soils (MacLean and Dekker, 1978).

The reviewers are familiar with many attempted studies of the toxicity of sludge-applied Cu. Addition of inorganic Cu salt to light textured, low organic matter soils has caused phytotoxicity in the field. However, as summarized by Webber, et al. (1981), sludge-applied Cu did not cause phytotoxicity at any cumulative application rate. Copper is very strongly adsorbed by sludge constituents such as humic acid and hydrous Fe oxide, and the toxicity of sludge-applied Cu is very dependent on the concentration of Cu in the sludge rather than the Cu application rate. Plant uptake of sludge-applied Cu has been observed to fit the plateau response model in many field studies (e.g., Chaney et al., 1982; Bell et al., 1988). Based on these data, and the wealth of field-sludge research showing "no-adverse-effect" of sludge Cu, it seems clear that the best approach for protecting against potential phytotoxicity of sludge-applied Cu is to regulate sludge Cu concentration, or to impose cumulative soil Cu limits only for sludges with excessive Cu concentration.

An alternative approach to that of the TSD is to use field data on Cu uptake by leafy vegetables, coupled with independent data which indicate the maximum Cu concentration in plants before significant yield reduction occurs. If the data from a field experiment are used to compute these two parameters (Dowdy, et al., 1978), an uptake slope of $(0.050 \mu\text{g Cu/g plant DW}) \cdot [\text{mg Cu/kg soil DW}]^{-1}$ results. [Note: This uptake slope was calculated from data presented in the original publication. These data (Dowdy, et al., 1978) are incorrectly entered in Table 4-51, page 4-296, of the TSD. The next to last line of Table 4-51 on page 4-296 should be corrected to read, left to right by column: Snap bean/edible; sludge (field); 5.3-5.8, 2.9-5.8; NR; 85.5; 4.2-10.0; increased yield; Dowdy, et al., 1978 (p. 255). The last line of Table 4-51 on page 4-296 should be corrected to read, left to right by column: Snap beans/leaf; sludge (field); 5.3-6.5; 4.5-7.5; NR; 85.5; 8.5-12.0; increased yield; *ibid.*] As no phytotoxicity was observed in this case (Dowdy et al., 1978), we proceeded to estimate the soil-Cu phytotoxic threshold concentration by assuming the foliar concentration of Cu to be $10 \mu\text{g Cu/g}$ for normal plants, and $40 \mu\text{g Cu/g}$ for plants

suffering Cu-phytotoxicity, respectively (Walsh et al, 1972). The RLC will then be estimated by using the slope of crop uptake of soil Cu:
 $(40-10 \text{ mg Cu/kg leaf DW}) \cdot [(0.05 \text{ mg Cu/kg leaf DW}) \cdot (\text{mg Cu/kg soil})]^{-1} = 30 \div 0.05 = 600 \text{ mg sludge-Cu/kg soil.}$

Excessive Cu applications have been found to prevent nitrification of ammonia at Cu levels below those which affect nitrogen mineralization or plant growth (Minnich and McBride, 1986). It is not clear whether this is a significant environmental effect of Cu which should be the basis for this Rule. Nitrification potential does not reduce yields in practice.

Substituting 600 mg Cu/kg soil for 42 mg/kg in equation 36 [page 4-305] results in a reference cumulative application rate of Cu: $\text{RPC} = [(600-19) \text{ mg Cu/kg soil}] \cdot [2000 \text{ mt soil/ha}] \cdot [10^{-3} \text{ kg/mt}] = 581.2 = \underline{1162 \text{ kg Cu/ha}}$ (this assumes 1.33 bulk density) which is substantially higher than the value derived in the TSD (46 kg Cu/ha). If the median sludge Cu concentration is about 500 mg/kg, the TSD limit would allow 92 mt sludge/ha. With a limit of 1162 kg Cu/ha, 2324 mt/ha of median quality sludge could be applied before reaching the Cu limit. This was a very significant error, and would cause sludge application on cropland to be impractical for most cities. [Note: Scientists at the University of Illinois (Hinesly et al., 1984) applied > 700 kg sludge-Cu/ha with no observable phytotoxicities.]

The Pathway 7 limit would be still higher if EPA chose to base this limitation on data from studies with low Cu sludges which caused no phytotoxicity to sensitive crops in strongly acidic sludge-amended soils (Chaney et al., 1982; Logan and Chaney, 1983).

Pathway 5 (sludge→soil→plant→animal): The readjustment of the two parameters in Pathway 7 shifted the limiting pathway of Cu to Pathway 5. According to the TSD [page 4-230], the plant uptake slope for wheat forage grown on sludge-amended field plots was $0.15 \mu\text{g Cu/g plant DW} \cdot [\text{kg Cu/ha}]^{-1}$; data derived from Shaeffer et al. (1979b). However, data tabulated in Table 4-44 [page 4-237] where the uptake slope according to Shaeffer et al. (1979b) was referenced, contains important scientific errors. In one error, the TSD records DTPA extractable Cu application, rather than the total Cu application for this experiment. The sludge contained 2200 mg Cu/kg DW, and was applied at 112 mt/ha at the start of the study resulting in 246 kg Cu/ha, not the 58 kg noted in Table 4-44. The correctly calculated slope is then $(3.7-2.1) \div (246-13.0) = 0.007 \text{ (mg Cu/kg plant DW)} \cdot [\text{kg Cu/ha soil}]^{-1}$. Data on sludge composition and control soil analysis (4.9 mg Cu/kg = 13 kg/ha) were reported in the companion paper (Sheaffer et al., 1979a). The TSD reported that the slope was 0.3 in Table 4-44, but used a slope of 0.15 on page 4-230 without explanation. Even using the data in Table 4-44 leads to a calculated slope of $(3.7-2.1) \div [(58-0.6) \cdot (2000 \text{ mt soil/ha}) \cdot (1000 \text{ kg/mt})^{-1} \text{ (to convert mg/kg to kg/ha)}] = 0.056 \text{ (mg Cu/kg forage DW)} \cdot [\text{kg Cu/ha}]^{-1}$, not 0.3 or 0.15. We also calculated the uptake slope using the third year corn silage data (Dowdy et al., 1983) $(5.3-4.2) \cdot [126.7 \text{ kg sludge-applied Cu/ha minus control of approximately } 20 \text{ kg Cu/ha}]^{-1} = 1.1/106.7 = 0.010 \mu\text{g Cu/g silage DW} \cdot [\text{kg Cu/ha}]^{-1}$. If one uses this typical Cu uptake response (0.010) of forage crops grown ≥ 1 year after sludge is applied, the maximum allowable pollutant loading rate using the diet maximum Cu from the TSD (25 mg Cu/kg) is $(25-2.1) \cdot [0.010]^{-1} = 2390 \text{ kg Cu/ha}$. This value is considerably greater than the

153 kg Cu/ha value in the Proposed Rule and TSD. Correction of the estimated maximum safe sludge-applied Cu which protects livestock, shifted the limiting pathway of Cu to Pathway 8.

In the course of our evaluation, we also found that the data used to derive feed concentration toxic to herbivorous animal ($TA_H = 25 \mu\text{g/g DW}$) were from an experiment where Cu salts were fed to Zn-deficient sheep. Because of the increased Zn concentration in forages grown on sludge-amended soils, forage grown on sludge-treated soil will not be deficient in Zn and should not allow any deficiency in animals foraging on this type of feed. Also, the potential toxicity of inorganic salts is invariably greater than the same element present in plant tissue. For these reasons, we feel the value of TA_H should be substantially greater than 25. We did not have time to investigate and recommend an appropriate substitute. The EPA should consider data noted by Chaney et al. (1987) for sheep grazing pastures treated with swine manure containing high levels of Cu, but which did not induce Cu toxicity. See also Baker (1974) for a discussion of Cu-Mo interactions in swine. Data from Bray et al., (1985), Dowdy et al., (1983a, b) and Dowdy et al., (1984) should be considered in all pathways considering sludge→soil→plant→animal. These data are from goat and sheep feeding studies where corn silage grown on sludge-amended soil constituted >90% of the animal diet. Silage contained elevated levels of Cd, Cu and Zn.

Pathway 8 (sludge→soil→soil biota): In Pathway 8, Cu is the only element listed in Table 6-3 of the TSD. Soil biota may be susceptible to toxic effects of many constituents in the sludge, but only Cu was identified in the risk evaluation.

In this exercise, EPA used the data of Ma (1984) to derive the soil concentration of pollutant toxic to soil biota ($TB = 131 \mu\text{g/g DW}$) and arrived at a maximum allowable pollutant loading of 224 kg/ha Cu. The experiment of Ma (1984) was conducted at soil pH 4.8, and with CuCl_2 added to produce a soil Cu concentration of $131 \mu\text{g/g}$. These experimental conditions clearly do not simulate soil chemical conditions of sludge-treated agricultural soils.

Hartenstein et al. (1980) cultured earthworms in municipal sludge whose Cu contents ranged from 380-610 $\mu\text{g/g}$. They reported no detrimental effects of this species of earthworm even when grown in 100% sludge. If the earthworms are able to tolerate 380-610 $\mu\text{g Cu/g}$ in undiluted municipal sludge [a far more relevant example than Ma (1984)], they should be able to withstand 380-610 $\mu\text{g Cu/g}$ in sludge-amended soils. Substituting 380-610 $\mu\text{g/g Cu}$ for 131 $\mu\text{g/g}$ in the computation results in a considerably higher maximum allowable pollutant loading under this pathway. Using 380 mg Cu/kg leads to the new limit of $(380-10) \cdot 2000 \cdot 1000^{-1} = 740 \text{ kg Cu/ha}$. Similarly, $(610-10) \cdot 2 = 1200 \text{ kg Cu/ha}$. Thus, the TSD value of 244 is increased by 3 to 5 fold. The highest no-adverse-effect level would be the 1200 kg Cu/ha. They noted other "no-adverse-effect" studies with this earthworm at 1500 mg Cu/kg sludge.

Pathway 6 (sludge→soil→animal): Adoption of the above corrections leaves Pathway 6 as the limiting pathway for Cu. In this simple and straight-forward pathway, threshold feed concentration and the fraction of the diet that is adhering soil or sludge are needed to estimate the reference application rate of pollutants.

The source of the threshold feed concentration (TA = 25 µg/g D.W.) was the same (metal salt study) as used in Pathway 5. However, the bioavailability of the sludge-borne Cu in sludges ingested by cattle and sheep has been shown to be significantly lower than that of inorganic Cu salts (Chaney et al., 1987). Further, the "most sensitive" Zn-deficient foraging animals are very unlikely to occur if they graze sludge-fertilized pastures. Thus, TA could be increased by 2-4 fold based on sludge-grazing and sludge-feeding studies (Fitzgerald, 1978, 1980, 1982; Smith et al., 1985). Clearly, sludges containing 1000 mg Cu/kg DW have not caused substantial increase in liver Cu, while very high Cu sludges have caused increased liver Cu. We believe that the best way to avoid Cu risk to livestock from ingested sludges or soil-sludge mixtures is to require injection or tilling of sludges containing over 1000 mg Cu/kg (or higher after review of the complete literature on sludge feeding) into soils before allowing grazing. Alternatively, once a new TA is determined, the maximum allowable pollutant input under this pathway can be recalculated.

The fraction of diet of grazing livestock that is adhering sludge is approximately 2.5%, not 10% (Chaney et al., 1987). Based on season-long analyses of feces to estimate sludge ingestion (whole season data are more appropriate than single highest result because prolonged chronic exposure is required before liver Cu is raised to injurious levels), the average intake of sludge from pastures which received surface applied liquid sludge or compost was 2.5% of dry diet. Surface applied sludge represents a much greater potential ingestion of sludge than would sludge mixed well with the surface 15 cm of soil as used in the TSD. Replacing the FL used on page 4-275 (10%) with 2.5% we calculate $RLC = (98_{RFC}/0.025_{FL}) + 10_{BS} = 3930$. However, as noted above, we believe research has shown that sludges containing > 1000 mg Cu/kg DW should be injected below the soil surface or mixed with the plow layer soil to minimize potential risk to grazing livestock. These practices would prevent any risk from this pathway.

Comparison of Estimated Sludge-Cu Application Limits.

Pathway	TSD Limit	Corrected Limit
---Maximum allowed kg Cu/ha---		
5:Sludge→Soil→Plant→Animal	153	at least 2390
6:Sludge→Soil→Animal	458	3930
7:Sludge→Soil→Plant	46	1160
8:Sludge→Soil→Soil Biota	224	1200

Zinc

The risk assessment for sludge-applied-Zn in the TSD contained similar deficiencies as those described above in our review of the TSD analysis for Cu risks. These include:

1. Determination of the plant's pollutant uptake slope and the soil's phytotoxic threshold concentrations from data derived from inappropriate experiments.
2. Food chain and/or trophic level was not properly considered in the selection of soil-biota predator, and
3. Assumptions on consuming 100% contaminated diet and of 100% relative effectiveness of ingestion exposure.

Pathway 7 (sludge→soil→plant): In this pathway, the reference soil concentration of pollutant (RLC) = 140 $\mu\text{g/g}$ was calculated from data in MacLean and Dekker (1978). This study added inorganic Zn salts to controls and sludge-amended soils in a greenhouse-pot study of lettuce grown at several soil pH levels. In our opinion, this set of data is not appropriate for estimating sludge-Zn application limits. An alternate source of appropriate published Zn data have been presented by Dowdy, et al. (1978) for snap beans. These data are from field studies with sewage sludge and should be included in Table 4-54 on page 4-330 of TSD to read from left to right by column: Snap bean/edible; sludge (field); 5.3-5.8; 26-36, NR; 486; 34-46; increased yield; Dowdy, et al., 1978 (p. 255). A second additional entry for this table, from left to right by columns: Snap beans/leaf; sludge (field); 5.3-6.5; 26-30; NR; 486; 42-51; increased yield; *ibid.* (p. 256).

Based on additional field data (Table 1), the Zn uptake slope for lettuce expressed as plant concentration ($\mu\text{g Zn/g DW}$) per unit of sludge-Zn applied (kg/ha) is $0.134 (\mu\text{g Zn/g}) \cdot [\text{kg Zn/ha}]^{-1}$. This calculation of slope ignores a separate analysis which showed that foliar Zn approached a plateau with increasing sludge Zn application rate.

If the phytotoxic foliar Zn concentration in lettuce is 500 $\mu\text{g/g}$ (for 25% yield reduction) or 400 $\mu\text{g/g}$ (for first detectable yield reduction) (Logan & Chaney, 1983), the RLC for Zn may be calculated:

$$\begin{aligned} \text{RLC} &= (400 - 32 \mu\text{g Zn/g DW}) \cdot [(0.13 \mu\text{g Zn/g DW}) \cdot [\text{kg/ha}]^{-1}] \\ &= 368 / 0.13 = 2750 \text{ kg sludge-Zn/ha.} \end{aligned}$$

Experiments at the University of Illinois (Hinesly, 1984) applied sludge-Zn at 2400 kg Zn/ha with no observable effects on plant yields. Further, Mahler et al., (1982) found no yield reductions in pot studies with Swiss chard or corn at soil Zn levels of 1760 mg Zn/kg .

Table 1. Concentrations of metals in lettuce and soil as affected by sewage sludge application ^{1,2}

Sludge Appl. (mt/ha)	Soil pH	Lettuce ³			Sludge-applied M ²⁺		
		Ni	Cu	Zn	Ni	Cu	Zn
		-----µg/g DW-----			-----kg/ha DW-----		
0	6.7	0.54 a	6.8 c	32 a	0.	0.	0.
56	6.5	1.29 b	8.9 ab	58 b	9.5	123.	246.
112	6.1	2.41 c	8.6 b	98 c	19.	246.	493.
Slope ⁴					0.098	0.0073	0.13

¹Personal Communication (Chaney, R.L., A.M. Decker, and C.C. Shaeffer, 1980, unpublished data).

²No effect on yields, field study, Beltsville silt loam, 6th year following sludge application. Study used a sludge with high Zn concentration, 4400 mg Zn/kg, which would cause relatively higher Zn uptake than equal amounts of Zn added in a median quality sludge. The background soil Zn = 31, soil Ni = 10., and soil Cu = 4.9 mg/kg D.W.

³Means within columns followed by the same letter are not significantly different at 5% level.

⁴Slope units are: (mg metal/kg leaf DW)·[kg metal/ha]⁻¹

Pathway 9 (sludge→soil→soil-biota→predator): The above calculations would shift the pathway limiting cumulative sludge-Zn applications to Pathway 9. In this case, we examined the data used for computing the input parameters (e.g. UB = 2.95 (mg/kg)·[kg/ha]⁻¹, BB = 228 mg/kg, and TA = 894 mg/kg). All were close to generally recognized values, and we propose no major changes. However, we note an omission of data from Helmke et al. (1979). This paper is one of the best ever published on metal uptake by earthworms from sludge-amended soils. The species examined in this study were Lumbricidae, the species usually considered "earthworms" in farmer's fields. In their Figure 2, the slope of earthworm body Zn concentration (corrected for soil contamination) vs. sludge applied Zn (15 mt/ha = 51 kg Zn/ha, 30 mt/ha = 102 kg Zn/ha, and 60 mt/ha = 204 kg Zn/ha) is about 1.0 mg Zn/kg earthworm·[kg sludge-Zn/ha]⁻¹. Beyer et al., (1982) examined long-term sludge farms, and found an average Zn-uptake slope for five cities of 3.25, with BB = 227 mg Zn/kg; the TSD cites data for four cities with an uptake slope of 2.95.

The selection of representative species of the trophic level/food chain was less than desirable. Earthworm was selected as representative of the soil biota. Japanese quail, however, is not likely to be the species representative of the next trophic level, and the other bird species listed tolerated considerably higher Zn levels. We do not believe it is ecologically sound to assume a mismatched food chain when one evaluates the transfer of toxicants to higher trophic levels. The current risk assessment scenario assumes that 100% of the predator's food intake is derived from contaminated soil biota. Nelson Beyer of U.S. National Wildlife Research Center (personal communication) indicated that, at most, one-third of a predator's diet can be attributed to earthworms in periods of maximal earthworm consumption. Thus, we feel the current risk assessment overestimates the exposure and undercalculates the

maximum allowable pollutant loading for this pathway. This deficiency applies to all pollutants being evaluated under this pathway.

Earthworms, including soil in the gut of the worm, are ingested whole by birds. This soil provides both exposure and Zn-adsorption capacity to reduce Zn absorption by the bird ingesting the earthworm. Even Zn in foods is not as bioavailable as the Zn salts fed in the animal toxicity tests used to generate the Zn tolerance estimate, TA (Bremner, 1970).

The allowed soil concentration of the pollutant = $[(894-228)(2.95)^{-1}] +$ background soil Zn = $(666/2.95) + BS = 226 + BS$. The 226 value should be divided by 0.33 (33% of predator's diet attributed to earthworms and 0.50 estimated 50% bioavailability of Zn in sludge-soil mixture). Using the adjustment factor of $0.50 \cdot 0.333 = 0.167$, we obtain $226/0.167 = 1353$ mg Zn/kg. A lower estimate of Relative Effectiveness would have increased the allowed Zn application even more. Correction for background soil Zn gives $1353 - 54 = 1299$ mg Zn/kg allowed sludge-applied-Zn. This is converted to kg/ha: $(1299 \text{ mg Zn/kg}) \cdot (2000 \text{ mt soil/ha} \cdot 15 \text{ cm}) \cdot (1000 \text{ kg/mt})^{-1} = 2600$ kg Zn/ha compared to the TSD estimate of 452.

However, no Zn toxicity has ever been reported for ingested sludge or soil in sludge grazing or sludge feeding studies. This pathway is now the most limiting pathway for Zn application, and a more thorough assessment is needed to accurately set Zn limits.

Comparison of Estimated Sludge-Zn Applications Limits:

Pathway	TSD Limit	Corrected Limit
	---Maximum allowed kg Zn/ha---	
7:Sludge→Soil→Plant	172	2750
9:Sludge→Soil→Soil Biota	452	≥2600

Nickel

Only three pathways were reported for Ni in Table 6-3 (TSD). These include Pathway 1, 5340 kg Ni/ha; Pathway 1F, 206 kg Ni/ha, and Pathway 7, 78 kg Ni/ha.

