RISK ASSESSMENT FOR ORGANIC MICROPOLLUTANTS:

U.S. POINT OF VIEW

By

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Summary

Basic research and monitoring of sludge utilization programs have identified specific Pathways by which potentially toxic constituents of sewage sludge can reach and cause toxicity to livestock, humans, plants, soil biota, wildlife, etc. In the process of preparing a new regulation for land application of sewage sludge in the US, a Pathway approach to risk assessment was undertaken. Two Pathways were found to comprise the greatest risk from persistent lipophilic organic compounds such as PCBs: 1) direct ingestion of sludge by children; and 2) adherence of sludge to forage/pasture crops from surface application of fluid sludge, followed by grazing and ingestion of sludge by livestock used as human food. Each Pathway considers risk to Most Exposed Individuals (MEIs) who have high exposure to sludge. Because 1990 sewage sludges contain very low levels of PCBs, the estimated risk level to MEIs was $<<10^{-4}$; low sludge PCBs and low probability of simultaneously meeting all the constraints of the MEI indicate that MEIs are at $<10^{-7}$ lifetime risk. We conclude that quantitative risk assessment for potentially toxic constituents in sewage sludge can be meaningfully conducted because research has provided transfer coefficients from sludges and sludge-amended soils to plants and animals needed for many organic compounds.

1. INTRODUCTION

U.S. approaches to sludge regulations have changed over the years as scientific information about the fate and effects of potentially toxic constituents has become more complete. Until the 1970s sludge was regulated only as a source of infection or as a public nuisance due to odors. Then, a program of constructing sewage treatment works which would increase sludge production led to consideration of how sludge could be handled safely. Research began to evaluate risks from toxic constituents of sludge in different "ultimate disposal" environments (agricultural land, incinerators, landfills, ocean). In 1979, the United States Environmental Protection Agency (34) published a draft regulation on land application and landfill disposal of sludge for public comment.

The 1970s were a period of intense research on land application of sewage sludge. One of the most important areas of risk from sludge utilization/disposal identified was from sludges sold or given to individual citizens (Distributed or Marketed, D&M) without controls. Many Publicly Owned Treatment Works (POTWs) dried sludge on sand beds during part of the year, and dried sludge was often given to anyone who would take it. As in Europe, research found examples of highly polluted sludges (Cd, PCBs, etc.) being given away for use on lawns, gardens, and farms (5, 10, 24, 25). This information dramatized the need for regulation of sludge use in situations other than farmland; either the practice should be controlled or prohibited (14). In 1980, US-EPA started efforts to regulate D&M and to finalize the 1979 proposed regulations, but this effort was never completed.

While reauthorizing the Clean Water Act in the mid-1980's, Congress decided that further sludge regulations were needed, partly because the first rule dealt with only a few pollutants, and partly because sludge D&M had not been regulated and still continued in many cities. At the same time, other Congressional and US-EPA actions have improved industrial pretreatment regulations for many industries which discharged unwanted pollutants to the sewers. Protection of the quality of sludge was judged to be a valid reason to require pretreatment; if public acceptance of sludge application, or meeting state regulations on sludge utilization required better industrial pretreatment, states and cities now had the power to protect sludge quality. Based on the recent National Sewage Sludge Survey (39), sludge utilization in agriculture has increased since 1980 (Table 1), and concentrations of contaminants in most sludges are much lower than found in previous surveys (Table 2). This survey (39) found many "not detected", partly because solids content in sludge samples was not considered in taking wet sludge sample weights. For those samples with many "non detected" sludges, the Maximum Likelihood Estimation procedure was used to provide a reasonable estimation of the geometric distribution of a constituent in dry sludges.

Table 1. Methods of utilization and disposal of sewage sludge in the United States based on the National Sewage Sludge Survey (39) of 479 POTWs in 1988-1989, and 208 POTWs in Analytical Survey.

Use/Disposal Method	Information Survey US-EPA, 1989 (39) # POTWs	Fraction	Analytical Survey US-EPA, 1989 (39) # POTWs	Fraction	Estimated US Distribution # POTWs	Fraction
		%		%		%
Land Application	161	33.61	78	37.50	3542	31.05
Distribution&Marketing	27	5.64	10	4.81	308	2.70
Municipal Landfills	76	15.87	51	14.90	1851	16.23
Monofills	28	5.85	6	2.88	203	1.78
Surface (e.g. lagoons)	59	12.32	13	6.25	3147	27.59
Incineration	63	13.15	23	11.06	294	2.58
Ocean	21	4.38	6	2.88	115	1.01
Other	24	5.01	25	12.02	1526	13.38
	459	95.83				

During the 1980s, it became clear that addition of equal amounts of a pollutant in sludge or as a pure chemical caused different effects. Sludge was found to add specific adsorption capacity for metals and organics to the sludge-soil mixture (15). In the case of sludge metals, the plateau response of plant metal concentrations to increasing application rates of a sludge (13, 15) showed that the concentration of a pollutant in sludge did affect potential for risk. Previously it had been believed that all sludges had equal effect at equal cumulative applied amounts of a constituent, and that limiting the cumulative amount of metals or organics was the proper form of regulations. With this new information that the concentration of a constituent in a sludge could strongly affect the potential transfer to plants or animals, there was a scientific basis for regulating sludge constituent concentrations. The final effect of these

Table 2. Composition of U.S. Sewage Sludge based on 200 POTWs sampled during 1988-1990 (8, 39).

Constituent	Geometric Mean	Median	90th	95th	98th	Maximum	Minimum
	mg/kg dry solids						

Pollutant	Comparison with the 1990 Nat. Sewage Sludge Survey				
	Normal Statistics			Maximum Liklihood[5]	
	Median	95th	98th	Median	98th
	mg/kg dry sludge				
As	6	43	62	5	33
Cd	7	21	25	4	19
Cr	40	635	1960	39	409
Cu	463	1940	2490	456	2180
Hg	4	17	43	2	19
Mo	11	42	56	5	32
Ni	29	223	438	18	159
Pb	106	296	444	76	373
Se	5	28	51	3	16
Zn	725	4100	4760	755	3270
PCB-1248	0.21	0.67	1.5	0.02	0.21

[1] Adjusted downward for pretreatment considerations.
[2] No adverse effects reported for any Cr^{3+} level in municipal sludge.
[3] Valid for all sludge uses except mushroom production.
[4] Mo limit raised because Mo slowly leaches from alkaline soil.
[5] Maximum Liklihood Estimation Procedure, assuming multicensored lognormality.

changes is the development of the NOAEL (the No Observed Adverse Effect Level) sludge approach in which sludge constituents are limited to concentrations which comprise low risk to Most Exposed Individuals (MEIs) under worst-case scenarios (27, 22, 8). Application of at least 1000 Mg of a NOAEL sludge/ha has been found to comprise no risk to agriculture, livestock, humans, or wildlife/ecosystems based on data from field studies (27,8). The comprehensive risk analysis effort which allowed development of the NOAEL sludge approach may be helpful to other nations which are considering sludge regulations. Further, the detailed analyses identified specific areas of needed research, research not yet conducted in the agricultural or environmental research communities. Thus, this paper summarizes the new US approach to sludge regulation and the general conclusions reached. We conclude that if sludges can be beneficially used in sustainable agriculture with so low risk to agriculture or environment, that utilization of farmland should be the preferred method of "Ultimate Disposal". Pretreatment of industrial and non-industrial sources of some pollutants will often be required to achieve the NOAEL sludge quality. Technology is presently available to achieve the needed pretreatment.

The details of the arguments and the data used for the risk analyses have been described in several papers (30, 27, 8) and official documents

(36). Details of the Cd risk analysis were recently described in Chaney (8). We have also reviewed plant uptake of toxic organics, and discussed at length the potential errors in research methods and methods of analysis which have often caused over-estimation of the risk of toxic organics added in sludges (26). After working on this reconsideration of the scientific basis for sludge regulations for the US, we believe that a detailed example of risk analysis for PCB transfer illustrates the efforts currently underway in the United States. The paper shows the principles of the Pathway Method of risk analysis. Data on PCBs are nearly as complete as needed. Further, as with many of the persistent potentially toxic organics in sludge, sludge concentrations have decreased with the prohibition of PCB use or disposal in 1979. Based on these evaluations, we conclude that PCB concentrations will not limit utilization of nearly any sludge in the US.

PATHWAY APPROACH FOR ANALYSIS OF THE RISKS TO HUMANS AND THE ENVIRONMENT FROM TOXIC ORGANICS IN LAND-APPLIED MUNICIPAL SEWAGE SLUDGES.

In the ongoing effort to develop regulations to protect the environment during land application of sewage sludge, EPA developed a "Methodology" to assess the potential risk of toxic organic transfer to humans or the environment from all identified pathways for this transfer (36). The EPA Pathways (Table 3) were selected after consultation with the research community (35). Under the Pathway Approach, risk assessment is conducted in such a way as to protect the Most Exposed Individual (MEI) who ingests sludge or sludge-grown foods as a high portion of his diet. The MEI can be a human child eating sludge or soil-sludge mixture, a human adult consuming foods grown on sludge-amended land for 70 years, livestock, earthworms, soil bacteria and fungi, birds consuming large amounts of earthworms, etc.