Pathway 7 (sludge→soil→plant): The reference soil concentration of Ni (RLC = 57 $\mu\text{g/g D.W.}$) was calculated from MacLean and Dekker (1978) whose experimental treatments consisted of metal salt and metal salt-spiked sludges. Using the more appropriate Ni data of Table 1, we were able to calculate the plant (lettuce) pollutant uptake slope ($0.098 (\mu\text{g/g}) \cdot [\text{kg sludge-Ni/ha}]^{-1}$) and used it to back calculate the reference soil concentration of Ni. We also assumed initial phytotoxicity to sensitive crops occurred when foliar Ni concentration reached 50 $\mu\text{g/g DW}$ (Logan and Chaney, 1983).

$$\text{RLC} = (50 \text{ mg Ni/kg leaf DW}) \cdot [0.098 \text{ (mg Ni/kg leaf DW)} / [\text{kg sludge-Ni/ha}]^{-1}] = 500 \text{ kg Ni/ha} = \text{RPC}.$$

Pathway 1F (sludge→soil→plant→human): The adjustment of the reference soil concentration of Ni as demonstrated above shifts the limiting pathway for Ni to Pathway 1F at 206 kg/ha.

However, we question the toxicity risk to humans indicated in the TSD. We are aware of data from feeding sludge-grown crops which tested the effect of Ni level in the food on the growth of voles (Alexander et al., 1979). In this work, the grain of soybean was harvested from plants which suffered a significant yield reduction on acidified field plots amended with a sludge compost containing admixed serpentine rock chips. Upon acidification of the plots, the crops took up much more Ni than at the original pH levels. Grain reached 30 mg Ni/kg. However, no negative effects were observed in the voles fed the grain.

Many livestock feeding studies have shown that animals tolerate much more Ni than would appear to be the case for humans based on EPA extrapolation of a long term feeding study with rats. EPA set the RfD at 20 µg/kg/d = 1400 µg Ni/d for adult males. Based on the review of Ni in human and animal nutrition by Nielsen (1987), we doubt that this RfD has much relevance to human Ni risk. This would be 1400 µg Ni/500 g food = only 2.8 mg Ni/kg food DW. Plants generally tolerate foliar Ni levels of ≤ 100 mg/kg DW. Essentially all grain, fruit, and tuber crops have lower Ni in the storage tissues than in the leaves. If the human tolerates only 2.8 mg Ni/kg dry diet, and crops tolerate as much as 50-100 mg Ni/kg DW (chlorotic symptoms apparent by about 50 mg Ni/kg), perhaps some limit is necessary. However, many studies have shown that Ni in test foods caused no toxicity (Alexander et al., 1979; Chaney et al., 1978a, 1978b)

Thus, we feel the use of the RfD derived from soluble salt feeding studies with rats in the TSD is inappropriate for protecting humans from sludge-applied Ni. Food affects the bioavailability of ingested Ni, as well as many other nutrients. In our judgement, there is clear evidence that protection of crop production (phytotoxicity) completely protects the food chain. Thus, no limitation is needed under Pathway 1 or 1F.

Comparison of Estimated Sludge-Ni Application Limits.

Pathway	TSD Limit	Corrected Limit
	---Maximum allowed kg Ni/ha---	
7:Sludge→Soil→Plant	78	500
1F:Sludge→Soil→Plant→Animal	206	>>500

Chromium

Pathway 7 (sludge→soil→plant): The TSD reports that chromium limits sludge application only under Pathway 7, with a limit of 530 kg Cr/ha. However, we are

familiar with much data which leads us to conclude that the TSD analysis is not valid for this element. The reference soil concentration of Cr (RLC = 200 $\mu\text{g/g}$) was obtained from a field study of snapbeans grown on soils treated with hexavalent chromium in the form of potassium chromate. (CAST, 1976; Mortvedt and Giordano, 1975). The TSD, nevertheless, ignored the authors' observation that an equal amount of Cr applied in composted (municipal waste + sludge) had no phytotoxic effect. Hexavalent chromium is more soluble and more bioavailable for plant uptake than the trivalent chromium usually found in sludges and field soils. [Chromium can be oxidized to the hexavalent state by soil MnO_2 (Bartlett and James, 1979) but exists at low concentrations.] Thus, the Mortvedt and Giordano (1975) data from chromate additions should not be used to derive a valid RLC for Cr in sludge-treated soil. Further, on page 4-295, a background soil Cr of 100 mg/kg is used. Most soils contain only 50 mg Cr/kg based on the U.S. Geologic Survey analysis of over 3000 samples from across the U.S. (Shacklette and Boerngen, 1984).

Chromium phytotoxicity is manifested as reduced root vigor without corresponding large increases in leaf Cr concentration. In a comprehensive review of observed effects of sludge-applied Cr for the European Economic Community, Williams (1988) indicated that Cr phytotoxicity had never been observed in sewage sludge-amended soils. One short term study of a tannery sludge (containing 32% Cr) observed phytotoxicity, but we consider these data non-relevant in estimating limits on municipal sludge-Cr application. Dowdy et al. (1983b) observed no yield reduction in corn silage with applications of 1790 kg of Cr/ha. Associated tissue Cr concentrations were 0.9 $\mu\text{g/g}$ and 0.9 $\mu\text{g/g}$ for control and sludge treatment, respectively.

Another example of the non-toxicity and non-plant-uptake of Cr is found in studies of plants grown on serpentine soils. The parent rocks of serpentine soils may contain high levels of Cr, and such soils naturally contain Cr levels as high as 1% Cr (10,000 mg Cr/kg). However, plants growing on these soils do not exhibit Cr-phytotoxicity. Recently, Cary et al. (1989) reported Cr concentrations in plants grown on serpentine soils. They used a new technique to correct for soil contamination of the plant sample because even a slight contamination can cause more Cr to appear in the plant sample than is truly taken up by the plants. Their analyses showed that soil contamination could account for all the Cr found in any of their plant samples, even those growing on soil containing 11,000 mg Cr/kg. All previous studies of Cr uptake from Cr-rich soils must be suspect in light of the Cary et al. findings.

Based on these considerations, we conclude that there is no scientific basis to limit application of sewage sludge-Cr based on phytotoxicity. Similarly, there is no known basis to limit sludge-Cr to protect the food chain (Pathways 1, 1F), livestock or children from Cr-toxicity due to sludge ingestion, or soil biota or wildlife.

Pathway 12 (sludge→soil→groundwater→human): There are data which indicate that freshly added Cr^{3+} can be oxidized to chromate in some soils high in MnO_2 (Bartlett and James, 1979). Thus, there has been some concern about formation of chromate which could then leach to groundwater at concentrations above the drinking water standard of 0.05 mg Cr^{6+} /L. No data are available from sludge research studies, or from serpentine soils with 10,000 mg Cr/kg, that Cr^{3+} in

surface soils is actually leached to groundwater in amounts violating the drinking water standard (Chaney, 1983).

Some scientists (Baker et al., 1985) feel that there should be a limit on Cr in sewage sludges applied on agricultural land, despite the lack of a technical basis for estimating a limit based on environmental protection. Generally, sludges containing over 500 mg Cr/kg have identifiable industrial inputs. Several groups recommend that land-applied sludges be limited to 1000 mg Cr/kg (Baker et al., 1985). However, sludges with over 5000 mg Cr/kg DW have been used in long-term sludge research studies with no significant negative effects compared to otherwise low metal sludge (Bidwell and Dowdy, 1987). We have no specific recommendation about sludge Cr limits, or sludge-Cr application limits because we can identify no scientific basis to estimate such limits.

Comparison of Estimated Sludge-Cr Application Limits.

Pathway	TSD Limit	Corrected Limit
	---Maximum allowed kg Ni/ha---	
7:Sludge→Soil→Plant	530	No basis
12:Sludge→Soil→Groundwater→human		No basis

Metals: Group II (Pb, Cd, As, Se, Mo, Hg):

Chemically and geochemically, Pb, Cd, As, Se, Mo and Hg are dissimilar elements. The mechanisms and environmental transport pathways that bring them to municipal sludges are also dissimilar. We grouped them together for discussion because they all can be toxic to humans and/or animals.

The risk assessment pathways for these elements involved an exposure scenario leading to a MEI. The MEI is so rigidly defined in the risk assessment exercise for agricultural land disposal that it becomes the driving force of the criteria setting. It completely overshadows other components of the risk assessment pathways even to the extent that it makes the issue of "inappropriate" technical parameter data almost irrelevant. Accordingly, we had difficulty directing our focus. The Sludge Application-Agricultural Land group proposed alternative MEIs where we were familiar with the data. The issue of a reasonable MEI must be resolved if the maximum allowable pollutant loadings as proposed for these elements are to be justified.

The remaining text assumes the concept of MEI as defined by EPA. We reviewed pathways for the Group II metals individually.

Lead

The TSD indicates that application of lead in sludge would be most limited by Pathway 9 (the toxicity of earthworm-Pb to birds), at 125 kg Pb/ha. The next most limiting pathways were 1F at 195 kg/ha, and Pathway 2F at 378 kg Pb/ha. The results calculated for Pb in Pathway 7 were not listed in Table 6-3 of the TSD.

Other parts of this report discuss errors in the daily sludge/soil ingestion value, and suggest that at least 0.5 g soil/day should be used. However, the TSD omits information about the bioavailability of Pb. Chaney et al. (1989) provide a detailed review of the available information on bioavailability of soil Pb. Sludge Fe and organic matter provide high ability to adsorb Pb in sludge and reduce its bioavailability.

Pathway 9 (sludge→soil→soil-biota→predator): Pathway 9 calculations also suffer from a lack of consideration of bioavailability of food-Pb. Water-borne soluble Pb salts have high bioavailability, with as much as 80% absorption of salt Pb by fasting humans. However, consumption of salt Pb with food lowers the retention to about 5% (James et al., 1985). Because earthworms are ingested with soil in their guts, the soil present can also adsorb Pb, lowering the bioavailability of earthworm-Pb substantially. Thus, the limit for Pathway 9 should be well above 1000 kg/ha, far higher than is safe for children who ingest soil (the limitation due to Pathway 2F).

The TSD relied on data from Pietz et al., (1983) when data from Beyer et al. (1982) provide a wider assessment of earthworm Pb accumulation from sludge-amended soils. [Soil analysis for the Pietz et al. plots failed to demonstrate that sludge metals remained in the plot soils. The metals may not have been present to expose the earthworms]. The effect of sludge on earthworm Pb concentration was significant, but very small (Beyer et al., 1982).

Perhaps the most serious error in the Pathway 9 assessment is the misuse of data from Coburn et al. (1951) to estimate the tolerance of dietary Pb by birds. Coburn et al. fed Pb salts to captured Mallard ducks on a mg Pb/kg body weight basis. The TSD used these data as if they were mg/kg diet basis, a significant error. Adult ducks chronically fed 6 mg Pb/kg body weight/day exhibited no toxicity, but a 12 mg/kg·day rate was quite toxic. The birds weighed approximately 1 kg each, and this weight bird consumes about 100 g dry diet/day. Thus, 6 mg Pb per day/0.10 kg diet per day = about 60 mg Pb/kg diet. (EPA attempted to make this conversion, but used food intakes for baby chickens rather than intakes of adult ducks). However, the Pb was administered as a solution of $Pb(NO_3)_2$ by a catheter directly into the gizzard once per day. This form of dose administration prevents food constituents (fiber, Ca, P, phytate, etc.) from binding much of the dose. In fact, the dose was meant to simulate the effect of ingesting Pb shot.

The errors noted above are confounded, because the errors in dose calculation, in food-Pb bioavailability, and in earthworm uptake of Pb from sludge-amended soils are multiplied together. The correct estimates should have been: (60 mg Pb/kg diet)·10(RE Pb in water/RE Pb in food) = 600 mg Pb/kg diet.

With the small slope of earthworm uptake of sludge-Pb from sludge-amended soil, it is likely that the most important exposure would be the fraction of soil inside the earthworms that are ingested. If one assumes 10% soil in earthworm dose, the slope would be higher than for the earthworm:soil slope reported for Beyer et al. (1982). The background Pb concentration in the control earthworms of Beyer et al. (1982) was 18 mg Pb/kg, whereas the worms from sludge-amended soils contained 21 mg/kg; the soils contained 24 mg Pb/kg (control) and 32 mg Pb/kg (sludge-amended). The small increase in soil Pb due to sludge application, and small increase in worm Pb, make this a weak test of the slope of earthworm response to sludge-applied Pb. The threshold toxic feed concentration (TA) is taken as 60 mg Pb/kg, but many animals tolerate this level without health effects if it is supplied with food (NAS, 1980).

From the TSD, the $RLC = [(TA - BB) \div UB] + BS$. Elsewhere we have noted the need to incorporate a RE in this equation, as well as a fraction of earthworms in the birds diet (33%). Because of the effect of food and of soil on Pb bioavailability, a RE of 0.10 for earthworm Pb seems reasonable. The revised equation using a TA from food Pb is $RLC = [(TA - BB) \div (UB) \div (RE) \div (\text{fraction of diet})] + BS = [(60 - 18) \div (0.10 \text{ RE for soil vs. food Pb})] \div (0.33 \text{ fraction of diet}) \div (3.2 \text{ mg increased earthworm-Pb on sludge-amended plots with } 8.5 \text{ mg increased Pb/kg soil}) = 420 \div (0.33)(0.38) = 3349 \text{ mg Pb/kg soil}$. Other data (Morgan and Morgan, 1988) indicate that the uptake slope is much lower than 0.38 mg (increased earthworm tissue Pb) \cdot [increased mg Pb/kg soil]⁻¹. Slope for earthworm Pb vs soil total Pb for worms inhabiting metal mine wastes was $\log_{10} Pb_{\text{worm}} = -1.073 + 1.042 \log_{10} Pb_{\text{soil}}$. For soil Pb = 1000 mg/kg, this calculation yields earthworm body Pb = 113 mg/kg. Alternatively, we can assume 10% soil in the live earthworms, and work backwards: 3349 mg Pb/kg soil x 10% soil in diet = 335 mg Pb/kg whole worms; consumption of 33% worms in diet dry matter gives an exposure of 112 mg Pb/kg diet. The soil Pb would have bioavailability of about 25% of food Pb (at 3350 mg Pb/kg soil), so the equivalent food Pb dose would be about 28 mg Pb/kg diet, a clearly non toxic dose. There are so many corrections to the data, and changes to the calculation method, that we will not estimate a soil Pb limit for Pathway 9 other than to say $\geq 1000 \text{ kg/ha}$ (= 500 mg/kg soil). However, it is clear that this limit is about 10 fold greater than the limit for Pathway 2F (the generally accepted limiting pathway).

Pathway 7 (sludge→soil→plant): The TSD omitted Pathway 7 from the summary Table 6-3, but the calculations are shown starting on page 4-305. The report of Giordano et al. (1979) did not find any evidence of Pb phytotoxicity. The Demayo et al. (1980) reference is a review paper, but is ignored because "the source of the Pb in the most sensitive case they discuss is not reported". We feel this is a poor reason to ignore the paper if the original source were obtained and shown relevant to regulating sludge applications. The W-170 committee is not aware of any data that sludge-Pb caused phytotoxicity in crops. Only salt additions have caused Pb toxicity, and then the conditions were so artificial that no specific Pb phytotoxicity could be alleged. The TSD concludes "Because no sludge studies were available in which lead levels were high enough to cause phytotoxicity, calculating the reference soil concentration is not possible." We agree with this conclusion.

Pathway 2F (sludge→soil→human): The consideration of Pathway 2F will be considered separately for D&M vs. Land Application-Agriculture because Pb in sewage sludge ingested by animals has proved to have low bioavailability. Pathway 2F-D&M should be the most important limitation on sludge Pb for D&M sludge materials, because one must assume that the materials remain on the soil surface in some exposure cases. However, for agricultural utilization, Pathway 2F-Agricultural Land must consider that sludge has been well mixed in the plow layer soil. Pb health effects on growing infants are much more prevalent than for adult males, and this is widely recognized in the scientific community (ATSDR Report to Congress, 1989). EPA has major research efforts underway to further assess and prevent this risk to U.S. children. Thus the critical importance of Pathway 2F in Pb risk is obvious.

In the TSD, EPA indicates that the RIA = 20 μg Pb/day, and the background soil Pb (BS) = 11 mg/kg. The loss rate is 0, as no process for volatilization of Pb from soils has been identified. The use of 0 mg Pb/day total background intake rate (TBI_t), however, is not justified.

Much of the Pb risk assessment discussion is unjustified. On page 4-55 of the TSD, EPA notes that children absorb more Pb from food than do adults, but suggests that children are less exposed to crops grown on sludge-treated soil. However, the food ingestion per unit body weight is much higher for growing children than for adults (at least 4-8 fold, depending on age). The problem with children vs adult males is that after one takes into account the log-normal distribution of blood Pb, and high intake/kg body weight for children, the present background level of blood Pb in urban children often exceeds the desired maximum level to avoid health effects. If part of the normal population exceeds the blood Pb associated with adverse Pb-health effects, no additional exposure to Pb (from D&M of sludge products or any source) should be allowed. On the other hand, part of the exposure of inner-city children (besides from paint, food, automotive emissions, and water) is Pb from historically polluted urban soils. The surface few centimeters of urban soil averages over 1000 mg Pb/kg in the inner city of most large cities (Chaney et al., 1989; ATSDR, 1989). Pb levels in house dust may be higher or lower depending on sources. Land application of sludge products may actually reduce both the concentration of Pb in urban soils (dilution) and the bioavailability of Pb in the mixed soil (adsorption). The principle consideration should be whether ingested sludge products comprises a significant risk. The bioavailability considerations in these paragraphs should justify marketing the low Pb concentration products available.

We believe EPA must consider the low bioavailability of Pb in ingested sludge products in making this Rule. The bioavailability of Pb in soil (and even lower bioavailability of Pb in sludge fed to livestock) indicates that a threshold Pb concentration, (≈ 300 mg/kg), must be exceeded before the Pb present adds significantly to risk. Chaney et al. (1989) found the bioavailability of Pb in urban garden soils to rats (in a chronic exposure test) was strongly dependent on the concentration of Pb in the soil. Thus, when soil containing 1000 mg Pb/kg is fed at 5% of the diet, the Pb is only 20 % as available as Pb fed in equivalent amounts as lead-acetate. At lower soil-Pb levels, the bioavailability was reduced further, and no increase in bone Pb occurred when background soil (11 mg Pb/kg) was fed at 5% of diet.

Sludges have been fed to many classes of livestock and experimental animals. In this work (summarized in Table 2), bone-Pb and liver- and or kidney-Pb concentrations were usually reported. Often, small increases occurred in liver- and kidney-Pb, whereas little or no increase occurred in bone-Pb. Cessation of sludge ingestion allowed soft tissue Pb concentration to revert to background levels, but bone-Pb was unchanged (e.g. Baxter et al., 1982). A very different response pattern is observed when soluble Pb salts are fed to livestock.

Table 2. Effect of ingesting sewage sludges with different properties on the concentration of Pb in bones of livestock.

Study	Sludge Source	Pb Conc. in sludge mg/kg	Sludge in diet %	Dietary Pb		Duration Fed days	Bone Pb	
				Control ----mg/kg	+sludge DW---		Control ----mg/kg	+sludge DW
1.	Ft. Collins	466	11.5	0.86	56.6	106	5.0	7.2*
2.	Ft. Collins	387	12.0	1.8	50.0	270	1.6	4.3*
3.	Denver	780	4.0	0.6	26.	94	1.	4. *
3.	Denver	780	12.0	0.6	77.	94	1.	11. *
4.	Washington,DC	215	3.3	6.0	11.2	180	3.7	4.7NS
4.	Washington,DC	215	10.0	6.0	19.9	180	3.7	3.4NS
5.	Las Cruces	150	7.0	-	+10.5	1440	-	- NS
6.	Chicago	-	-	-	-	-	-	- NS

* Bone Pb concentration significantly increased by sludge ingestion.

1. Johnson et al. (1981). Hereford steers.
2. Baxter et al. (1982). Cows and steers.
3. Kienholz et al. (1979). Feedlot steers.
4. Decker et al. (1980). Cows, calves, and steers. Composted sludge, high in Fe and CaCO₃.
5. Smith et al. (1985). Sheep. No significant change of Pb in liver.
6. Hansen et al. (1981). Foraging sows. Soil Pb in 504 mt/ha plot = 131 mg/kg, while control plot soil was 37.7 mg Pb/kg. Feces were 7.9 and 41.7 mg Pb/kg FW in March. Bone not analyzed, but liver and kidney showed no significant change in tissue Pb.

The conclusion from the above discussion of the risk of Pb toxicity to humans from direct ingestion of sewage sludge or sludge compost has to be set in the context of information about bioavailability of Pb in ingested soil and sludge materials. A 2-6 year old child may ingest 0.5 g soil/day (95th percentile) or even 5-10 g/day (99th percentile) (Calabrese et al., 1989), compared to 250 g dry diet per day (obtained from Mr. R. Bruins, EPA, Cincinnati, who converted the Pennington diet values to dry matter basis). This would convert to 5/250 = 2% of diet to 10/250 = 4% of diet. Although water borne Pb is of much higher risk if ingested between meals, there is no evidence that soil-Pb or sludge-Pb is of unusual risk if ingested between meals.