Previous reviews have considered the possible transfer of toxic organics from sludge to humans (e.g. 6, 9, 16, 19, 26, 28). These reviews have focused on the direct ingestion of Distributed or Marketed (Pathway 2-D&M) sludge products by children, and on human consumption of a large fraction of ingested meats from livestock grazing sludge sprayed pastures (Pathway 4-Surface) (19). It has become generally accepted that all other Pathways transfer organics to humans at much lower levels than do Pathways 2-D&M and 4-Surface. However, a quantitative estimation of the allowed applications of sludge PCBs under all the pathways should clearly demonstrate why these two Pathways are so important. If these are the critical pathways for all persistent TOs, then research on other TOs should focus on the critical transfer coefficients involved in these Pathways.

Assessing Risk From Soil/Sludge Ingestion (Pathway 2-D&M; Sludge→Human).

Direct sludge ingestion by humans is the simplest Pathway for pollutants in sludge to reach humans. Research on Pb risk from ingested soil and dust (2, 32, 12) has shown the importance of hand-to-mouth play and of *pica* (intentional ingestion of non-food items) on transfer of soil-Pb and other strongly soil-adsorbed metals and TOs to children. Clearly, soil Pb comprises much greater risk to children with *pica* than any other way soil Pb can reach humans (e.g. plant uptake by garden food crops [12]). Because of the concern about soil ingestion by children, information needed to assess Pathway 2-D&M risks has been accumulated.

In the EPA Methodology, the algorithm for calculating Pathway 2 starts by calculating the allowed daily ingestion of PCB so as to protect against development of cancer in the exposed population. Cancer from excessive

Table 3. Pathways for risk assessment of potential transfer of sludge-applied trace contaminants to humans, livestock, or the environment, and the Most Exposed Individual to be protected by regulation to be based on the Pathway Analysis (36, 27).

	PATHWAY	MOST EXPOSED INDIVIDUAL
1	Sludge→Soil→Plant→Human	General food chain; 2.5% of all food for lifetime.
1F	Sludge→Soil→Plant→Human	Home garden 5 yr after last sludge application; 50% of garden foods for lifetime.
1D&M	Sludge→Soil→Plant→Human	Home garden with annual sludge application; 50% of garden foods for lifetime.
2F	Sludge→Soil→Human Child	Residential soil, 5 yr after last sludge application; 200 mg soil/d.
2-D&M	Sludge→Human Child	Sludge product; 200 mg sludge/d.
3	Sludge→Soil→Plant→Animal→Human	Rural farm families; 40% of meat produced on sludge amended soil, for lifetime.
4-Surface	Sludge→Animal→Human	Rural farm families; 40% of meat produced on sludge sprayed pastures, for lifetime.
4-Mixed	Sludge→Soil→Animal→Human	Rural farm families; 40% of meat produced on sludge amended soils, for lifetime.
5	Sludge→Soil→Plant→Animal	Livestock fed feed forages and grains, 100% of which are grown on sludged land.
6-Surface	Sludge→Animal	Grazing livestock on sludge sprayed pastures; 1.5% sludge in diet.
6-Mixed	Sludge→Soil→Animal	Grazing Livestock; 2.5% sludge-soil mixture in diet.
7	Sludge→Soil→Plant	"Crops"; vegetables in strongly acidic sludged soil.
8	Sludge→Soil→Soil Biota	Earthworms, slugs, bacteria, fungi in sludged soil.
9	Sludge→Soil→Soil Biota→Predator	Birds; 33% of bird diet earthworms affected by sludge.
10	Sludge→Soil→Airborne Dust→Human	Tractor operator.
11	Sludge→Soil→Surface Water→Human	Water Quality Criteria; fish bioaccumulation, lifetime.
12	Sludge→Soil→Air→Human	Farm households.
12W	Sludge→Soil→Groundwater→Human	Farm wells supply 100% of water used for lifetime.

D&M refers to sludge products distributed or marketed.

ingested PCBs is the most sensitive risk endpoint for humans from chronic ingestion of PCBs. The q_1^* is the cancer potency slope from the Cancer Assessment Group of EPA. In this assessment of the cancer potency of a compound based on lifetime feeding experiments with rats and other animals at the maximum tolerated dose, the upper 95th percent confidence limit of the slope is used as the limit to add further protection. This method of estimating potential cancer incidence after lifetime exposure of humans is generally agreed to lead to very conservative regulatory controls (1). The q_1^* is used with other assumed parameters (RL, BW, RE) to calculate the Adjusted Reference Intake (RIA). The RIA is the average daily intake of PCBs that may not be exceeded if Risk Level is to be $\leq 10^{-4}$.

$$RIA = \left[\frac{RL \cdot BW}{q_1^* \cdot RE} \right] \cdot 10^3 = \left[\frac{10^{-4} \cdot 10 \text{ kg}}{7.7 \cdot 1} \right] \cdot 10^3 = \frac{1.00}{q_1^*} = 0.130 \ \mu g/day$$

where RIA = Adjusted Reference Intake (μg/day).
q_1^* = human cancer potency slope ($[mg/kg \ BW/day]^{-1}$).
RL = risk level = 0.0001 of MEIs for EPA Proposed 503 Rule.
BW = body weight of 1-5 year old child = 10 kg.
RE = relative effectiveness, or bioavailability of pollutant in ingested sludge compared to pure chemical form (used in cancer potency slope assessment) added to diet.