Sludge products (including compost) which are to be marketed must be considered in light of the potential for direct ingestion of pure sludge from the soil surface or from the bag or piles awaiting utilization at private homes. For many chemical reasons, and because of the low Pb deposition (bioavailability) during the sludge-feeding experiments described above, it is clear the Pb in sludge products can be expected to have very low bioavailability. The data are incomplete, because sludges have been fed to few monogastric animals, and seldom has Pb-acetate been fed to livestock as a 100% bioavailable control. These feeding studies usually included up to 10% sludge product because the researchers tried to evaluate a worst case of short-term exposure, not the chronic long-term exposure usually considered to be about 2.5% of diet.

A reconsideration of the relationship of sludge dose (g sludge ingested per day) and response (blood or tissue Pb concentration) indicates that the strong adsorption of Pb by sludge appears to cause tissue Pb to reach a plateau with increasing sludge ingestion. The usual consideration of the "pica" child is that tissue Pb will be a linear response of the ingested sludge dose. This plateau response follows the concepts of metal adsorption to the sludge specific adsorption sites, much like the plateau response of plant uptake to increasing sludge application rate (Corey et al., 1987). If increasing amounts of sludge-Pb is ingested, increasing amounts of sludge metal adsorption sites are ingested. Only one published study has evaluated the dose response of Pb in ingested soil or dust (Stara et al., 1973). Their data fit the plateau model.

How much sludge product may the EPA valid "MEI" 1-5 year old child ingest? Are fibrous sludge products likely to be ingested at as high a rate as the fine fraction of soils adhering to children's hands and toys? Usually the fine fraction (< 0.1 mm diameter) is considered to constitute the bulk of the "soil/dust" material actually ingested by children. However, the true "pica child" ingests whole soil including large sand grains (> 1 mm diameter). This true "pica child" has to be the worst case MEI, but he is a very small fraction of children. Studies feeding sludge containing less than 300 mg Pb/kg to animals showed no increased bioavailability of Pb over control animals (Table 2). The percent of sludge in the diet of the true pica child is similar to that of the animal feeding studies. Therefore, if we assume that bioavailability of the pica child is similar to that of animals, a concentration of 300 mg Pb/kg sludge should be considered to be safe. Furthermore, the true pica child who ingests 5-10 g soil/day (2 to 4% of the dry diet) represents less than 1% of the children between 2 and 6. Thus, on a U.S. population basis this represents an extreme individual who has a very low probability of occurrence, but would represent the MEI.

A limit of 300 mg Pb/kg would allow marketing of sludge materials from POTWs controlling industrial Pb inputs; cessation of use of Pb as a gasoline additive has significantly lowered the Pb concentration in sludges. Composted sludges and heat-dried activated sludges are even lower in Pb than digested sludges. Perhaps a limit of 300 mg Pb/kg could be used without practically limiting sludge D&M, but still not risking Pb poisoning of the MEI pica child.

In the Pathway 2F-Agricultural Land Application scenario, soil ingestion occurs from the sludge-soil mixture. As with other models, we assume that sludge

is uniformly mixed with 15 cm soil. Using the same reasoning as above, the soil could be up to 300 mg Pb/kg. Background soil would contain about 10 mg Pb/kg, so 290 mg increased Pb/kg could be allowed if the reasoning is accepted. This is 580 kg sludge-Pb/ha.

Pathway 1 (sludge-soil-plant-human): We discussed in the previous section the importance of protecting children from increased Pb exposure. A substantial portion of urban children exceed the 10-15 μg Pb/dL presently recommended as the maximum limit of Pb for children. Surprisingly, however, white male blood pressure was selected as the health effect to limit sludge Pb applications in the TSD.

However, the greatest flaw in the TSD estimation of Pb risk under Pathway 1 is the slopes of Pb uptake by crops used. Many studies have been conducted with crops grown on sludge-amended soils, and some have included Pb transfer during animal feeding studies. In nearly every case (even with sludge Pb > 1000 mg/kg), crop Pb was not influenced by sludge application (e.g., Chaney et al. 1978b). Often sludge application significantly reduced crop Pb concentration. As in other cases, EPA ignores this literature because they could not estimate positive slopes for plant uptake from available field sludge studies. Because sludge adds Pb-adsorption capacity to the sludge-amended soil, it is inappropriate to use any data from non-sludge Pb research studies.

The RE for Pb in crops grown on sludge-amended soils is low, apparently lower than that of crops grown on normally fertilized soils. This can be estimated from the results of numerous animal feeding studies, such as those conducted by Chaney et al. (1978b). Even though Swiss chard was slightly higher in Pb on some of the sludge-treated plots, there was no significant change in Pb in tissues of the guinea pigs fed the chard for 80 days.

It is important to note that nearly all the published results for Pb concentration in foods are too high. Unless "clean rooms" are used to prevent Pb contamination of samples, the Pb pollution of urban dust causes analytical results to be falsely high (Patterson, 1980; Wolnik et al. 1983a; 1983b; 1985). Thus, most of the research assessments of Pb uptake by crops are flawed, including data from study of all kinds of Pb sources. Because of these errors, it is especially important that EPA consider the data from animal feeding studies. In most such studies, feeding sludge-grown crops caused no change in tissue Pb for several experimental animals (Chaney et al., 1978b; Logan and Chaney, 1983).

All these considerations must be made in relation to the limit that will be imposed to protect the pica child in Pathway 2F. Direct ingestion of sludge (2F-D&M) allows much greater Pb ingestion risk than does consumption of crops grown on sludge-treated soils, especially when considered on a body weight basis. Thus, the soil will be limited to no higher than 100% sludge in Pathway 1, because that is the case considered in Pathway 2F-D&M. In practice, other elements will limit the cumulative application of sludge to far lower than 100% of the surface 0-15 cm soil. At 1000 mt/ha, the soil is 50% sludge DW. Using the 300 mg Pb/kg "clean sludge" to protect Pathway 2F-D&M limits soil Pb to 150 mg/kg at 1000 mt/ha [(3000 mg Pb/kg sludge DM) \cdot (1000 mt sludge/ha) = 300 kg Pb/ha = 150 mg Pb/kg which is lower than required in Pathway 2F -Agr. Land. Field

studies of Pb uptake by crops clearly demonstrate no increase in risk of Pb transfer to foods at this low application of sludge-Pb. Of course, this is true for the case 1F, worst case ($\approx 50\%$) garden foods scenario also.

As noted above, all sludge-Pb human exposure cases become Pathway 2F for D&M products. Thus, setting the Pathway 2F Pb application limit on the basis of soil and sludge Pb bioavailability upon ingestion by the pica child is a promising basis for minimizing human health effects from sludge-Pb.

Comparison of estimated sludge-Pb application limits.

Pathway	TSD Limit	Corrected Limit
	-Max. kg Pb/ha-	
9 (Sludge→Soil→Soil Biota→Predator)	125	> 1000
7 (Sludge→Soil→Plant)	-	>> 1000
1F (Sludge→Soil→Plant→Human)	195	> 1000
2F-Agr. Land (Sludge→Soil→Human)	378	580
2F-D&M (Sludge→Human)	378	300 mg/kg
1 (Sludge→Soil→Plant→Human)	1190	>> 1000

Cadmium

Pathway 1F (sludge→soil→plant→human): The summary Table 6-3 (TSD) indicates that Pathway 1F most limits the Cd input in the agricultural land application. The limit is 18.4 kg Cd/ha. This pathway is complicated because it involves not only the use of a MEI but also varieties of crop plants, and livestock animals in the exposure computation. Even with the aid of RAMMS, it was difficult for us to follow the computation or to examine the validity of data used. Instead, we scanned the references to learn which data EPA used to estimate the transfer coefficients. While there were entries of data from "salt" spiked experiment, their effects on the overall outcome of the risk assessment is difficult to estimate as they constituted only a fraction of the plant or animal products entered into the calculation. We recognize deficiencies of the available data and do not consider this type of infraction a major flaw unless a majority of the data used in a category are derived from inappropriate sources.

Except for generic deficiencies on assumptions (eg. fraction of the diets affected, relative effectiveness, duration of exposure, etc.) which have been discussed elsewhere in this report, we feel the final result of this pathway is realistic because it is close to the application limit estimated by Chaney et al. (1987) when they corrected the acidic garden scenario to account for the Pennington (1983) food ingestion data, and for the differences among crop species in relative uptake of Cd from acidic sludge-amended soils.

Pathway 7 (sludge→soil→plant): Interestingly, the TSD calculated a limit (178 kg Cd/ha) based on Pathway 7. Although we agree that we are not familiar with published field studies which measure specific Cd toxicity of sludge-applied

Cd to plants, there were many Cd-salt-spiked sludge studies published by Bingham and co-workers (e.g. Bingham et al., 1979; Mahler et al., 1982) over the years. Part of that work used acidic soils, and rice, spinach, bean, and other species more sensitive to soil Cd, than the most sensitive case described in the TSD (Cd-salt added to an acidic organic soil). The high soil organic matter content in the study cited in the TSD (John, 1973), makes Cd much less toxic than would be observed in light-textured soils of the U.S. southeast. Actually, the data in Table 4-49 of the TSD essentially all violate one or several criteria for data use in this kind of assessment: 1) no evidence was provided that Cd caused the observed toxicity; and 2) Cd salts can never simulate the true potential for phytotoxicity of sludge-applied Cd. Further, Heckman et al. (1987) noted that 21 kg salt-Cd/ha (field application) caused Cd-specific phytotoxicity to soybean in a strongly acidic soil. Sludge-applied Cd did not cause equal phytotoxicity under strongly acidic conditions.

We believe that phytotoxicity from sludge-applied Cd is less limiting to sludge-Cd application than the potential for food-chain toxicity of Cd using a conservative model. So the EPA conclusion about the risk from Pathway 7 compared to Pathway 1F is correct even if the estimate for Pathway 1F is 10-fold too high.

Pathway 9 (sludge→soil→soil biota→predator): The TSD calculated a limit based on Pathway 9, but the specific limit is not shown in section 4.9.2.2, or in Table 6-3. Further, the Cd application limit from Pathway 9 appears to be much lower than the limit EPA estimated for Pathway 1F (the present limiting pathway). If this estimated Pathway 9 limit were properly based, it would have unexpectedly limited sludge Cd in the Proposed Rule.

As we have noted above, a number of errors were allowed to enter the estimations in Pathway 9. The most important errors were the fraction of diet represented by the sludge-influenced soil biota, and the bioavailability of earthworm-Cd to animals which ingest live earthworms with significant soil contamination. Further, studies of Cd tolerance by birds often included animals with Zn or Cu or Fe-limited, purified diets. Such diets allow greater toxicity of Cd than do normal "earthworm diets. The estimate under the TSD method would be: $RLC = [(6.0_{TA} - 4.8_{BB}) / 2.3_{UB}] + 0.2_{BS} = [1.2/2.3] + 0.2 = 0.7 \text{ mg Cd/kg}$. The sludge-applied increment would be 0.5 kg Cd/ha. This estimate used the lower Cd accumulating species of worm studied by Hartenstein et al. (1980), which we believe is not a proper predictor of the uptake slope for soil earthworms.

The slope estimate from Beyer et al. (1982) is only 13.7 mg Cd/kg earthworm DW per mg Cd/kg (from the TSD) or 20.1 (our calculation using $(57-4.8)/(2.7-0.10) = 52.2/2.6 = 20.1$). The slope for the highest Cd soil, 8.2 mg Cd/kg, was only 14.1 mg Cd/kg earthworm DW per mg Cd/kg soil. Using the 18.4 kg Cd/ha allowed under Pathway 1F, we obtain $18.4/2 = 9.2 + 0.2_{BS} = 9.4 \text{ mg Cd/kg soil}$. Using the above slope (14.1), the expected earthworm Cd would be: $(14.1) \cdot (9.2) = 130 \text{ mg Cd/kg DW}$. If birds consumed 1/3 of their diet as earthworms from one sludge-amended field, their diet would contain 43.2 mg Cd/kg DW. Again, we must consider that soil inside the ingested earthworms should further reduce the bioavailability of the ingested Cd. However, in contrast with Pb, the earthworms bioaccumulate Cd and the accumulated Cd is the basis for risk estimation,

compared to Pb where the soil in the ingested earthworms is the basis for the risk estimation.

Is this level of Cd in earthworms a toxicity risk to the birds consuming adequate levels of Cu, Zn, and Fe? Adequate levels of these metals prevent the dietary deficiency-induced sensitivity of animals to Cd ingestion. Another toxicity consideration is research on shrews ingesting earthworms from a Cd + Cu polluted soil in the UK (Dodds-Smith et al.; 1986, and Hunter et al., 1981). Hunter et al., (1983) also attempted to evaluate the toxicological significance of metals to wildlife. They observed injury to kidneys in shrews with very high body burdens of Cd and Cu. These research sites were highly contaminated with Zn, Pb, and/or Cu, 34000 mg Pb or Zn/kg and/or 50000 mg Cu/kg, but only 10-50 mg Cd/kg), and do not allow unequivocal conclusions regarding Cd pollution. Information in Hunter et al. (1983), plus that in a paper describing the food-chain relationships of Cd and Cu at the same locations (Hunter and Johnson, 1982), indicates that very high soil contamination with Cd would be necessary for Cd to affect the health of these short-lived (< 2 yr) mammals. To use these data, one must be careful to determine the dry vs. wet weight basis of the information reported. Kidneys did not exceed 200 mg Cd/kg fresh weight.

The potential toxicity of Cd to birds was examined in the TSD (Table 4-42, page 4-225) which contains a listing of many sources of data. Again, few of these data are relevant to evaluating risk to birds ingesting earthworms from sludge-amended soils. Stoewsand, et al. (1986) fed earthworms from control fields to Japanese quail; no toxicity resulted, although kidney and liver did accumulate Cd. Thus, we conclude that Pathway 9 is not more limiting to sludge application than Pathway 1F.

Comparison of estimated sludge-Cd application limits.

Pathway	TSD Limit	Corrected Limit
---Max. kg Cd/ha---		
Pathway 1F (Sludge→Soil→Plant→Human):	18.4	Near Correct
Pathway 7 (Sludge→Soil→Plant):	178.	> 20
Pathway 9 (Sludge→Soil→Soil Biota→Predator):	-	> 20

Arsenic

Pathway 2F (sludge→human) or (sludge→soil→human): Arsenic is included in the risk assessment because of its toxicity to humans. Inorganic As causes skin cancer in humans when excessive amounts of arsenate are ingested in drinking water over a prolonged period. In the TSD, Pathway 2F (sludge→soil→human) limits

the input of As in agricultural land application. This is a relatively simple pathway. We feel the equation used for the calculation is acceptable if the proper data are used. We know of no basis to use daily As ingestion limits other than using the As MCL of the National Drinking Water Standard as the threshold in determining reference daily intake (RfD = 0.0014 mg/kg body weight/day). However, as discussed below, because this number is based on the possibility of developing skin cancer after 70 years of continual exposure, it may be necessary to treat As like the carcinogenic organic chemicals in the TSD calculations. Further, the Drinking Water Science Advisory Board has recently advised EPA that a threshold of 250 µg As/day should be used in developing Rules regarding As. This is 2.5 fold the present limit.

The final human receptor of Pathway 2F is a child who ingests soil. As the arsenic induced skin cancer results from long duration chronic exposure, is it realistic or reasonable to assume a child (with, at the most, five years of maximum As exposure through this pathway) will develop cancer from As in ingested soil or sludge? This RfD is based on a cancer potency of 70 years exposure duration. This number should be adjusted for the Pathway 2F short term exposure. Other carcinogenic chemicals were approached with a potency factor, and an exposure duration. The As MCL was calculated from the potency factor by another EPA office. Thus, the TSD failed to correct for the short exposure durations of children to ingested soil-As.

Another weakness in the model is the assumption that As remains in the soil indefinitely. Applied As has a half-life in soils of about 7 years because trimethylarsine is formed and volatilized from the soil (Woolson, 1975). Thus, As cumulative applications should reflect this loss pathway. The loss rate constant (k) for a 7 year half-life would be $= \ln(2) \div 7 = 0.1 \text{ yr}^{-1}$.

The Pathway 2 calculations also assumed 100% absorption of sludge/soil As from the gut. In sludge, As bioavailability is likely on the order of 5-10%, (while soil As probably has higher bioavailability than sludge, say 10-20%) compared to the 100% bioavailability of Na arsenate in drinking water (Chaney, personal communication).

The TSD assumes that all As in the background diet has equal likelihood to induce cancer as Na arsenate in water. Research has shown that most food As is in fish products, and that As in fish exists largely as an organic derivative, arsenobetaine. This chemical As species is nearly all excreted intact, and does not undergo metabolic reactions necessary for As to be involved in skin cancer. Much of the As in vegetable foods also exists as organic As compounds, with little potential for toxicity to humans (Pyles and Woolson, 1982).

One key assumption in Pathway 2F is the amount of soil ingested each day. In the discussion of Pb, we note that soil ingestion by the 95th percentile youngster is about 0.5 g/day (Calabrese et al., 1989), rather than the mean 0.1 g soil/day used in the TSD.

Calculation of the 14 kg sludge-As application allowed for Pathway 2F in table 6-3 was instructive. For example, 14 kg As/ha = 7 mg As/kg soil. Ingestion of 0.1 g soil/day would allow increased ingestion of 0.7 µg As/day. If exposure is limited in the original calculation by the RfD - TBI = 14 µg/d

- 13 $\mu\text{g/g}$ = 1 $\mu\text{g/day}$, the allowed application would be $1/.1 = 10$ mg/kg; 10 (max.)
- 3 (background) = 7 mg/kg (addition) = 14 kg/ha. However, this does not adjust for RE and DA, nor volatilization.

If soil As bioavailability is assumed to be 20%:

$$\text{RIA} = [(0.0014_{\text{RFD}} \text{ mg/kg/d} \cdot 10 \text{ kg Body Weight}) \div 0.2_{\text{RE}}] - 0.013_{\text{TBI}} \text{ mg/day}] \cdot 10^{-3} = 70 - 13 = 57 \mu\text{g soil-As/day.}$$

This equation is approximate because the RE is used to adjust only the increased exposure, not the total dietary exposure.

One then calculates the RLC using the RIA, soil ingestion rate ($I_s = 0.5$ g/day), and exposure duration adjustment ($DA = 0.07$). $\text{RLC} = (57 \mu\text{g soil-As/day}) \div [(0.5 \text{ g soil/day}) \cdot 0.07_{\text{DA}}] = 1628$ mg As/kg soil to cause this exposure. This number would be still higher if As volatilization was considered (equation 6 on page 4-113). Even pure sludge has not been observed to have this high level of As (mean sludge As = 18.5, median = 13.1, range of 15 small cities = 0.1-89.8 in Mumma et al., 1988; median = 4.4 mg As/kg in 40-city study). Thus, there appears to be little risk from this route.

Other pathways were not examined in detail as these As limitations would not influence sludge utilization. However, other risk assessments fail to find large transfer of soil As to plants needed for risk in Pathways 1 and 1F.

Comparison of Estimated Sludge-As Application Limits:

Pathway	TSD Limit	Corrected Limit
	--Max. kg As/ha--	
1:Sludge→Soil→Plant→Human	6960	?
1F:Sludge→Soil→Plant→Human	382	?
2F:Sludge→Human	14	1628

Selenium

Pathway 5 (sludge→soil→plant→animal): Selenium occurs naturally in all soils. Selenium is required by animals. Disorders associated with selenium deficiencies are commonly observed, whereas toxicities are occasionally observed, to both humans and animals, because of localized soil Se enrichment from geochemical sources. Although Se is not known to be an essential plant nutrient, Se is readily absorbed by plants if it is present in the soils. Plant uptake of Se is dependent on many soil chemical factors, most importantly, soil pH, oxidation state of Se, and sulfate concentration. Selenium concentrations in municipal sludges are generally low (median levels of 1-2 mg/kg). A few field studies of Se in sludge-amended soils did not show significant plant response to sludge-borne Se. Logan et al. (1987) found Se in Swiss Chard grown in a sludge-amended calcareous soil (total Se input approximately 6 kg/ha) was not significantly different from that of the control. Similarly, Chaney et al.

(1978a, 1978b) did not observed significantly increased Se uptake by lettuce or Swiss chard grown on soil amended with several sludges, whereas fly ash usually increased crop Se (Gutenmann et al., 1976). One conclusion of that research was that fly ash could be applied as a Se fertilizer to help correct Se deficiency in crops used as food or feed. Other than this evidence that the plant uptake of sludge-applied Se has a lower slope than found in traditional studies with added selenate, we have no additional information that would improve the current assessment of the sludge-borne Se toxicity to foraging animals. The maximum tolerated dietary Se, 2.3 mg Se/kg, is higher than the NAS (1980) recommendation of 2.0 mg/kg for chronic Se ingestion. However, within the methodology, 2.3 mg Se/kg is the proper number.

Recent identification of Se problems in California (Kesterson Reservoir) has significantly improved the data base for Se uptake by grain and forage crops. Alfalfa is a relative accumulator of soil Se, and has been used in several tests; however, sulfate strongly inhibits Se uptake by alfalfa, and sulfate will be present at substantial levels in sludge-treated soils.

Basic to any discussion of Se is appreciation for the different forms of Se that can exist. Se may exist as selenite or selenate, and the availability to plants is greater for the selenate form (selenite is much more strongly adsorbed by soils). Sulfate inhibits plant uptake of selenate. Further, over a period of years, Se slowly leaches through the soil. Thus, some effort should be made to account for Se leaching and possible effects on reducing the soil Se inventory as well as Se contamination of groundwater.

Using the allowed forage Se, 2.3 mg/kg, and the slope for Se uptake of 0.07 [(mg Se/kg forage DW)·(kg Se/ha)⁻¹], and the background crop Se of 0.03 mg Se/kg forage DW, one calculates $(2.3-0.03)/0.07 = 32.4$ kg Se/ha. The median sludge (2 mg Se/kg) could be applied at a cumulative application rate of 16,200 mt/ha under this limit. Sludge Se is normally less than 10 mg/kg (e.g., the median sludge Se in the Mumma et al. (1988) paper cited above was only 2.1 mg/kg DW; for the 40-city study, median Se was 1.45 mg/kg, and the 90th percentile was 9.06 mg/kg). Thus, the cumulative Se limit of 32.4 kg Se/ha would allow 3240 mt of the median sludge DW/ha, and would not practically limit sludge utilization. However, the 40-city study did identify 2 POTWs with much higher Se than reported in previous surveys, 45 and 193 mg Se/kg. Such data support the need to identify the very few POTWs which suffer from industrial Se discharge sufficiently great to cause a problem in livestock, if sludge were used on forage crops.

Molybdenum

Pathway 5 (sludge→soil→plant→animal): Sludge Mo applications were estimated by EPA to be limited to 5.07 kg/ha, using Pathway 5. This pathway involves plant uptake of sludge-applied Mo by forage crops and toxicity of crop Mo to ruminant livestock. Excessive soil Mo, in neutral pH soils, can poison livestock by this pathway (Logan & Chaney, 1983). The toxicity mechanism is well characterized: Mo is transformed in the rumen to thiomolybdate, which binds Cu and prevents both Cu absorption from the gut and Cu utilization within the animal. The most sensitive livestock are Cu-deficient sheep and cattle (NAS, 1980). However, forage crops grown on sludge-amended soils are not Cu-deficient;

rather, these crops have normal to somewhat enriched Cu levels depending on soil and sludge properties. Therefore, the impact of Mo is reduced considerably.

Another consideration is that cured forage from high Mo areas, when consumed by ruminants, will be less toxic than the same forage grazed in a succulent state (Mills and Davis, 1987). The higher the energy level of the diet, the more sulfide is produced in the rumen, thus forming the thiomolybdate which causes the toxic effect of Mo. Accordingly, the form of Mo, as well as the forage type and crop species, must be taken into consideration when relating dietary levels of Mo to the degree of toxicity to ruminants.

The amounts of Mo absorbed by crops vary with soil properties. Generally, the availability of Mo to crops increases with increasing soil pH. Higher soil pH also increases the potential for Mo leaching. Results for farm fields contaminated by a Mo smelter indicated that the plow-layer accumulation of Mo in the field was inversely related to the pH maintained in the soil over a 40 year period (Hornick, et al., 1977). Two miles from the smelter, Mo decreased from 71.6 mg Mo/kg soil at pH 4 to 19.2 at pH 6.

Plant materials are tolerant to relatively high concentrations of Mo. Cabbage, an accumulator of Mo, grew normally at a plant concentration of 1060 mg/kg Mo. (Hornick, et al., 1977). Jarrell, et al., (1980) also observed that large quantities of Mo may be added to soils with little effect on growing plants.

The TSD considers Mo in section 4.5.2.3 and identifies the threshold Mo feed concentration toxic to herbivore animals (TA_H) = 5 mg/kg DW. The document claims this is the lowest feed concentration showing a toxic effect on cattle when normal dietary Cu levels in the feed are 8-10 mg/kg DW. It is claimed that "because no other concentration of Mo was tested in this study, it is not possible to calculate the mean between the level that barely causes an effect and the highest level that does not cause an effect". However, the next 11 pages contain tables summarizing Mo toxicity to all classes of livestock.

The Buck (1978) reference relied on is a review or summary of general understandings or a recommendation to management, not the specific results of an experimental test of forage Mo toxic to livestock. If only a review article was to be considered, surely the National Academy of Sciences (1980) expert committee report [Mineral Tolerance of Domestic Livestock], which was subjected to extensive internal and external review, is more credible. They evaluated low level chronic Mo toxicity to the most sensitive livestock (beef cattle) as "5 to 10 ppm (mg/kg) Mo, which have been weakly associated with impaired bone development in young horses and cattle". It must be emphasized that substantially higher levels of Mo would be tolerated in the presence of adequate copper and inorganic sulfate. Sludge grown forages are normal in Cu and sulfate, so the higher recommendation of about 10 mg/kg forage Mo is more appropriate. A large body of data on the toxicity of Mo toxic forages grown on soil naturally high in Mo (not Mo salt additions to diets) supports use of 10 mg/kg Mo for forage with normal Cu concentration (NAS, 1980 Table 1 [page 5]).

The next component of the exposure estimate involves the linear Mo uptake slope of forage crops. The TSD used $0.769 \text{ mg Mo/kg forage DW} \cdot [\text{kg Mo/ha}]^{-1}$,

calculated from results of a field study of sludge applications on composition of fodder rape (Andersson and Nilsson, 1972). The background plant tissue concentration of 1.1 ± 0.11 mg Mo/kg DW was selected from the same study. Although this study generally fits the criteria for reliable studies, the range of applied Mo was limited. Other data are available to test the risk model more reliably. Only a small change in forage Mo was observed in Andersson and Nilsson (1972), because a sludge with normal, low (7.4 mg Mo/kg) concentrations was used. The linear extrapolation was from the observed maximum of 1.7 mg Mo/kg dry rape forage to 5 mg/kg, the estimated maximum forage Mo before toxicity occurs to the cattle. Applied Mo was approximately 0.83 kg/ha (0.0074 kg Mo/mt sludge DM, times 14 mt sludge/ha·2 years, times 8 applications) (background soil contained 0.53 ± 0.02 mg Mo/kg, while treated soil contained 0.69 mg Mo/kg). Table 4.46 incorrectly indicates that the Mo application rate was 0.78 kg/ha. The table then reports an uptake slope of 0.769 when the correct value should have been 0.8 with the correct number of significant figures (1.7 mg Mo/kg in sludge fertilized forage - 1.1 mg Mo/kg control forage = 0.6 mg Mo/kg increase due to sludge application over a 15 year period (1 significant figure of crop Mo change). Table 4.46 (Uptake of Mo by plants) contains only this one forage crop example, although other direct human food crops are reported. We believe the method used to estimate safe applications of Mo in sludge can be improved.

Experiments have been conducted to test the risk potential of sludge Mo. Field data are available for Mo-rich sludges which readily caused high increase in forage Mo. Actually, only highly Mo enriched sludges have been shown to cause high Mo forages. A median sludge (6.5 mg Mo/kg sludge), (11.0 mean; Mumma et al., 1988) did not raise forage Mo to risk levels in any tests. However, as noted below, sludges with high Mo levels can readily cause increased forage Mo. Further, the data indicate that sludge Fe or other element oxides (known to adsorb Mo in soils) increase the Mo adsorption of sludge-amended soils.

One field test of the plant uptake slope for sludge-applied Mo was reported by Webber et al., (1983). They evaluated corn leaf Mo concentration at 10 field sludge utilization sites. Sludges contained <20 to 206 mg Mo/kg, with estimated loadings of <0.2 to 19.4 kg Mo/ha over the known application period. The soils were analyzed at the one site where excessive forage Mo was achieved, and contained 19.2 mg Mo/kg D.W. soil. Among the 10 locations, forage Mo was significantly decreased due to sludge application at 2 locations, not significantly changed at 4 locations, and not above background at 3 others sampled. Only the high Mo sludge (206 mg/kg) caused high soil and forage Mo. Thus, soil Mo of 19.2 ppm (presume 19.2 mg Mo/kg soil·2000 mt soil/ha·15 cm = 38.4 kg Mo/ha) caused corn forage Mo to increase from 0.72 to 32.2 mg/kg. This gives a slope of $31.5/38.4$ or 0.560 mg Mo/g forage DW·[kg Mo/ha]⁻¹. Using the control forage Mo concentration (0.72 mg/kg) and Mo uptake slope (0.538), one calculates 7.64 kg Mo/ha to reach the Mo toxicity threshold of 5 mg/kg forage Mo (for Cu-deficient forages) or 16.6 kg Mo/ha to reach 10 mg/kg Mo (for normal forage Cu concentrations).

In the 40 city survey, only 4 sludges were analyzed for Mo (0, 27.6, 35.6, and 7.5 mg Mo/kg DW). Other analyses suggest a median Mo value of 6.5 mg/kg (Mumma et al. 1988). Thus only Mo-rich sludges could cause the risk calculated. A more appropriate control would require pretreatment by industrial polluters causing sludge Mo enrichment above the approximately 20 mg Mo/kg found in

unpolluted sludges. Normal sludge use would require about 100 years to apply 10 kg Mo/ha:

$$[(10 \text{ mt sludge DW}) \cdot (\text{ha} \cdot \text{yr})^{-1} \cdot (0.010 \text{ kg Mo} \cdot [\text{mt sludge DW}]^{-1}) = 0.1 \text{ kg Mo/ha} \cdot \text{yr}].$$

Further, substantial leaching of sludge-applied Mo would likely occur during the 100 year application period based on many studies, including Hornick et al. (1977).

Another approach to setting sludge-Mo application limits would be to use the recommendations of the Water Quality Criteria for irrigation water. The EPA Water Quality Criteria (1973) recommend that Mo in irrigation water not exceed 0.01 mg/L (for indefinite application on light-textured soils) or 0.05 mg/L (maximum 20 year application on heavy-textured soils). Assuming that the EPA Water Quality Criteria Document represents a no-adverse-effect level of applied Mo, at 1.2 m annual water application, at least 12 kg Mo/ha could be applied over 20 years with no detrimental effects. Pratt et al. (1988) recommended that Mo input from application of irrigation water not exceed 0.5 kg/ha/yr. If adequate leaching is provided, Mo loading can be maintained at this level indefinitely. Using either the EPA Water Criteria values or Pratt's newer numbers, the maximum allowable Mo loading exceeds the value calculated from the current risk assessment.

Mercury

Pathway 3 (sludge→soil→plant→animal→human): In the Proposed Rule, sludge-Hg was most limited by Pathway 3 at 14.9 kg Hg/ha. This value is likely non-limiting to sludge utilization because nearly all sludges have low Hg concentrations. Nevertheless, this estimate is apparently in error because researchers have detected no significant increase in plant uptake (leafy vegetables or forage crops) of Hg when sludges are applied to cropland. [Note: Page 4-176 is supposed to cover the Pathway 3 data for Hg, but discusses information on sludge ingestion and soil which belong in Pathway 4.]

The plant Hg-uptake slope is discussed on page 4-179, but the discussion omits several important sludge-Hg studies. Research from Denver reported no increase in forage crop Hg on sludge-fertilized pastures (Baxter et al., 1983). The large body of work by Lisk and co-workers who used neutron activation to obtain precise analyses of trace levels of Hg in numerous crops failed to identify significant increases in crop Hg concentrations due to application of even high levels of sludges (e.g., Chaney, et al., 1978 a,b). In fact, application of sludge reduced Hg concentration in Swiss chard grown on soils amended with 56-224 mt/ha of three sludges. Hg salt addition to soils caused some increase in plant Hg (Hogg et al., 1978, cited in the TSD), but such data are not relevant to sludge application. Hg is strongly bound by the organic fraction of the sludge at the time of application. Field research has shown that sludge reduced crop Hg even while the soil Hg was increased. This is further evidence that sludge metal adsorption sites control metal availability in sludge-amended soils. Thus, the risk estimated for Pathway 3 is erroneous.

Researchers recognize only three potential pathways for movement of sludge-Hg to humans or livestock, two by direct ingestion of sludge by livestock or children, and a third from culture of mushrooms on composts including sewage sludge Hg. Erosion of sludge to become sediments in aquatic ecosystems may allow conversion of Hg to methyl-Hg and promote bioaccumulation by fish.

Pathway 4 (sludge→soil→animal→human): Several studies of sludge ingestion by livestock reported Hg in tissues. In particular, the study by Kienholz et al. (1979) found a very small increase in liver and kidney Hg in cattle consuming 12% sludge, but no increase in blood-Hg or Hg in muscle or fat. A slope for "animal uptake of Hg from ingested sludge" can be estimated from these data. Pathway 4 for Hg, begins on page 4-217 (TSD). Uptake by livestock is addressed in paragraph vi on page 4-217. This cites "The uptake of mercury in animal tissues for each food group (UA) is described in 4.3.2.8, vi." That specific section, however, is for PCBs. Section 4.3.2.7 (page 4-170) is for Hg, but the source of the Hg is crops or other materials, not sludge. The cited paper of Vreman et al. (1986) has no relationship to sludge ingestion. The Johnson et al. (1981) study found no significant increase in muscle Hg from ingested sludge, nor did Baxter et al. (1980), or Kienholz et al. (1979). Small increases were observed in liver in several of these studies, but these were reported on a dry weight of liver basis by the Colorado researchers. Sludge feeding studies are available for swine (from Florida and Illinois) and sheep (from New Mexico), again showing no increase in tissue Hg except liver, and then very low slopes for the response. The present assessments are lacking because non-sludge sources were relied upon.

Pathway 1 (sludge→soil→plant→human): The selection of data for uptake of Hg by plants from sludge-treated soils (page 4-179) is especially poor. The Bull et al. (1977) data represents an aerosol source of Hg which polluted the shoots of plants directly, as was the Lindberg et al. (1979) data. The work of Hogg et al. (1978) represents surface-applied irrigation water containing isotopic Hg. The John, MacLean, and Weaver studies were each for freshly added Hg salts. The last line of 4.3.2.7.vi (TSD) claims that the Hogg et al. paper was a sludge/pot study, when in fact, no sludge was used in this research. Soils were mixed to contain 10 mg Hg/kg as three Hg compounds. The soils then were irrigated with sewage effluent, and bromegrass harvested three times. Crop Hg fell from 2.5 ppm maximum in the first harvest to 0.2 ppm in the third harvest, much as would be expected for equilibration of added metal salts with soils. Nothing in these data is relevant to preparing a limitation on sludge-Hg application to soils! As noted above, valid sludge field research are available showing that most sludges actually decrease crop Hg. These data are much preferable to the data used in the TSD to estimate risk.

Pathway 1M (sludge→soil→mushrooms→human): One pathway has been shown to require regulation of sludge-Hg when proper sludge-derived Hg data were used the assessment. The bioaccumulation of Hg by mushrooms appears to be so great that utilization of sludge compost or refuse-sludge co-compost in mushroom production may have to be prohibited. Domsch et al. (1976) showed that even low levels of sludge-borne Hg cause mushrooms to exceed 0.5 mg Hg/kg fresh weight, the limit now used by FDA for fish species which bioaccumulate methyl-Hg. Few data are available to develop a slope of Hg accumulation by mushrooms from compost. No data are available on bioavailability of mushroom-Hg (although mushroom-Cd has

been shown to have very low bioavailability due to Cd sorption on chitin in the cell wall of these fungi). Perhaps the proper response of EPA would be to encourage any POTW wanting to market sludge compost for use in mushroom production to conduct experiments to test their site-specific response compared to the FDA standard. When enough data are available, a general standard might be prepared. It is conceivable that many sludge composts will be low enough in Hg, or contain some additive that lowers the potential for mushrooms to accumulate Hg. However, we are not familiar with data which supports use of sludge products in mushroom production at this time.

Pathway 9 (sludge→soil→soil biota→predator): Earthworm accumulation of Hg was tested by Helmke et al. (1979). After correction for soil contamination of the earthworm bodies, there was no significant accumulation of Hg from sludge-amended soils. Thus, Pathway 9 would not comprise a risk to wildlife, other than due to direct soil ingestion as Pathway 6.

The TSD estimates for maximum kg Hg/ha via Pathway 4 is 1000 kg Hg/ha, and for Pathway 2F is 110 kg Hg/ha. These greatly exceed loading rates expected with typical sludges. Thus, we made no further evaluation of the TSD on Hg.

Comparison of Estimated Sludge-Hg Application Limits:

Pathway	TSD Limit	Corrected Limit
--Max. kg Hg/ha--		
3:Sludge→Soil→Plant→Animal→Human	14.9	?
2F:Sludge→Human	38.9	?
1F:Sludge→Soil→Plant→Human	110.	?
4:Sludge→Soil→Animal→Human	1000.	?
1:Sludge→Soil→Plant→Human	2000.	?
1M:Sludge→"Soil"→Mushroom→Human	?	?

Organics

Polychlorinated Biphenyls (PCBs)

The PRC has strong reservations regarding the derivation of limits for PCBs in Pathway 3 and Pathway 4. Because of the time constraints, it was not possible to examine the validity of the assumptions nor appropriateness of data used in the analyses of Pathway 3 (sludge→soil→animal→human) and Pathway 4 (sludge→soil→animal). The PRC is particularly concerned about the level of uncertainties/errors introduced into the PCB pathway analyses from the use of ¹⁴C derived data, inappropriate use of data from pure compound studies conducted on unique soils (sands with extremely low organic carbon), and use of data from studies which do not clearly identify the specific PCB Aroclor evaluated. While we believe these errors to be large, their cumulative is unquantifiable at this time. In the limited time available, it was possible for the PRC only to spot

the very obvious errors in the EPA's analyses of these two limiting pathways, and to provide the corrections below to the EPA number which appear in their analyses. Since time did not allow any examination of the numerical values used by the EPA in their analyses of these pathways, and the outcomes are inconsistent with the experience from the field experiments with sludge-applied PCBs, the PRC strongly urges the EPA to perform a detailed re-evaluation of their data selection and assumptions, and completely redo the analyses of these pathways.

The pathways most limiting sludge applications based on PCBs were Pathway 3, 0.00564 kg PCB/ha/yr (sludge→soil→plant→animal→human) and Pathway 4, at 0.0192 kg/ha/yr (sludge→soil→animal→human). These estimates are highly dependent on the diet model used, fraction of sludge/soil in diet (Pathway 4) or slope of plant/soil response curve (Pathway 3), and slope of the animal fat PCB concentration/diet PCB concentration.

The last transfer coefficient, diet to animal fat, was assigned a value of 4, based on Fries et al. (1973). A subsequent detailed review of this subject by Fries (1982) supports use of this value. No better data have been identified. However, it should be recognized that these data came from studies of ingestion of pure PCB compounds mixed with diet. One would expect equilibrated sludge-PCB or soil-PCB residues to have somewhat lower bioavailability.

Transfer coefficients in Pathway 3 are available for few toxic organic compounds, but are often < 0.1, and frequently < 0.01 mg/kg plant DW/[mg/kg soil] (Overcash et al., 1986). O'Connor (1988) reported similar results for food-chain crops grown in sludge-amended soils contaminated with diethylhexylphthalate (DEHP), pentachlorophenol (PCP), and PCBs. Given the normally low concentration of priority organics in municipal sludges, minimal (below detection limits) uptake of priority organics is expected (O'Connor, 1988).

Pathway 3 (sludge→soil→plant→animal→human): We believe the value of the soil→plant transfer coefficient used $[(0.25 \text{ mg PCB/kg forage}) \cdot (\text{mg PCB/kg soil})^{-1}]$ is grossly inappropriate. This value is 10 fold greater than other transfer coefficient values in Table 4-20 (pg. 4-81) which should have suggested potentially unique data.

Most plant "uptake" studies with toxic organics utilized fresh additions of pure chemical, often to coarse-textured soils. "Uptake" is often measured by ¹⁴C-labeled chemicals. Several recent studies suggest such experimental approaches can be seriously misleading. Fresh additions of ethylene dibromide (EDB) exhibit maximum bioavailability, but become decreasingly available with time (soil→plant ratio declines) due to bound residue formation (Frink and Bugbee, 1989). A number of low molecular weight halogenated compounds behave similarly (Pignatello, 1989; Sawhney, 1989). Others have found that hydrophobic organics become increasingly resistant to desorption, and thus presumably less available for plant uptake (DiToro and Horzempa, 1982; Karickhoff, 1980, 1984; Wu and Gschwend, 1986). Similarly, toxic organic behavior (especially hydrophobic organics) in coarse-textured, low organic matter soils has been shown to be different than in fine-textured, or higher organic matter content soils (Strek et al., 1981; Fairbanks and O'Connor, 1984; Fairbanks et al., 1983). Depending on the chemical used, reliance on ¹⁴C assay to characterize compound uptake can also be misleading (Aranda et al. 1989; Bellin and O'Connor, 1989).

These factors and others (eg. use of fresh weights vs dry weights to express results; excessive chemical concentrations, etc.) complicate selection of appropriate transfer coefficients from the literature.

Fortunately, data from appropriate studies of sludge-PCBs are available upon which to base plant uptake slope calculations. One such study cited in the TSD (Webber et al. (1983), however, is misquoted and misused. Webber et al. (1983) found significantly increased soil PCB residues at several sludge-treated locations in Ontario, Canada. However, corn foliage or oat shoots growing on the soil were not significantly increased in PCBs due to sludge use. The TSD (Table 4-20) reports slopes for corn and oat when no significant difference was found, a serious misuse of data. Table 8 in Webber reports only the control oat sample, with no value reported for PCBs in oat samples from the sludge-treated soil! Thus, the data point which was most controlling on PCB uptake from sludge-soil mixtures according to the TSD was used incorrectly since it does not even represent a sludge-treated soil and plant sample! The Webber corn data which were next most limiting were from measurements where no significant difference was observed between sludge-treated and control crop. Webber et al. (1983) even concludes: "There was no evidence for increased PCB uptake from sludge-treated soils."

Recently, additional studies of sludge PCBs were undertaken using Madison, WI, aged-sludge containing 52 ppm total PCBs. Greenhouse pot studies of plant uptake of PCBs by tall fescue showed no detectable PCB residue regardless of sludge PCB application rate (O'Connor, 1989). From this work, the highest slope could have been ≤ 0.02 based on non-detection. If the control is also treated as non-detected, the uptake slope is zero. Taylor (1988) studied the same sludge in the field. Corn grain did not have a detectable PCB residue at any rate. Again, the uptake slope would be zero. The slope selected from the research of Weber and Streck (1980) on tall fescue uptake of PCB from soil treated with pure PCB compounds (0.25) is at least 12.5 fold too high, but probably 125-fold too high or more. Because data obtained from appropriate research with PCBs in sewage sludge under field conditions are available, the data from inappropriate pot studies should not be used.

Data listed for plant uptake of PCBs (Table 4-20) are lacking in other ways. For example, a reference by Hafner (1982) is supposed to represent lettuce uptake of PCB. The title of this reference, however, clearly identifies the compound as PCNB (pentachloronitrobenzene), not PCBs. New data for sludge-PCB amended soils that should be added are those of O'Connor et al. (1989). Crops were grown in pots of soils amended with aged Madison, WI sludge. Crops studied included carrots, lettuce, and tall fescue (noted above). No detectable PCB residues were found in plant tissues other than carrot peel. Use in the summary table on page 4-79 (TSD) of incorrect crop uptake estimate data from Table 4-20 (e.g. lettuce data for PCNB; peanut shoot data in place of peanut grain, etc.) falsely estimates higher PCB food chain transfer in Pathways 1 and 1F than would be obtained only through consumption of unpeeled carrot (slopes for other root vegetables are significantly lower than for carrot).

Presuming that the present Pathway 3 calculations were conducted correctly, a more appropriate PCB annual application rate would be $0.0056 \cdot \geq 125 = \geq 0.7$ kg/ha/yr. With a median sludge PCB of 0.26 mg/kg (Mumma et al., 1988),

$(\geq 0.7 \text{ kg PCBs/ha}) \div (0.00026 \text{ kg PCBs/mt sludge}) = 2692 \text{ mt/ha}$ of a median sludge could be safely applied under Pathway 3. The result of using appropriate plant uptake slope data is to shift the controlling pathway to Pathway 4. The direct ingestion pathway is generally agreed to allow the greatest transfer of sludge adsorbed organics into animals (Fries, 1982).

Pathway 4 (sludge→soil→animal→human): Transfer of PCBs from sludge to animal tissues in Pathway 4 is largely controlled by the soil/sludge portion of diet. The fraction used was found in section 4.6.2 (pg. 4-275) of the TSD as the fraction of diet that is adhering soil (FL) = 0.10 g soil/g diet; or the fraction of the animal diet that is sludge (FS) = 0.08. Sludge adherence to forage crops in short term research studies, measuring sludge in/on forage at 30 d after application, is about 5% (Chaney et al., 1987). However, season long average sludge intakes by grazing cattle on pastures which received surface-applied sludge as fertilizer, were about 2.5% sludge when sludge was applied at the rate necessary to supply crop nitrogen requirements, as required elsewhere in the Proposed Rules. Some of the higher sludge contamination results were for higher sludge application rates, and thus comprise a false-high estimate of sludge ingestion by grazing livestock. The sludge intake value used in the TSD (8-10%) is thus too high compared to field data based on fecal analysis. This would add a 8/2.5% fold error. It seems clear that $\leq 2.5\%$ sludge in diet is the maximum exposure to livestock continuously grazing pastures amended with sludge 30 days before the animals enter the fields. If sludge were injected into soils, or intimately mixed in the plow layer, the potential for sludge ingestion is much lower. As noted elsewhere, the optimum regulatory approach to prevent risk from Pathway 4 is to require injection or tilling sludge into soils when sludge exceeds the PCBs concentration identified in this section as limiting sludges with typical N fertilizer value.

Ingesting 10% soil at 224 mt sludge/ha (10% sludge in soil) allows only 1% sludge in diet compared to ingesting at most 2.5% of surface applied sludge. Thus, the highest exposure scenario is through surface applied or adhering sludge.

Therefore, an appropriate estimate for annual application of sludge PCB to avoid risk through Pathway 4 is:

$$(0.0192 \text{ kg PCB/ha}\cdot\text{yr}) \cdot [8 \div 2.5] = 0.06 \text{ kg/ha}\cdot\text{yr}.$$

This would allow surface applications of 236 mt/ha·yr of the median sludge containing 0.26 mg PCB/kg (indicated by Mumma et al., (1988).

Pathway 2F (sludge→soil→human): As an example, for organics in Pathway 2, PCB will again be examined. For organics, the pathway assumes that equilibrium will be reached after 34 applications. The decay constant and annual compound application control exposure. The TSD sets the $T_{1/2}$ at 6 years based on pure compound (Aroclor 1254) added to soils. More chlorinated congeners have longer half-lives, and environmental PCB residues are depleted in lesser chlorinated congeners (Fries, 1982). Fries (1982) selected 10 years as the $T_{1/2}$ for PCB in soil. Residues that equilibrate with soil are expected to have still longer half lives. (Frink and Bugbee, 1989).

The daily soil ingestion of 0.1 g/day is inappropriate. The 95th percentile at 0.5/day is more protective, although this is likely an overestimate of 5 year average daily ingestion. As with Pb in Pathway 2, other soil ingestion studies should be considered (Calabrese et al., 1989; Clausing et al., 1987; Richland, WA study of EPA, unpublished).

For perspective, 34 applications of sludge at 10 mt/ha/yr applications (340 mt/ha), are about 15 cm of composted sludge. Thus, this scenario inadvertently requires a massive and unlikely cumulative sludge application.

The present limit for PCBs in Pathway 2F is 0.264 kg/ha·yr. This would be reduced by 0.1/0.5 to protect the pica child, giving 0.05. If a median quality sludge (0.26 mg/kg, Mumma et al., 1988) applied this PCB, the resulting application rate would be 203 mt/ha.

The PRC wishes to stress that the corrections offered are intended only to remove obvious errors from the EPA's calculations, and that the final outcome of these corrections do not produce acceptable limits on PCB content since they are in conflict with our experience with data from field studies using sludge applied PCB.

Additional Elements of Concern

Iron

The Proposed Rule includes no controls on sludge Fe. However, other risk assessments for sludge utilization (e.g. Dean, et al., 1985) have noted sludge-Fe risks. Fe has been shown to harm cattle grazing pastures top-dressed with Fe-rich, anaerobically-digested sludge (Decker et al., 1980). Cu in sludge has low bioavailability, and appreciable amounts of the Fe in liquid digested sludge exists as the more toxic ferrous form. Thus, high Fe levels in digested sludge (11%) harmed the cattle by inducing Cu-deficiency. Certainly sludge Fe should not be ignored by the Proposed Rule when actual Fe has been observed detrimental to animal health in an experiment. When sludges are more stabilized aerobically, the Fe is essentially all present as Fe³⁺ and, Fe toxicity was not observed. Nor was Fe toxicity observed when sludge Fe was only 4%, and a 21-day waiting period after sludge application was imposed before grazing was permitted (Decker et al., 1980). The best regulatory approach would likely be to require anaerobically digested sludges which have high Fe concentration ($\geq 4\%$) be injected or mixed with soil. Research has led to a recommendation to increase the Fe concentration of sludges to limit plant uptake of Cd, Zn, etc. (Corey et al., 1987). Thus, the potential for Fe toxicity problems from surface applied sludges could increase in the future.

Fluoride

Risks from sludge-F were also neglected in the Proposed Rule. A few sludges contain very high levels of F due to industrial discharge, (particularly by the ceramics and electronics industries). Excessive sludge-F may injure livestock ingesting sludge from the surface of pastures. Research has not found

appreciable risk from plant uptake of F or any other pathway considered in the Proposed Rule except direct sludge ingestion. In a study by Davis (1980), a sludge containing 33500 mg F/kg was applied to a silt loam soil in pots such that soil F was raised from 150 to 304 mg/kg. F concentration in the first cutting of ryegrass was 51.7 mg/kg DW, exceeding the 30 mg/kg maximum recommended dietary F level for cattle (NAS, 1980). However, the second cutting was just above 30 mg F/kg, and the third cutting near the background level in ryegrass. Thus, sludges containing extremely high levels of F may cause F uptake similar to additions of soluble F salts until the F has time to react with the soil. In contrast, normal sludges contain only about 300 mg F/kg, and no study has found increased plant uptake of F from these sludges.

Kienholz et al. (1979) found bone F was increased when Denver sludge (200 mg F/kg DW) was fed at high levels (12% of DW) in the diet of cattle. Bone F doubled after a 94 day feeding period. We have not attempted to develop a specific recommendation, but note that the median sludge F is about 260 mg/kg (from Davis, 1980; and Rea, 1979). This level would not appear to constitute appreciable risk to animals consuming sludge. Further, sludges rich in Ca would have lower bioavailability of sludge F because CaF_2 is relatively insoluble. Again, the best regulatory approach may be prohibition of surface applications of sludges with F levels above some injurious level.

DATA OMISSIONS

Table 3 (Table 6-3 of EPA, from page 6-6 the TSD) is a summary of the calculated limitations on sludge application for each regulated sludge constituent. One expects this to be a listing of all of the results from each of the pathway evaluations in Section 5 of the TSD. However, upon checking Section 5 pollutant transfer and risk analyses, we noted that four pollutant-by-pathway limitations were not listed in Table 6-3 (see highlighted numbers). These were Cd-Pathway 2F; chlordan-Pathway 3; Pb-Pathway 7 and Cd-Pathway 9. Especially prominent by its absence is the Cd pathway value. It appears to be more limiting than the other listed pathways for this element! All pathway values should be included in Table 3 and discussed.

Table 4 summarizes the PRC's analysis of the various pathways considered by EPA and illustrates that our review is not complete. It is apparent that EPA needs to continue the analysis that we have started and purge existing errors in the proposed rule.

SLUDGE MANAGEMENT USING THE "CLEAN SLUDGE" APPROACH

Sludge researchers have learned that realistic assessments of heavy metal risk to humans, livestock, wildlife, and plants is highly dependent on the concentration of elements in the sludge. The danger of Cu, Pb, Zn, and Cd in directly ingested sludges is negligible in median quality sludges. The danger of sludge Zn, Cu, Ni, etc., phytotoxicity was also negligible in median quality sludges.

Regulation and management of sludge utilization would be much easier, and would likely comprise less true risk to the health of animal and human populations, if the "Clean Sludge" approach were adopted. In this approach, cumulative element or compound applications are imposed only if the element or compound concentration in the sludge or compost exceeds some set value. Because sludge Fe plays a significant role in adsorbing sludge-applied Cd, Zn, Cu, Ni, etc., it may be necessary to consider element ratios, e.g. Cd:Fe. However, the potential savings to the country should compel EPA to evaluate whether the "Clean Sludge" approach is appropriate.

From the values presented in Table 4 a risk free sludge (i.e., "clean sludge") concept could be developed by assuming that for the worst case (maximum cumulative application) the soil would be 50% sludge. This would allow conversion of application rates to sludge concentration. Table 5 represents values for a clean sludge based upon this concept. In the case of some elements it may be more appropriate to use different assumptions about the percent of soil which is sludge. Also, in situations where such an analysis shows concentrations in sludge substantially greater than those attainable by pretreatment programs in effect, prudence would dictate the establishment of lower levels which still would encourage beneficial use but would not discourage pretreatment.

Table 3. Summary of cumulative pollutant application limits for each pathway as summarized by EPA with missing values highlighted.

POLLUTANT	Path 1	Path 1F	Path 2F	Path 3	Path 4	Path 5	Path 6	Path 7	Path 8	Path 9
-----cumulative kg/ha-----										
Aldrin	0.77	2.17	264.	0.15	0.044	0.0164
As	6960.	382.	14.
BaP	0.83	6.5E6	2.0E9
Cd	309.	18.4	?????	580.	2.6E4	49.1	.	178.	.	?????
Chlordane	.	.	2.25	?????	15.9
Cr	530.	.	.
Cu	153.	458.	46.0	224.	.
DDT	0.27	0.046	9.35	0.0055	0.046
DN1
HEPC	0.98	2.5	.	0.15	0.073
HXBE	0.37	0.10	59.4	0.038	0.173
HXBU	.	.	41.0	.	0.339
Pb	1190.	195.	378.	?????	.	125.
Lindane	4.61
Hg	2000.	110.	39.8	14.9	1000.
Mo	5.07
Ni	5340.	206.	78.0	.	.
PCB	4.1	0.264	7.3	0.0056	0.019
Se	1310.	162.	.	46.6	.	32.4
Toxaphene	1.4	0.16	21.7	0.049	0.75
TCE
Zn	82000.	5870.	.	30000.	.	4720.	.	172.	.	452.
	1	1F	2F	3	4	5	6	7	8	9
	Sludge→ Soil→ Plant→ Human	Sludge→ Soil→ Plant→ Human	Sludge→ Soil→ Human	Sludge→ Soil→ Plant→ Animal→ Human	Sludge→ Soil→ Animal→ Human	Sludge→ Soil→ Plant→ Animal	Sludge→ Soil→ Animal	Sludge→ Soil→ Plant	Sludge→ Soil→ Soil Biota	Sludge→ Soil→ Soil Biota→ Predator
	Food Chain	Future Home Garden	Pica Child	Animal Food Chain	Sludge Ingestion Food-Chain	Animal Feeds	Grazing Livestock	Phyto- toxicity	Earthworms	Wildlife Food-Chains

Table 4. PRC Summary of pollutant application limits pathways analyzed.

POLLUTANT	Path 1	Path 1F	Path 2F	Path 5	Path 6	Path 7	Path 8	Path 9	Path 12
-----cumulative kg/ha-----									
Cu				>2390	3930	1160	1200		
Zn						2750		>2600	
Ni		>>500		500*					
Cr						no basis			no basis
Pb	>>1000	>1000	580**			>>1000		>1000	
Cd		18				>20		>20	
As			1628						
Mo				17					

*See text for explanation of this value.

**For Pb and analysis of Pathway 2F for D&M the PRC concludes that sludge concentration should be 300 ppm or less.

Table 5. Comparison of suggested "Clean Sludge" composition with median pollutant concentrations in several recent surveys of sludge composition. Research findings summarized in the PRC report indicate that below the "Clean Sludge" limits, no cumulative limits are required for use of municipal sludges on cropland with no-adverse-effects.

POLLUTANT	Maximum in "Clean Sludge"	40-City Median	Mumma ¹ Median
	-----mg/kg-----		
Aldrin	a	0.0049	-
As	1600	4.4	13.1
BaP	a	0.001	-
Cd	18	11.2	5.6
Chlordane	a	0.0049	-
Cr	1000*	248.	449.
Cu	1200	411.	761.
DDT	a	0.0049	-
Dimethylnitrosamine	a	0.28	-
Heptachlor	a	0.0049	-
Hexachlorobenzene	a	0.040	-
Hexachlorobutadiene	a	0.11	-
Pb	300**	266.	168.
Lindane	a	0.0049	-
Hg	a	1.7	4.3
Mo	17	13.2	6.5
Ni	500	70.1	55.4
Polychlorinatedbiphenyls	a	0.0049	0.26
Se	a	1.4	2.1
Toxaphene	a	0.0049	-
Trichloroethylene	a	0.53	-
Zn	2700	980.	1001.

¹Mumma et al., 1988.

a These values need to be developed following a procedure similar to those we have outlined.

* No adverse effects reported at any municipal sludge Cr level. This value comes from Baker et al. (1985).

**For Pb Pathway 2F for D&M was utilized.

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NONAGRICULTURAL LAND APPLICATION OF MUNICIPAL SLUDGE

NONAGRICULTURAL LAND APPLICATION OF MUNICIPAL SLUDGE

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SUMMARY

The EPA's approach of lumping all practices into one category and regulating on the basis of the 98th percentile is seriously flawed.

Nonagricultural land should be placed into two categories: 1) those sites which have a high potential for conversion to another land use, and 2) those sites which have a low potential for conversion to another land use.

Sites which have a high potential for conversion should be required to abide by the cumulative metal loading required for agricultural land and land conversion should not take place for 5 years after the last sludge application. Sites with a low potential for land conversion should be restricted to certain management practices regarding land slopes and public access.

The regulations for nonagricultural use of sludge should allow exceptions on a case-by-case basis when the POTW can demonstrate that additional management practices or controls other than those specified in the regulations would allow such exceptions.

By lack of statements to the contrary, EPA has taken the position that when analytical data for organics are reported as less than the limit of detection, the limit of detection shall be used to determine regulatory compliance. The PRC does not believe that this position is scientifically valid. The PRC therefore recommends the following approaches:

1. The EPA should establish acceptable analytical detection limits for the organics based upon a study of analytical detection limits reported by 10 different laboratories testing 10 different sludges.

2. Any POTW reporting a limit of detection less than or equal to the acceptable limit of detection found in 1) above shall be considered to be in compliance with any EPA concentration-based regulatory limit.

3. Any POTW reporting a limit of detection less than or equal to the acceptable limit of detection specified in 1) above can use zero for the purpose of determining pollutant application rates.

4. Any POTW reporting a limit of detection greater than the accepted limit of detection in 1) above must use the actual limit to determine compliance with a concentration-based regulatory limit or the pollutant application rate.

EPA PROPOSED REGULATORY APPROACH

EPA chose to lump several practices into one category and refer to them collectively as nonagricultural land application. EPA conducted an aggregate risk assessment for nonagricultural land application which focused on two pathways: 1) surface runoff and 2) groundwater. The aggregate risk assessment, using worst case exposure scenarios, indicated that current practices are safe. Recognizing this, EPA then determined that a reasonable approach for regulating nonagricultural land application was to protect against extremely poor quality sludge being recycled by specifying "acceptable concentrations" in sludge based on a 98th percentile approach.

The PRC concluded that EPA's approach of lumping all practices into one category and regulating on the basis of 98th percentile concentrations was seriously flawed. These flaws are discussed and specific recommendations for regulating non-agricultural land applications are made in the following pages.

USE OF 98TH PERCENTILE APPROACH

EPA proposed numeric limits for sludge applied to nonagricultural land application. These limits are based on either a 98th percentile approach or concentrations derived from the agricultural land application pathways--whichever results in the higher number. Most of the parameters are controlled by the 98th percentile approach. The rationale for using a 98th percentile approach is arbitrary although several reasons have been suggested by various groups. These reasons include: 1) to encourage industrial pretreatment, 2) to insure that sludge quality does not get any worse, and 3) the approach satisfies groups that want some form of numeric limits in the regulation, while recognizing that nonagricultural land application does not pose significant human health risks.

None of the above reasons justifies regulating non-agricultural land application on the basis of 98th percentile concentrations. The 98th percentile approach will either over- or under-regulate. In cases where concentrations reported by POTWs for certain parameters are extremely low, as is expected for many of the organics, the 98th percentile approach over-regulates because even the highest concentration may be insignificant from a risk standpoint. In other cases the 98th percentile approach may under-regulate, allowing application of sludges with high concentrations of pollutants at rates that may pose significant risks.

In examining EPA's 98th percentile-based sludge pollutant limits, the PRC observed that the 98th percentile value was derived from the frequency distribution for each pollutant; that is, 2% of concentrations specified by the log-normal distribution for each pollutant would exceed the proposed limit. If pollutant concentrations are assumed independent, then the expected percent of POTWs having sludge which exceeds the 98th percentile for at least one of the regulated pollutants is $1-(0.98)^n$, where n is the number of pollutants regulated on the basis of the 98th percentile values. For nonagricultural land application, 13 pollutants are limited by 98th percentile values and 9 are less restrictively limited by the exposure assessment model. For these conditions, at least 23% of POTWs would be rejected. The PRC concludes that the 98th

percentile-based limits are overly restrictive. Further, because larger POTWs tend to have more highly contaminated sludges, the 2% POTW rejection rate will result in a far greater than 2% sludge mass rejection rate. In fact, it is easy to see that if EPA just increases the number of pollutants to equal the priority pollutant list (129 pollutants), then about 93% of all sludges would be rejected based upon EPA's 98th percentile approach. Clearly, this approach does not meet EPA's stated objectives.

The PRC believes that the proposed 98th percentile-based approach has no technical merit, and recommends that this approach not be used in regulating nonagricultural land application. As a viable alternative, the committee recommends that EPA take the management practice approach discussed below.

RECOMMENDED REGULATORY APPROACH

Not all practices in nonagricultural land applications can be grouped into one category and still accurately reflect sludge uses and potential impacts. It is strongly recommended that EPA recognize the differences among these practices in the final rule.

Nonagricultural land application practices should be placed in two distinctive categories which more truly reflect the underlying premises for the proposed rule. These two categories are:

Category 1: practices in which the potential for future conversion and subsequent exposure are very low.

Category 2: practices in which the potential for conversion and subsequent exposure are high.

It should be the obligation of each POTW to provide the permitting authority with a clear statement regarding the relative likelihood of conversion. The permitting authority would make the final determination as to the likelihood of conversion.

Category 1: Low Potential of Conversion

The recommended approach for this category is to require a minimum list of sound management practices. Nonagricultural practices such as application to interstate medians, cemeteries, many forest systems, remote nonforest systems and remote land reclamation sites would generally be included in this category.

In addition to the management practices specified by EPA for nonagricultural land application, the committee recommends the following for Category I practices:

- 1) A setback distance be established from the sludge application boundary to a public or private drinking water supply well. Many state regulatory agencies (e.g., Wisconsin, Illinois, Ohio) require

setback distances from sludge application boundaries to drinking water supply wells. A common setback distance is 60 m.

- 2) Slope restrictions be maintained as generally given by the EPA Process Design Manual, EPA 625/1-83/016.

<u>Slope</u>	<u>Comment</u>
0-3%	Ideal; no concern for runoff or erosion of liquid sludge or dewatered sludge.
3-6%	Acceptable; slight risk of erosion; allow surface application of liquid sludge or dewatered sludge.
6-12%	Incorporation of liquid sludge required for general cases, except in a closed drainage basin and/or extensive runoff control. Surface application of dewatered sludge is usually acceptable.
12-15%	No liquid sludge surface application without effective runoff control; surface application of dewatered sludge acceptable, but immediate incorporation recommended.
15-30%	Application to forested sites with both good vegetative cover and slopes less than 30% is acceptable, provided that buffers around surface waters are required in the permit (as described in the EPA Guidance for Writing Case-by-Case Permit Requirements for Municipal Sludge, Sept., 1988). Application to slopes exceeding 15% should generally not be allowed during an extended wet season.

3) Restricted public access as per definitions of Class A, B, and C sludges in subpart F of the proposed rule. This means that the requirement under 503.16(d) should be eliminated. For the purpose of this rule, the committee recommends that public access could be restricted by virtue of remote location, fences, signs, or other appropriate means. This would require that appropriate changes be made in the definition of access restrictions for Class B and Class C sludges.

4) Hunting or foraging limitations should be consistent with the access limitation in 3) above. This should not preclude limited use of the site for those individuals who are informed of site conditions. The EPA's five-year preclusion for hunting or foraging for food as described in the Preamble is not supported by technical data. Studies have suggested that there is no accumulation of trace metals in the muscle tissue of wild animals (Haufler and West, 1985). Data have also shown no statistical difference in wildberry metal accumulations (Zabowoski and Zasoski, 1986). Furthermore, an unrealistic amount of berries would need to be ingested to accumulate excessive trace metals (Munger, 1983). Thus, it is unrealistic to assume excessive human exposure to pollutants from periodic ingestion of wildlife or other foods foraged from nonagricultural application sites (EPA, 1984).

5) For those practices where the primary goal of application is to provide nitrogen to a non-human food chain crop (silviculture, turf farm, etc.) sludge application should be based on the nitrogen requirement of the crop grown or other relevant pathways.

In certain situations, a POTW may wish to satisfy several years of crop nitrogen needs in single or multiple sludge applications. EPA should also consider allowing sludge applications higher than annual vegetation assimilative rates on a case-by-case basis. For these applications, an initial flux of nitrates may result in elevated groundwater nitrate nitrogen concentrations for a short period of time. However, it should not result in extended elevated nitrate nitrogen concentrations in the groundwater. These types of applications must consider the dynamics of the groundwater aquifer in determining the impact of this initial nitrogen flux (EPA, 1983; EPA, 1988).

6) For those practices where the primary goal is to provide additional organic matter, such as in land reclamation, application rates should not be based on nitrogen requirements. Although high application rates may result in initial nitrate concerns as in 5) above, the overall net benefits outweigh this concern.

7) The PRC strongly recommends that EPA allow for exceptions to all of the management practices on a case-by-case basis. Dedicated land application sites that are used to grow animal feed are examples of why the rule needs to provide a mechanism for case-by-case determinations. The proposed rule states that crops grown on nonagricultural land cannot be used for animal feed. However, these sites can be managed so transfer of pollutants to animal feed crops is lower than that allowed under agricultural land application. If sites were managed in this manner, there would be no scientific basis to prohibit the use of these crops for animal feed.

Category 2: High Potential of Conversion

Some nonagricultural practices such as application to forested sites located near urban fringes may have a high potential for conversion. The recommended approach for this category is to require several management practices as specified below:

- 1) Sound management practices as previously described for low potential conversion,
- 2) EPA should specify maximum pollutant mass loadings for metals. These should be consistent with the cumulative metal mass loadings specified for agricultural land application as amended by the recommendations described in the agricultural land application section of this report. These limits would also protect against potential conversion to agricultural or residential use. Annual pollutant mass loading limits for organics are not necessary if there is a specified land conversion period. A sufficient land conversion period would allow for degradation of most organics.

- 3) EPA specifies a 5-year waiting period for conversion of nonagricultural land application sites. The presumed underlying assumption made by EPA is that all sites have received high sludge loadings. Although the PRC generally agrees with the 5-year waiting period for conversion, the PRC recommends that exceptions be made to the 5-year conversion period on a case-by-case basis, because many sites may receive low sludge loadings or have other management practices which reduce the 5-year period or make it unnecessary.

EPA has expressed opposition to the use of management practices such as those recommended by the PRC for nonagricultural land application. However, many states have successfully used management practices as a regulatory mechanism for land application programs (e.g., North Carolina, Delaware, Maryland, Pennsylvania, Wisconsin).

ANALYTICAL LIMITS OF DETECTION

With the intensive sludge monitoring provisions for all practices, these comments are relevant across all proposed regulations.

The limit of detection can reasonably be defined as the lowest concentration that can be determined to be significantly different from a blank for that analytical test method and sample matrix. The limit of quantitation can reasonably be defined as the concentration of an analyte at which one can state with a reasonable degree of confidence (for a specific analytical test method and sample matrix) that an analyte is present at a specific concentration in the sample.

By lack of statements to the contrary, EPA has taken the position that when analytical data are reported as less than the limit of detection, the limit of detection shall be used to determine regulatory compliance. The PRC does not believe that this is an appropriate method for handling analytical detection data. EPA has shown reluctance to consider alternatives to this approach in the past because of the poor quality of data reported by the regulated community. The PRC recognizes this concern and recommends the following approach to address the detection limit issue:

1. EPA should establish an acceptable detection limit in sludge matrices for those parameters regulated under Part 503. Emphasis should be focused on the organics since detection limit concerns are less for the metals. The PRC recommends the following approach for establishing acceptable limits of detection. Based on data from the National Sewage Sludge Survey, EPA should select at least 10 sludges with varying solids contents which are known to have organic concentrations at or below the limits of detection. Samples of these sludges should be sent to 10 contract laboratories. Each contract laboratory should be required to establish detection limits for each organic parameter in each sludge matrix. Establishing detection limits in sludge matrices is extremely important because each sludge matrix is unique. Laboratories typically determine detection limits in water (with virtually no interferences) and apply these detection limits to sludge. Because of matrix interferences, detection

limits determined in sludges will be significantly different from those determined in water.

The resulting data base can then be used to determine an acceptable limit of detection for each organic parameter. A statistical procedure should be used to eliminate poor data points. It is the committee's understanding that the National Sewage Sludge Survey assigned specific analytical tasks to each laboratory used (e.g., one laboratory did all of the PCB analyses). Therefore, the National Sewage Sludge Survey cannot be used for the purpose of establishing acceptable limits of detection for the organics.

2. Any POTW reporting a limit of detection less than or equal to the acceptable limit of detection specified by EPA shall be in compliance with concentration-based numeric limits.

3. Any POTW reporting a limit of detection less than or equal to the acceptable limit of detection specified by EPA can use zero for the purpose of determining pollutant application rates. The two extremes are to use either zero or the detection limit value. Technically, neither is correct and the true value lies somewhere in between. However, use of zero to determine pollutant mass loadings seems to be appropriate because there would be no measurable increase in soil concentration resulting from an application under this scenario as a result of mixing in the top 15 cm of the soil. This mixing results in a 20-100 fold dilution of the sludge land pollutant. Thus use of zero is more appropriate.

4. Any POTW reporting a limit of detection greater than the acceptable limit of detection specified by EPA must use the reported detection limit to determine either compliance with a concentration-based numeric limit or the pollutant application rate.

MULTIPLE POLLUTANT CATEGORIES

Another major issue is how data in multiple pollutant categories is handled. This affects at least 3 pollutant categories: 1) aldrin/dieldrin, 2) DDD/DDT/DDE, and 3) PCBs. The current EPA practice is to add the individual limits of detection for each parameter within a category to get a total limit of detection for that category. This approach is not technically justified and may cause a larger number of unwarranted failures with regulatory numeric limits (either concentrations or mass loadings). A reasonable alternative to EPA's current approach when all parameters within a category are reported as less than the limit of detection would be to use the highest limit of detection for any individual parameter to determine regulatory compliance.

METHODOLOGIES

The proposed rule allows for alternatives to the isotope dilution methodologies (Methods 1624 and 1625) used in the national sewage sludge survey.

The committee feels that flexibility in the choice of analytical methodologies for all parameters should be preserved in the final rule.

MONOFILLS

For this municipal sludge disposal practice, the groundwater and the volatilization pathways have been identified by EPA as the most critical. These same pathways occur in many of the other reuse/disposal practices and thus the substantial criticisms offered here have relevance in other reuse/disposal practices.

Monofill Siting

Siting requirements for monofills with regard to unstable areas as given in 503.32 (1) of the rule are unclear. Unstable areas are presently undefined in the rule, but are discussed in the Technical Support Document. In the latter, unstable areas are defined to include landslide areas, areas with expansive clays, and areas with subsidence problems. This definition should be included in the rule.

There is a major philosophical flaw in the consistency of EPA's stated approach in regards to use of site-specific data. Many of the unstable areas cover large geographic regions. In Section 6.6.3, of the Technical Support Document, Landfilling Sewage Sludge, the proposed alternative for regulating the siting of monofills in unstable areas is to require the owners/operators to perform geotechnical studies of all proposed sites to demonstrate that unstable conditions do not exist at the site. These studies would require that subsurface investigations be performed and geotechnical characterizations of various strata be made; in other words, site-specific information is required. However, the current philosophy for developing the contaminant transport models is that site specific data are not required. Because a geotechnical site investigation removes the need for using the hypothetical site conditions, at least in terms of stratigraphy, the current philosophy appears flawed. The PRC believes that incremental costs for developing site-specific parameters for the transport models would be small, and the resulting benefit of more accurate representation of the contaminant transport scenario would be large.

Air Modeling Issues

The principal limiting monofill pathway was organic losses to the atmosphere. The same models, assumptions, and rationale occur in other sludge practices. Thus, the comments offered here are important across the entire proposed rule package.

Serious inconsistencies exist in the air quality modeling approaches. In the SLAPMAN model for land application, the assumption that 100% of a chemical volatilizes, and simultaneously, 100% of the chemical leaches, is impossible. This assumption violates mass balance principles and goes beyond a conservative approach to one that is totally indefensible. A similar inconsistency exists

in the SLUDGEMAN model for monofills, which partitions chemicals to the vapor pathway using a Henry's Law constant (K_H). Using only K_H to partition chemicals to the air greatly overpredicts the amounts volatilized because considering only the air-water partitioning ignores other important processes such as adsorption and the water content of the sludge/soil. The committee recommends that partitioning to the air pathway for both models be computed using the relations developed to predict volatile chemical partitioning from soils:

$$\frac{C_g}{C_t} = \left[\frac{K_d \cdot B_d}{K_H} + \frac{N_w}{K_H} + N_t - N_w \right]^{-1}$$

where

- C_g = concentration of chemical in gas phase,
- C_t = concentration of chemical in soil/sludge,
- K_d = soil-water partition coefficient,
- B_d = bulk density of the soil/sludge,
- K_H = dimensionless Henry's constant,
- N_t = total porosity,
- N_w = water filled porosity.

The air models for land application and monofills overpredict exposure as a result of their assumptions. For example, the MEI is assumed to remain continuously in the plume for 70 years and to breathe only the contaminated air. In addition, the mixing zone is assumed to be 1 m thick.

The committee recommends that EPA use better air dispersion models that have been developed and used in other programs, such as the model used for incineration, to give improved predictions of risk from air exposure. However, if the simple models are used, more realistic and reasonable assumptions should be incorporated in the models, such as a 2 or 3 m mixing zone for the air concentrations and long-term average atmospheric conditions. Also, the committee does not believe the MEI can be continuously exposed for 70 years, and recommends that the exposure time be adjusted to a more reasonable duration.

Another inconsistency is that the two most volatile compounds, benzene and trichloroethylene, are excluded from consideration in the air pathway modeling, but are included in the leaching pathway to groundwater. The rationale given by EPA is that these compounds are so volatile that they are lost from the sludge in the digestion, drying, handling, etc. and therefore are not present in the sludge in significant amounts and can be ignored. If this is true, they should also be ignored in the leaching pathways. The PRC recommends that EPA adopt a consistent approach for handling these volatile compounds.

Groundwater Modeling Issues

An analytical model is used by EPA to evaluate contaminant migration from monofills. A similar model is used for land application practices. The criticisms of the SAB regarding groundwater modeling were largely ignored by EPA. The PRC believes SAB was correct in criticizing the model, and offer additional comments which should be considered by EPA.

Specifically, EPA recommends using the program SLUDGEMAN (EPA, 1989b) to evaluate the groundwater pathway for monofills. In SLUDGEMAN, transport through both the unsaturated and saturated zones is modeled by combining several existing computer codes. Unsaturated flow is evaluated using the CHAIN code. The code MINTEQ is used to calculate metal ion reactions at the interface between the unsaturated and saturated zones. Output from CHAIN is used as input to AT123D, the saturated flow model. The program SLAPMAN (EPA, 1989a) is used to evaluate the groundwater pathway for land application and distribution and marketing of sewage sludge. In SLAPMAN, flow through the saturated zone is not considered.

Unsaturated zone

Modeling unsaturated zone chemical transport is accomplished with CHAIN, an analytical solution of the advection-dispersion equation that describes chemical movement through a homogeneous soil profile under constant (steady-state) water flow conditions. The PRC understands the reasons such a model was selected; it demands limited input information and is easy to program and execute on a desk-top computer. However, the PRC recommends that use of CHAIN be discontinued for the following reasons:

1. CHAIN assumes a constant flow of water through the soil. However, this assumption prevents the use of CHAIN for estimating solute flux under transient field conditions that will be present in all instances of sludge disposal where there is an unsaturated zone between the bottom of the disposal area and the top of the water table.

2. CHAIN simulates transport through a single homogeneous soil stratum and is incapable of describing layered soils. It cannot describe the behavior of engineered liner systems such as a compacted clay liner with a granular leachate collection system. Current understanding is that many of the input parameters assumed constant in CHAIN, e.g., K_d , decay rate, and water flow properties, are in fact spatially and temporally variable in nature. Additionally, versions of SLUDGEMAN and SLAPMAN average the input data to estimate an average homogeneous soil of one layer. The current version of the model, which requests input by layers, is deceptive in this regard. Consider a synthetic liner which is essentially impermeable (e.g., 10 mil thick and 10^{-8} cm/s hydraulic conductivity) overlying 50 ft of sandy soil at 10^{-3} cm/s hydraulic conductivity. The model asks for layer-by-layer information and then calculates an average for the pertinent parameter. In this case the average hydraulic conductivity is nearly 10^{-3} cm/s, yet in reality practically no water moves past the liner if it has been properly installed. This deceptive calculation is particularly critical because the field reality is so obviously disregarded. The same technique is used for chemical adsorption, and fails to

recognize that a thin clay layer can dramatically alter heavy metal behavior. The PRC believes that the ability to adequately model the effects of distinct soil strata should be present in the model.

3. Application of the model MINTEQ at only the saturated-unsaturated zone interface may result in large over-estimations of the metal movement to the saturated zone. A more representative procedure would be to calculate metal ion reactions at appropriate positions (node intervals, layers) along the travel path in the unsaturated zone. Alternative modeling approaches, as described below, can incorporate such calculations. The current neglect of any metal reactions in the bulk of the unsaturated zone prevents the removal of any metals from solution before reaching the groundwater. Hence the total mass delivered to the interface is greatly overestimated.

In SLUDGEMAN, EPA converts the output of CHAIN into a square wave for input to AT123D. However, the process, as contained in the current computer code, can dramatically overestimate the total mass of metal or organic in the system to the point where more mass may enter the groundwater than is put into the monofill.

5. EPA's sensitivity analysis of SLAPMAN and SLUDGEMAN lacks credibility. Their sensitivity analysis is an analysis of model sensitivity, not process sensitivity. A number of assumptions have been made in adopting CHAIN or AT123D that greatly simplify natural processes. The resulting models are not useful to test the sensitivity of the natural system. Rather, the sensitivity analysis that is accomplished is only useful in testing the sensitivity of the presumed (and incorrect) models.

Alternate modeling approaches to CHAIN exist for use in unsaturated soil under transient field conditions. The PRC recognizes the need for any alternative model to not be overly data-demanding. However, EPA must recognize that soil-water-chemical systems are complex, and must be characterized, if even to a minimum extent, if site-specific leaching assessments are to be made. The PRC recommends that the model PRZM (produced by EPA), RUSTIC (evolution of PRZM), LEACHM (Cornell University), or some similar approach be strongly considered as core models in revised editions of SLAPMAN and SLUDGEMAN.

Alternative modeling approaches for the unsaturated zone will better estimate concentrations of chemical moving into the saturated zone. This is true whether the sludge is disposed of in monofills or recycled to agricultural or nonagricultural land. In conjunction with the revised unsaturated zone models, conversion of calculated unsaturated zone concentrations into a square wave for input to the saturated zone model must be accomplished using a revised procedure that conserves total mass.

It seems unnecessary to even use CHAIN to estimate loading to groundwater when one considers that (1) CHAIN can be used only under monofills over short distances (about 1 meter), and (2) information on delivery to groundwater is required only in terms of an approximated square wave. For such short distances a calculation can be accomplished with the required accuracy without any model by assuming an exit leachate concentration from the landfill and an appropriate retention factor. Beyond a distance of 1 m to the saturated zones (typical of

the vast number of landfills), CHAIN is not realistic and is subject to the PRC's and SAB's criticisms. The committee also recommends that geologic, hydraulic and chemical site-specific parameters be developed for each monofill.

Saturated zones

The AT123D model for steady state saturated flow is an analytical model that simulates advective-dispersive contaminant transport. In the AT123D code, advection is limited to one-dimension, while dispersion is allowed to occur in three dimensions. Sorption and contaminant decay are also considered in this model. Because the model uses an analytical solution, the flow and chemical input parameters are taken as constants. Both the heterogeneous character of porous media and the travel distance of 150 m assumed by EPA make it difficult to select K_{sat} and dispersivity values that are representative of in situ behavior, much less to select a functional dependence of the parameters. Thus the major problem is parameter identification. Because the main mechanisms of transport are modeled adequately in AT123D, the committee recommends that AT123D be used for contaminant transport through saturated porous media. However, the square pulse input from the unsaturated flow model must be one that maintains conservation of mass from one regime to another.

The SLAPMAN land application model assumes that sludge leachate migrates through the unsaturated zone to groundwater at 1 m below land surface. No dilution by the groundwater is allowed. This is an unreasonably restrictive and unrealistic constraint. Even a conservative estimate of groundwater concentration would allow mixing with some depth of groundwater. The PRC recommends use of the AT123D model (as used in the landfill modeling) or use of a conservative dilution depth under the land application area. Either option would still be very conservative because no one would use a very shallow well for drinking water. A drinking water well would normally be greater than 15 m deep to prevent pathogen contamination from septic tanks.

If the EPA adopts a setback distance for drinking water supply wells for non-agricultural land application of sludge, then the SLAPMAN model is inadequate to realistically model the pathway because it contains no provisions to model saturated flow. With a setback requirement, a minimum distance of saturated flow can be counted upon to provide dilution of the contamination. A corrected version of SLUDGEMAN should be used to more accurately model this pathway.

Leachate concentration

The monofill model assumes concentrations of contaminants in sludge leachate as given in Table 3-7 of the Technical Support Document on Landfilling of Sewage Sludge. These values were not all obtained from sludge leachate compositions as inferred, but were actually obtained from a variety of sources including sewage effluents containing particulates. As such, they are grossly in error for some constituents and include values that are orders of magnitude larger than even the water solubility of the compound. We recommend that conventional partitioning be incorporated in the model as given as Option B in

Appendix A of the Technical Support Document. Leachate concentrations are easily computed from sludge concentrations and Kd values.

The PRC recommends that, whenever possible, site-specific Kd values be used in the analysis. In lieu of site-specific data, sludge-metal Kd values are available in the same reference reported as the source of the sandy soil-metal Kd values. Sludge-organic contaminant Kd values can be determined from the organic carbon content of the sludge and the K_{oc} values for the individual contaminants listed in the support documents. The PRC recommends the same partitioning approach be used to compute leachate concentrations for surface application of sludge in the SLAPMAN model. However, with the use of an average Kd for the entire profile calculated by averaging separate layers, the actual sequential effect of high Kd layers is lost.

A further assumption in the monofill model is that the entire metal content of the sludge will exit the disposal site in a square pulse of uniform concentration. There is no scientific justification for this assumption. Both empirical observations and theoretical considerations indicate this assumption to be invalid and overly restrictive. Field observations at landfills indicate that the initial leachate concentration decreases over time. Based on Illinois State Geologic Survey data, the decrease in concentration can be estimated using a first-order decay rate with a 6.5-year half-life for the most mobile constituents. The PRC recommends that a first-order decay expression be incorporated into the model to yield more realistic estimates of the contaminant loadings to the groundwater flow pathway.

Model input data

The validity of the input data to all models must be carefully considered by EPA. Some of the most sensitive input parameters are Kd, decay rates, K_H , dispersion coefficients, and saturated hydraulic conductivity. The committee recommends the use of site-specific input values whenever possible and flexible computer model input requirements. "Hard wired" model parameters should not be used because literature values for some parameters such as K_H and decay rates can vary over several orders of magnitude. Careful evaluation of model input parameters must be carried out and the models must be able to accept new data as they become available.

The Kd values listed in Table 3-8 of the Technical Support Document, Landfilling Sewage Sludge, are unrealistically conservative. They were computed using an organic carbon fraction (f_{oc}) of 0.0001. Such organic carbon contents would only be found in clean beach sands, and are not typical of any other types of soil that could be found under a sludge application or disposal site. The committee recommends use of f_{oc} values 5-10 times higher (i.e., f_{oc} of 0.001 to 0.0005).

Default data for unsaturated and saturated water flow parameters given in the Technical Support Documents, Landfilling Sewage Sludge, for use in SLAPMAN and SLUDGEMAN are inconsistent, and, in some cases, in error. These data appear in Tables 3.1 and 3.4 and as default input to the two computer codes. For example, the worst case scenario of geologic conditions beneath a sewage sludge

landfill is assumed to be sand. Default values of effective porosity, N_e , and saturated hydraulic conductivity, K_{sat} , of sands are assigned to be 0.34 and 3200 m/yr, respectively, in SLAPMAN. In contrast, SLUDGEMAN's default values of N_e and K_{sat} are 0.1 and 2000 m/yr, respectively, and are used for saturated flow as modeled by AT123D. This latter N_e value is low by a factor of four and is more representative of sandstone than sand. Because these material parameters are for the same assumed soil, they should be the same values no matter where they are used in the computer codes. However, because geologic media are so variable across the U.S., EPA's use of a single value of K_{sat} for each soil type is simplistic and indefensible. A better approach would be to give ranges of K_{sat} for each soil type in the Technical Support Document to provide a user with a reasonable sense of the uncertainties involved with a non-site specific parameter. Moreover, site-specific K_{sat} can be determined in many ways, the best estimates are obtained from results of field pumping (granular soils) or ponding (cohesive soils) tests. In order of decreasing confidence of parameter identification, K_{sat} values may also be found from borehole permeability tests, laboratory tests, and empirical correlations with grain size.

Other comments concerning the technical data base as related to the computer models as described in the Technical Support Documents and User Manuals include:

1. There appears to be a conceptual or sign error in the derivation of Eq. (4) in Chapter 2 in the Technical Support Document, Landfilling Sewage Sludge. More details on this derivation should be provided. It appears to the reviewers that a more reasonable relationship would be derived as:

$$T = \frac{1}{d} \ln \frac{XR}{XR+dM_i}$$

where M_i = initial mass in the system, kg,
 T = pulse time (yr)
 d = degradation rate constant, yr^{-1}
 X = leachate concentration, kg/m^3
 R = recharge rate, m^3/yr

2. Presentation of Eq. (5) in Section 2 of the Technical Support Document, Landfilling Sewage Sludge, is meaningless without further description of how it is used in the model. A number of further simplifying steps are invoked in order to utilize K_{sat} , the slope of the moisture release curve and other related variables.

In addition to hydrologic and chemical input parameters mentioned before, one additional item needs to be clarified as to the input data to AT123D. Selection of the mixing depth of the leachate in the aquifer is not adequately described in the Technical Support Document. Guidance should be given based upon results of field studies (i.e., MacFarlane et al., 1980) or results of computer simulations of two-dimensional advective flow to give a potential user some guidance in this selection.

Other Issues

1. EPA failed to consider the potential for nitrogen contributions to groundwater from monofills. Sikora et al. (1978, 1979, 1980) mentioned that the lightly loaded trenches in their studies contained an average nitrogen loading of 10,000 kg/ha. For a landfill containing a 2 m deep layer of 20% sludge cake containing 3% nitrogen, the nitrogen loading is approximately 122,000 kg/ha. Thus a potential nitrogen problem could exist at monofills and needs to be addressed.

2. EPA does not differentiate between trench monofills and area monofills. Conditions under area monofills are likely to be anaerobic. This is generally not the case for trench systems. This difference will have a significant impact on transformation and loss of nitrogen.

The PRC recommends that the EPA differentiate between trench monofills and area monofills because of the differences in the potential for leaching from these types of monofills.

3. There is some indication that there is no significant leaching of metals from trench systems (Sikora et al., 1978, 1979, 1980). EPA should consult this information before the regulations are finalized.

4. 503.32(f) of the Federal Register. It is the experience of municipal sludge management agencies that municipal sludge placed in a monofill with daily cover does not attract birds. Sludge is distinctly different from municipal garbage or solid waste. The siting requirement with respect to airports should be eliminated. These requirements appear to have been inserted from other regulations without recognition of differences in landfill wastes.

5. 503.32(g) of the Federal Register. It is required that sewage sludge units be designed to withstand the maximum recorded horizontal ground surface acceleration. In the Technical Support Documents, procedural guidelines to evaluate stability of the monofill are suggested. This requirement is inconsistent because there are no guidelines to design the cut slopes of the monofills under gravity loading conditions. Once again if even a superficial geotechnical investigation is made to evaluate either gravity or earthquake loadings of the monofill's excavated slopes, then there is no reason not to develop other, more important, site-specific data.

6. The need for the Class B pathogen standard in a properly sited monofill does not appear justified. Migration of pathogens, under any realistic design standards within these proposed regulations, is very unlikely. The PRC recommends the Class C pathogen standard for sludge placed in monofills.

SURFACE DISPOSAL SITES

Definitions and Approach

The current definition of surface disposal must be modified to reflect the operational difference between storage with no intent for further management

and storage as an essential component in an overall sludge management scheme. This can be achieved with a minor change in the definition of surface disposal.

EPA defines surface disposal as impoundments, bermed facilities or piles where the intent is not treatment (e.g., dewatering) or temporary storage, but disposal. EPA further states that storage for longer than one year is considered as disposal. The PRC recommends that if the material is to be removed for ultimate reuse/disposal within 3 years, that the practice should not be considered surface disposal. The PRC also recommends that exceptions to the 3-year time period be allowed on a site-specific basis. This definition recognizes that temporary storage for periods longer than one year is often required to efficiently manage sludge reuse/disposal programs. Storage longer than 3 years would generally imply little intent of further management, and thus would be regulated as a surface disposal unit. Further, the PRC recommends that lagoons operated as fill-and-draw units or treatment units for sludge should not be considered as surface disposal units.

EPA intends to adopt a risk assessment model for surface disposal. The PRC supports a risk based approach. It is assumed that the risk based approach would draw heavily on the approach used for monofills.

Other Issues

1. 503.44(a) (1)-(4) of the rule. EPA requires monitoring for methane at surface disposal sites. This may be logical at municipal solid waste landfills where daily cover and a clay cap at closing prevent free exchange of gases with the air. However, because daily cover and clay caps are not used at surface disposal sites, free exchange of gases with the air will occur. Under this condition methane will not build up to excessive levels. The committee recommends that the methane section should be eliminated from surface disposal.

2. 503.45 of the rule. If there is no intended use of the sludge as provided by the definitions given for surface disposal, requiring Class A and B pathogen reduction is unjustified. Sludge should not be regulated for use if it is not intended for use. This undermines the concepts and emphasis being proposed in describing municipal sludge practices.

3. 503.42 of the rule. It is the experience of municipal sludge management agencies that sludges processed to reduce vector attraction do not attract birds. Therefore, there is no need to regulate the placement of surface disposal sites based upon distance from airports.

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DISTRIBUTION AND MARKETING

DISTRIBUTION AND MARKETING

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SUMMARY

The proposed rule on D&M is unique. Although the exposure scenarios used to calculate risk estimates and to determine pollutant loading limits are similar or identical to those in AgLA and NonAgLA, the approach to regulate, however, is quite different. Instead of relying entirely on the specific numerical value of pollutant loading limits, EPA imposed several policy/ administrative requirements which would severely hinder the D&M of sludge and sludge products. While we attempted to point out the technical deficiencies of the D&M proposals, a large part of the problem with D&M regulation was the result of EPA's policy decisions. Unless these decisions are reviewed and modified, the inherent flaw of the proposed D&M rule can not be remedied simply by revising the risk and exposure computations.

In light of comments and suggestions on improving the risk assessment methodology and exposure and risk estimation for both AgLA and NonAgLA, it seems prudent that EPA also review its approaches proposed to regulate D&M sludge products.

INTRODUCTION

The risk assessment and exposure scenarios used for regulating Distribution and Marketing (D&M) of sludge products in the proposed rule were a subset of those used for the Agricultural Land Application (AgLA) option. The D&M workgroup recognized that the AgLA workgroup was providing a thorough evaluation of the input data selected and assumptions used for these pathways. Therefore, we did not attempt to duplicate their efforts by conducting separate evaluations. We fully support the evaluations of and conclusions for pathways 1, 2, 7, 8, 9, and 11 reached in the AgLA and NonAgLA sections. These pathways and their results were the basis of setting pollutant loading limits for D&M.

The D&M workgroup focused its efforts mainly on "questions" posed in the D&M portions of the preamble of the proposed rule. A point-by-point response to these questions is presented in this report. The "responses" provided also include wherever applicable, the diverging opinion of one member who did not agree with the other five members of the D&M workgroup on several points.

Upon answering the questions posed in the preamble, we were not satisfied that our concerns on the assumptions made in the exposure and risk analysis and technical correctness of the results were fully expressed. We therefore went

¹The D&M workgroup acknowledges the valuable suggestions/comments and contributions received from the following individuals during the drafting of this section: Truett Garrett, Jr., Kathryn Kellogg, Daniel Landis, Henry Leibee, and James Spindler.

ahead to engage in more comprehensive discussions and identify other issues. Unlike the proposed regulations of other sludge management options (e.g., AgLA, NonAgLA, and monofills and surface disposal), whose numerical limits on specific pollutants are directly extrapolated from results of the risk assessment computations, the regulations of D&M involve extensive administrative (policy) decisions in regard to labeling, performance agreements, and quality control and quality assurance requirements.

These decisions, made by the EPA, are strictly judgemental and cannot be disputed or supported by scientific arguments. But they have far-reaching impacts on the D&M of sludge products. In our opinion, the EPA did not conduct an adequate background data gathering effort nor nationwide survey to fully understand this industry. Many requirements are academic in nature, difficult to enforce for the regulator and impractical for the industry to implement. Since the technical issues which concern D&M are similar to those of the other review groups, particularly AgLA, and were dealt with in depth by these groups, we focused on the implications of EPA's policy decisions.

D&M QUESTIONS POSED BY EPA

1) Sewage sludge products are included within the definition of sewage sludge no matter how small the percentage of sewage sludge in the product. Are there products that contain so small a percentage of sewage sludge that they no longer have the characteristics of sewage sludge? If so, should these be excluded from the definition?

Response Our understanding is that current Federal regulations do not regulate any sludge product marketed in the U.S. The definition for "sludge" in the proposed rule would include all products containing >0% sludge, necessitating their regulation. To include all sludge-derived products, such as the examples listed in Table 1, would discourage these beneficial reuse practices by placing an unnecessary requirement for extra labeling and an unnecessary burden of chemical analysis on distributors, re-blenders, etc. who receive D&M sludge/sludge products for distribution. As an example, one product listed in Table 1 contains 5% heat dried sludge with the rest of the product composed of sulfur-coated urea, superphosphate and potassium sulfate. This product is basically a fertilizer (6-8-12) used for turf fertilization. The rate of application is strictly governed by its nutrient value which would likely be less than 200-300 kg/ha. At this rate, the amount of sludge applied would be 10-15 kg/ha, hardly enough to present any human or environmental hazard. Yet, under the proposed rule, this product would now have to be regulated as a sewage sludge rather than as a fertilizer. We are not sure that the EPA intended to include all such products under the proposed rules.

We recommend that EPA develop a standard for "clean sludge" which the generator of the sludge or sludge product must meet before these materials are passed along to distributors, re-blenders, etc., because of divergent end uses of sludge products and difficulties in tracking

D&M products. By using such a mechanism, the labeling provisions and quality control, required by the proposed rule, would hold the sludge generators accountable but would not pass the regulatory burden along to products manufactured by the distributors, re-blenders, etc.

2) For D&M, specific numerical limits for 22 pollutants, (Federal Register, Feb. 6, 1989 Table III-4, p. 5761) are proposed. Are there any pollutants, not included in this group, which should be evaluated immediately? Are there some chemicals which should be deleted from this group of 22 pollutants?

Response The AgLA workgroup has suggested that fluoride (F) and iron (Fe) be included, and we concur. We also suggest that some pollutants could be selectively deleted for two reasons. First, we question whether banned pesticide chemicals (e.g., aldrin, chlordane, DDD, DDE, DDT, dieldrin) need to be included among those selected for evaluation, unless the National Sewage Sludge Survey (NSSS) data suggest that sludges contain significant concentrations of these chemicals. Previous summaries (Jacobs et al, 1987) suggest that median concentrations of these organics are generally less than 1 mg/kg of dry sludge solids.

A second basis for deleting a pollutant occur when exposure assessment pathways show no significant risk. For example, three organic compounds (chlordane, hexachlorobutadiene, lindane) evaluated for D&M pathways (Table 6-1, p. 6-3 in the TSD) suggest that the most limiting annual whole sludge application rate (AWSAR) for addition of each organic is 32.2, 41.0, and 917 kg/ha, respectively. When these allowable loadings are converted into allowable concentrations in sludges for different sludge application rates of 1 to 50 mt/ha, ridiculously high concentrations are obtained compared with the levels normally found in sludges. The following table illustrates this point and provides more than a reasonable basis to exclude each pollutant from the pollutant list and make the regulations for D&M more credible.

Pollutant	Concentration ^a Allowed at the Following Sludge Rates (mt/ha):				Median Sludge Concentration ^b
	1	5	50	500	
	----- mg/kg -----				
Chlordane	32,200	6,400	640	64	2.75
Hexachlorobutadiene	41,000	8,200	820	82	0.036
Lindane	917,000	183,400	18,340	1,834	0.18

^aConcentration values taken from Table 6-2, p. 6-4 of TSD except for values for 500 mt/ha rate which were calculated. (Values given in Table 4, p. 5882 of proposed Rule, for Chlordane and Lindane are somewhat lower, for some unexplained reason.

^bHighest median value reported by Jacobs et al (1987) from among sludge analysis data cited.

TABLE 1. Examples of D&M Sludge products currently marketed without federal regulations which would require regulation under "sludge" definition of proposed 40 CFR Part 503 sludge technical standards.

Product Name	Nutrient ^a Analysis	%	Non-Sludge ^b Sludge	Components/Uses of D&M Product	
				Products Using Composted Sludge	
Nitrohumus	0.75-1.5-0	40	Wood products	Soil conditioner	
Amend	(0.1-0.5 N)-	11	Proprietary mix	Vegetable planting mix	
Gromulch	(0.2-1.4 P ₂ O ₅)-	18	Proprietary ingredients	Planting mix, trees, shrubs	
Topper	(0.1-1.2 K ₂ O)	24	Wood products	Seed cover & soil amendment	
Azalea/Camellia		10	Proprietary ingredients	Planting azaleas/camellias	
African Violet Mix		5	Proprietary ingredients	Planting African Violets	
Potting Soil	1.35-0.2-0.85	5	Proprietary ingredients	Potting medium	
Compgro	3.0-2.5-0.1	40	60% Fir bark	Soil conditioner	
Gen. Landscape Soil		25/10 ^c	Soil plus fir humus	Topsoil for ornamentals	
Rhododendron Blend		10/4	Soil plus proprietary	Acid loving plants	
Turf Blend		33/13	Soil plus proprietary	Establishing Lawns	
Turf Top Dressing		50/20	Soil plus proprietary	Lawn maintenance (1/4 in.)	
Multi-Purpose Mix		18/7	Soil, sand, vermiculite	Home container plantings	
Nursery Mix (Special)		20-30/8-12	Soil plus proprietary	Nursery special potting	
Tropical Mix		15/6	Soil plus proprietary	Special mix large scale indoor	
Ultra-Light		20/8	Soil plus volcanic sand	High-rise containers	
50/50 Blend	1.5-1.5-1.0	50/20	Fir humus	Soil amendment	
Clodbreaker w/ Compgro		30/12	Volcanic sand, expanded	Conditioner for clay soils	
Mil-Chem (PA)	22-4-8+1% Fe	28	Urea, DAP, KCl	General turf fertilization	
Mil-Chem+weed contr	22-4-8	23	Urea, DAP, KCl	General turf fertilization	
Mil-Chem	12-4-8+2% Fe	63	Urea, DAP, KCl	General turf fertilization	
TIECO Brands (SC)	14-3-8+2% Fe	51	? or Proprietary	General turf fertilization	
TIECO Brands (SC)	15-3-8+2% Fe	50	? or Proprietary	General turf fertilization	
TIECO Brands (SC)	17-3-8+2% Fe	45	? or Proprietary	General turf fertilization	
TIECO Brands (SC)	24-2-8+1% Fe	25	? or Proprietary	General turf fertilization	
Rockland Chemical Co. (NJ)					
Mil-An-Chem I	12-4-8+2% Fe	63	Urea, DAP, KCl	General turf fertilization	
Mil-An-Chem II	22-4-8+1% Fe	28	Urea, IBDU, KCl, DAP	General turf fertilization	

TABLE 1. (continued)

Product Name	Nutrient Analysis	% Sludge	Non-Sludge Components	Uses of D&M Product
<u>Products Using Heat Dried Sludge</u>				
Spring Valley Turf Products (WI)				
Natural Green "Spring"	20-2-8+TEAM+1% Fe	25	Urea, SCU, DAP, KCl, Ammonium sulfate, TEAM	General turf fertilization plus crabgrass control
Natural Green "Summer"	25-2-4+1% Fe	25	Urea, SCU, DAP, KCl, Ammonium sulfate	General turf fertilization
Natural Green "Fall"	12-12-20+1% Fe	25	Urea, DAP, KCl, Ammonium sulfate	General turf fertilization
Water Saver & Hydro-Wet	10-1-0+2.5% Fe	63	Ammonium sulfate plus proprietary	General turf fertilization
Milorganite Pro "Spring" + TEAM	20-2-5+1.5% Fe	40	Urea, SCU, DAP, K ₂ SO ₄ , Nitroform, TEAM	Golf turf fertilization plus crabgrass control
Milorganite Pro "Summer"	20-3-6+1.5% Fe	40	Urea, DAP, K ₂ SO ₄ , Nitroform	Golf turf fertilization
Milorganite Pro "Fall"	10-5-15+2.0% Fe	50	Urea, SCU, DAP, K ₂ SO ₄ , KCl	Golf turf fertilization
Milorganite Pro Golf Pro	13-2-4	37	Urea, K ₂ SO ₄	Golf turf fertilization
	12-4-8+2.0% Fe	50	Urea, MAP, K ₂ SO ₄ , Nitroform	Tees & greens fertilization
Golf Pro	6-1-12+2.4% Fe	65	Nitroform, MAP, K ₂ SO ₄ , Nitroform, K ₂ SO ₄	Greens fertilization
Golf Pro	5-1-10+2.5% Fe	70	Nitroform, K ₂ SO ₄ , Hydro-Wet	Golf turf fertilization
Flower Bed Planter	6-12-8	41	Nitroform, K ₂ SO ₄ , Triple super phosphate, Hydro-Wet, Gelscape	Flower bed fertilization
Confidential	21-7-7	36	SCU	Professional lawn fertilization
	21-7-7	31	SCU, Sul-Po-Mag	Professional turf fertilization
	21-7-7	9	SCU	Turf fertilization & broadleaf control
	21-7-7	23	SCU	Turf fertilization & crabgrass control
	6-8-12	5	SCU, Superphosphate	Turf fertilization
	10-6-4	75	K ₂ SO ₄ , Urea, KCl	Professional lawn fertilization
	7-7-7	11	? or proprietary	All purpose fertilization
	10-2-4	13	? or proprietary	Tree & shrub fertilization
	3-11-0	50	Superphosphate	Bulb fertilization
	12-10-10	3	? or proprietary	Evergreen fertilization

TABLE 1. (continued)

Product Name	Nutrient Analysis	% Sludge	Non-Sludge Components	Uses of D&M Product
<u>Products Using Heat Dried Sludge (continued)</u>				
Sunniland Turf-Gro Products	16-3-12	9	NH ₄ NO ₃ , ? or proprietary	Golf greens fertilization
	15-0-15	13	? or proprietary	Golf greens fertilization
	10-10-10	45	? or proprietary	General fertilization
Lykes Fertilizer Co. Lakeland, FL	custom blend	10	Commercial fertilizers	Citrus crops
	Florida Favorite Lakeland, FL	10	Commercial fertilizers	Citrus crops
<u>Products Using Air Dried Sludge</u>				
Hi-K 666 All purpose KARE fertilizers (Several different products are made for: blooming plants, new plantings, roses, camellia/azalea, tomatoes/vegetables, citrus/fruit, grass lawns, etc. under the "KARE" label.)	custom blend	80-90	Urea, K ₂ SO ₄ , phosphate	Turf fertilization
	custom blend	80-90	Urea, K ₂ SO ₄ , phosphate	Turf fertilization
	custom blend	80-90	Urea, K ₂ SO ₄ , phosphate	Lawn & garden fertilization
	custom blend	80-90	Urea, K ₂ SO ₄ , phosphate	Lawn & garden fertilization

^aConcentration of N, P₂O₅, and K₂ as percent dry weight.

^bDAP = diammonium phosphate; KCl = potassium chloride; IBDU = isobutylidene diurea; SCU = sulphur-coated urea; MAP = monoammonium phosphate; TEAM = crabgrass preventer.

^cA number of products contain Compagro/sludge mixtures. The %Compagro and %sludge in each product are given as numbers separated by a slash, i.e., 25% Compagro/10% sludge.

3) The MEI scenario for D&M is a rural non-farm family growing 60 % of their fruits and vegetables in a sludge-amended home garden. Is this scenario for the MEI reasonable? Does it reflect a scenario which could occur?

Response The MEI scenario does not reflect a probable occurrence for D&M products. The majority of D&M products are utilized within urban environments which, by their nature, would be more restrictive relevant to the size of garden areas that people could be expected to use for home-grown vegetables. In rural areas, other sources of readily available and "less expensive" organic amendments (e.g., animal manure, crop residues, etc.) undoubtedly compete for the same outlet with municipal sludges. The costs of bagged sludge compost products are likely to discourage anyone from using D&M sludge products in quantities needed to support the exposure scenario of the MEI. To produce the quantity of food to satisfy dietary requirements of the MEI, approximately 1,000 m² of land per capita is needed (figure estimated by R. Horvath). If a sludge product, such as Kellogg's Nitrohumus (Carson, CA) were applied at the 50 mt/ha/yr, 200 bags of this material would be needed at the cost of about \$1,000 per year. The likelihood of any gardener purchasing this much D&M product annually is questionable.

The exposure scenario which leads to the MEI of D&M products is entirely hypothetical. Whether this scenario would ever occur is obviously speculative. More importantly, the probability that such an event may take place is unknown. In order to project risk, it is essential that one starts with a reasonable realistic exposure scenario and is able to determine the uncertainty associated with the risk estimate. Based on information provided in the TSD, we are not sure that the uncertainties of the risk estimate, in this case, are quantifiable. As the rule "shall be adequate to protect public health from any reasonably anticipated adverse effects of each pollution" [Section 405 (d) and (e) of Clean Water Act], it is perhaps appropriate to assume a reasonable exposure scenario.

Therefore, we recommend that the MEI be "an urban resident with considerably less than 60% of the fruits and vegetables in his/her diet being grown on D&M amended soils. We see this MEI as a more plausible one for D&M than the one proposed.

4) Three "key parameters" were used in exposure assessment models or as a basis to exclude certain pathways from consideration:

a) raising animals for human consumption, or growing feed crops for animals raised for human consumption, would not be done on sludge-amended soils for the D&M MEI home garden scenario;

b) the background concentration of metals in the soil corresponds to the average soil concentration of rural agriculture land; and

Response Because of the great difference between D&M products, it is unrealistic to consider only one rate for all these products. Since the 11 mt/ha is probably a "compromise" between heat-dried and composted sludges, this rate does not really apply to either. It would not be uncommon for a compost product to be applied at a rate of 200 mt/ha over a 20 year period, while heat-dried sludge could be applied at an annual rate of 4 mt/ha for 20 years (i.e., 80 mt/ha total). The benefits obtained from each type of product are different, the rates needed for different end uses are different, and associated risks will be different depending on that end use. Therefore, it is inappropriate to purpose only one application rate to all these conditions.

9) Is the assumption that 20 applications of D&M sludge/sludge products would be applied to land, for purposes of calculating the pollutant limits for metals, logical? Is there documentation to show that a greater or smaller number of applications are generally applied to home gardens?

Response We know of no documentation to support or dispute the use of 20 annual applications as a basis for calculating cumulative pollutant limits for metals. Whether the 20 annual applications are made consecutively in 20 years or made over a longer time period appears to be a reasonable policy decision by EPA for D&M end uses where products are applied to land at regular intervals. However, the concept of "20 annual applications" (or 20 AWSAR additions) to land is not applicable to higher, non-annual end uses of D&M products. This non-applicability is further discussed under Issue no. 7.

10) Will the apparent anomaly of less restrictive pollutant limits for D&M, compared to ag land application, create problems for those POTW's involved in the distribution and marketing of sludge?

Response With the exception of differences in the degree of pathogen destruction, the same quality sludge product can be marketed as sludge compost, potting mix, etc. for urban use or provided to farmers/growers for crop production. Therefore, there really is no anomaly.

11) Is it appropriate for EPA to assume that use of D&M sludge/sludge products can be controlled with a product label? Is it correct for EPA to assume that users of D&M sludge/sludge products will follow the instructions on the proposed label or information sheet to be provided (with the products) to end users?

Response Sewage sludge is one of the final products of the urban wastewater management scheme accomplished by the POTW. Final disposition of sludges, therefore, should not be viewed as an independent event but as an integral component of the wastewater collection and treatment system. If an effective industrial pretreatment program is in place and the treatment performance of the POTW is maintained, we would expect the quality of the sludge it produces to be "good" and suitable for land application. If the risk assessment to evaluate hazards

associated with pollutants in sludge is properly performed, we can also expect the risk associated with the application of this sludge to be minimal.

Technically, then, if the sewage is not properly treated and industrial discharges controlled and/or the risk assessment is inadequate, labeling of D&M products will be a poor way of guarding against the unsafe use of these products. As there is no real technical reason to label D&M products, we consider the product labeling a policy issue, and the label should be used to provide consumer information on proper use of the product rather than provide warning on its hazardous chemical content.

We recognize the concern of one group member that too many Americans are illiterate, and these individuals are not able to follow written guidance on labels. However, labeling of application rates as inches of compost or bags of heat-dried products per 1000 ft² (108 m²) of lawn or garden could be done simply and clearly with diagrams. In addition, the assumptions used by the EPA seem appropriate and consistent with expectations assumed by other federal and/or state agencies when requiring labeling for other consumer products, such as fertilizers, prescription drugs, pesticides, etc.

12) Are the provisions required by EPA for labels or information sheets to accompany D&M sludge/sludge products appropriate? Should any provisions be deleted or added to those proposed? [Federal Register, Feb. 6, 1989, p. 5883, Sec. 503.24 (b)]

Response Provisions (1), (2), and (6) are reasonable requirements.

Provision (3): Listing the nitrogen (N) and phosphate (P₂O₅) content of D&M products is important for the proper management of these nutrients relative to groundwater and surface water quality concerns. Requiring a listing of concentrations for all of the 22 selected pollutants in Table 4 of the proposed rule (Sec. 503.23, p. 5882) would cause undue confusion by potential users of D&M products. The reasons such information is unnecessary have been stated in response (11). We recommend the following statement be substituted for this part of Provision (3), as well as for Provisions (5) and (12), which could then be deleted -- "Use of this product must be done strictly in accordance with instructions. This product complies with the EPA limits on trace pollutants for sewage sludge products. For a listing of these trace pollutants and the concentrations of each in this product, write to: (name, address and telephone number of D&M generator added)."

Provisions (4), (7) and (8): We suggest that these provisions be combined under a statement that would address commonly accepted/recommended management practices which should be used when D&M products are applied to land surfaces. These management practices would include (a) matching nutrient additions from D&M products to the needs of the crop, especially to avoid excess N loadings and (b) utilizing good soil

and water conservation practices to prevent runoff/erosion of particulates and nutrients, especially P loss to surface waters. In addition, we recommend that a mechanism be available for case-by-case considerations by states or regions where specialized uses of D&M products may require some variation from these recommended management practices.

Provision (9): Some rewording is needed to clarify that the concern with children is for ingestion.

Provision (10) and (11): The premise of using the urban MEI (as suggested above) and the fact that the common end uses of D&M products are in urban environments do not warrant that these provisions be included on labels and information sheets.

We recommend that these provisions be deleted.

13) Are the provisions required for the "performance agreement" [p. 5881, Sec. 503.22 (b)] appropriate? Are there ways to simplify this agreement? Should any provisions be deleted or added to those proposed?

Response Some modifications are needed to provide for the use of a "clean" sludge standard rather than an AWSAR for selected D&M end uses identified in Issue no. 6. Where a "clean" sludge standard is used, Provisions (3) and (4) would indicate that the sludge product has passed an EPA quality standard for pollutant composition and can be used according to labeling instructions or further diluted by mixing with non-sludge materials. However, any non-sludge materials used for blending or remixing with the sludge product cannot contain concentrations of pollutants which exceed the concentrations defined in the "Clean Sludge" standard.

14) EPA is proposing that records for D&M sludge/sludge products be retained for 5 years (some consideration of 3 years was made; for land application, records must be retained for the life of the POTW). Is 5 years appropriate? [Federal Register, Feb. 6, 1989, p. 5896, Sec. 503.83 (b)]

Response Generally the record keeping information required to be kept for 5 years is acceptable. Provisions (3) and (5) could be a deterrent for distributors, re-blenders, etc. if these record keeping requirements were passed along. Under a program that would allow a "quality sludge standard" to be used for some D&M end uses, as recommended in preceding questions, record keeping requirements would not be necessary for distributors, re-blenders, etc.

ADDITIONAL D&M ISSUES OF CONCERN

1) The rate-limiting concentrations of many pollutants in the proposed regulation, especially the organics, are below the limit of detection of present analytical methods.

Comments In our opinion, this is a very serious flaw of the proposed regulations. The technical deficiencies of this issue are reviewed in the AgLA and NonAgLA sections, so it will not be repeated here. The implications of this requirement to POTWs and their D&M contractors, however, are far-reaching. Since compliance with the regulation is dependent upon accurate chemical analysis, it is essential that the limiting concentration set by the regulations are technically achievable by routine analytical methods used by certified laboratories. Otherwise, they will be required to perform costly chemical analyses to generate compliance data which is meaningless.

Assuming that the concentration of a pollutant in a sludge/sludge product is equal to the detection limit, when that pollutant concentration is somewhere between zero and the level of detection, is not a good regulatory approach. It is unreasonable that the limiting concentration of pollutants are set at concentrations below the limits of detection. More detailed comments about the use of (a) detection limits for organics or (b) concentrations of organics below analytical detection limits in the proposed rule can be found in other workgroup reports.

2) Use of unreasonable MEI's for exposure assessment.

Comments In addition to the MEI scenario for D&M being a rural non-farm family growing 60% of their fruits and vegetables in sludge-amended home garden, several other assumptions on MEIs of other D&M pathways are equally unreasonable. For example, is it reasonable to make the assumption that someone will drink 2 liters of water per day for 70 years from streams as the MEI of pathway 11 is defined? It is not reasonable to expect that residents of urban areas, where D&M products are primarily used, would consume this quantity of water directly from streams and rivers flowing through or near urban areas and are contaminated by runoff from sludge-amended areas. Nor would one expect the consumption of 6.5 g per day (again for 70 years) of fish taken from these contaminated waters.

Human dietary habits, as well as food consumption, change with genders and ages. It is unreasonable to assume that the MEI's consumption of food from each food category equals the highest estimated consumption of the food category. Realistically, no one is able to sustain this type of dietary habit for a 70-year life span.

Since the unrealistic MEI leads to severe restrictions on pollutant loading limits, we urge EPA to reconsider developing reasonable and realistic exposure scenario for the risk assessment.

3) Relative effectiveness (RE) of Dose should not equal 1.

Comments EPA has assumed that the relative effectiveness of the dose to humans equals 1. Sufficient data is present in the literature to demonstrate that sludge-borne pollutants and plant absorbed pollutants are far less biologically available to humans and to other animals than reagent-grade chemicals commonly fed to laboratory test animals during toxicity assays. In the section reviewing the AgLA, pollutant by pollutant and pathway by pathway discussion along with relevant reference sources are presented. The same issue is further articulated by the section reviewing risk assessment methodology.

Proper validation of model parameters, such as RE, is essential for a creditable risk assessment. The assumption that RE=1 overestimates hazards of the pollutant and lower the permissible pollutant loading. EPA should adopt realistic RE for the exposure and risk computations.

4) Lead exposures through the D&M home garden scenario.

Comments For this exposure it is necessary to consider the true pica child who has a very low probability of occurrence as being the MEI. Further, in light of the potential for direct ingestion of undiluted sludge products (including compost) from the soil surface or from the bag or piles awaiting utilization at private homes, his/her exposure must be considered to be direct. This direct exposure is discussed in the AgLA section, and we agree with the analysis and conclusion that a limit of 300 mg Pb/kg limit should be acceptable for unrestricted use.

5) Selection of data in computing plant uptake slope.

Comments In the past several years, data from field experiments have become readily available. While in many incidences field experiments demonstrated no significant adverse effects on yield and no accumulation of pollutant in plant tissue, EPA elected to by-pass these data and adopted data from pot experiments in which soils were treated with "pure chemicals" or "pure chemical"-spiked sludges. Notably, data in MacLean and Decker (1978) were repeatedly used; this is an example of inappropriate data selection. As the pathways considered in D&M were identical to those considered in AgLA, we referred the readers to that section for additional details.

6) Use of sensitivity analysis in exposure and risk assessment.

Comments Section Five of the Technical Support Document detailed results of "sensitivity analysis". As the results in this section were not referenced elsewhere and the term sensitivity analysis was not defined, we were uncertain as to the purpose of this section. Barbara Corcoran (of EPA) indicated to us during one of our sessions that this section had been prepared for a three-tiered rule option which EPA did not choose to use. However, we would support this type of exercise, where sensitivity analysis refers to "a process of testing which data and assumptions inputted into the risk assessment model have the greatest effect on the most limiting pollutant loading determined by the various pathways". Conducting a sensitivity analysis would allow one to identify those data and assumptions which are the most critical to the end result obtained for each pathway. These data and assumptions should then be selected with the utmost care so as not to generate unrealistic values in an effort to accomplish a rational risk assessment.

7) The definition for D&M in the proposed rules is not adequate to reflect actual D&M end uses.

Comments D&M encompasses a divergence of uses of sludge and sludge products. This is an area where technical ingenuity and entrepreneurship in sludge management can be expected to flourish. Under the current practices, sludge products contain typically 5-75% sludges and are marketed as fertilizers, soil conditioners, potting mixes, etc. (Table 1). According to the proposed rule, all products containing sludge are sludges and must comply with land application rule.

We have no argument with calling products whose primary ingredient is sludge or whose primary use is soil conditioning as "sludge". What happens to these materials in soils will not be different from the sludge in other land application settings. But we have serious reservations of labeling a product which contains small percentage of sludge as a "sludge". Under this situation, the sludges are often used as a carrier of plant nutrients or a medium to control nutrient release. As a result, their application rates are typically 50-300 kg/ha instead of 1-50 mt/ha. The amount of sludge received by land, even with repeated applications over a long period of time, would be small and the risk this type of practice poses is insignificant. It is inappropriate to call such types of products "sludge". The regulation is better served to focus its implementation and enforcement efforts elsewhere and allow the entrepreneur to creatively distribute and market the sludge products provided the sludge used meets a minimum quality standard.

8) D&M uses can not all be lumped into one category.

Comments A provision is needed within the proposed rule to allow D&M product generators to continue some end uses which do not fit under the assumed "20 annual application" garden conversion scenario for D&M treated areas. End uses to be allowed for high rate or one-time batch applications include:

a) turf establishment -- the D&M product would be incorporated into the top 6 inches prior to establishing a vegetative cover; examples could be home lawns, parks, cemeteries, roadsides and medians, landfill closures, etc.

b) landscaping/nursery -- the D&M product would be mixed with soils in preparation of installing or growing landscaping plant species such as shrubbery, floriculture/ground cover, trees, etc.

c) potting mixes -- D&M products would be used as components of potting soils or media and container mixes for landscaping or growing nursery stock.

The concept of an AWSAR is not applicable to several of the end uses identified in Tables 2 and 3. Also, the likelihood of conversion to a garden area, which might be used to grow fruits and vegetables for human consumption, would be very small. We propose that two approaches which allow for higher non-annual application rates or one-time "batch" uses of D&M products:

a) one or more applications that would add an equivalent loading of a pollutant as allowed by 20 AWSAR applications, or

b) unrestricted use if a D&M product meets a "clean" sludge standard.

Under a), metal loadings to the soil would be the same. For organics, one large loading would not allow for the annual decomposition currently allowed for in the various pathways. However, within 2-3 years, a majority of most organics are decomposed or effectively bound to soil organic matter. Therefore, a restriction against conversion to a vegetable garden for 3 years or longer could be a labeling requirement as a condition when using a high application rate. (This type of restriction is similar to that used for Class B pathogen requirements on AgLA restricting food crops from being grown for a least 18 months after sludge application.) Under b), little if any restriction on use of D&M products would be needed if it met a "clean sludge" standard. As a first attempt, Table 2 lists maximum pollutant concentrations allowed in the D&M product in order to qualify for unrestricted use.

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