The Reference Soil Concentration (RLC) which cannot be exceeded at the selected risk level is then calculated from the RIA. In this case the Pathway 2-D&M RLC is the maximum allowed sludge PCB concentration for a sludge D&M product. Pathway 2F (ingestion of pollutants 5 years after cessation of mixing sludge with soil) would provide appreciably less exposure than Pathway 2-D&M.

The average soil ingestion by children has been estimated by several researchers. The Calabrese et al. (7) paper shows the most reliable published estimation at this time. The 95th percentile (log normal) of soil/dust ingestion by 2 year old children was about 0.5 g/day, while the geometric mean soil ingestion was < 50 mg soil/day. We believe that the peak soil ingestion period by children is about 2 years long, and that use of the 0.5 g sludge/day provides a conservative estimate of risk (27). As it happens, use of either 0.2 g/day (the number used in the EPA Superfund program [37]) for 5 years, or the 0.5 g/day for 2 years are the same amount of sludge ingestion exposure.

The Duration Adjustment (DA) must be made when cancer risk slopes for 70 year lifetime exposure are used to estimate allowed exposures for soil/sludge ingestion which lasts only a part of the lifetime. Thus, the calculation can use 0.2 g/day for 5 years (DA = 0.0714) or 0.5 g/day for 2 years (DA = 0.0286). Values of RIA, I_s, and DA are used to calculate the RLC.

$$RLC = \frac{RIA}{I_s \cdot DA} = \frac{0.130 \ \mu g/day}{[(0.5 \cdot 0.0286) = 0.0143] \text{ or } [(0.2 \cdot 0.0714) = 0.0143]} = 9.09 \ \mu g \text{ PCB/g dry sludge.}$$

RLC = Reference Soil/Sludge Concentration of the pollutant (μg/g DW).
DA = Duration Adjustment for < 70 year: 5/70=0.0714; 2/70=0.0286.
I_s = Soil Ingestion Rate (g DW per day).

Thus, for PCBs, the RLC = 9.09 μg/g DW. The Pathway 2-D&M risk assessment, in which children are assumed to ingest sludge directly for 2-5 years, indicates that the required sludge PCB concentration limit is much higher than present levels of PCBs in sludges (Table 2). Based on data discussed below for bioconcentration of PCB from sludge ingested by cattle compared to bioconcentration from pure PCB added to cattle diets, the relative effectiveness of sludge PCB may be about 0.50, which would increase the RLC estimate accordingly.

Assessing Risk From Sludge ingestion by Grazing Livestock Used as Food by Humans (Pathway 4; Sludge→Soil→Animal→Human and Sludge→Animal→Human)

Fat in the human diet which comes from livestock which graze in sludge-amended pasture fields is the source of the human exposure calculated in Pathway 4. Pathway 4 has two quite different kinds of exposure, and we believe they should be considered separately. The first involves direct ingestion of sludge by livestock, where sludge has been surface applied to pasture crops. Livestock can ingest sludge adhering to the crops, or sludge lying on the soil surface. Each year the grazing livestock are presumed to be exposed to freshly applied sludge with no time for dissipation of the organic chemicals (this is *Pathway 4-Surface Application*). Alternatively, sludge can be injected into the soil or mixed with the plow layer soil, and the grazing livestock ingest the soil-sludge mixture. Injected sludge is not at the soil surface, so injection minimizes exposure until the plow layer soil is mixed. The highest exposure under the *Pathway 4-Mixed* scenario would be livestock ingesting soil while grazing a crop seeded immediately after mixing the applied sludge into the plow layer soil.

Sludge ingestion by grazing livestock was expected after Chaney and Lloyd (11) observed that sludge adhered to forages for a prolonged period if the fluid sludge was not washed off the plants immediately after application (23). If sludge is applied to standing forages, the rate of application and solids content of the sludge affect sludge adherence. N-fertilizer rate applications of typical fluid sludges containing 5% solids to standing forage crops caused sludge to reach about 15% of the forage dry matter. This evidence led to prohibition of sludge application on standing forages (34), and thus reduced the potential for sludge ingestion by livestock during sludge utilization on pastures.

Chaney et al. (9) reviewed several studies in which cattle grazed pastures to which sludge was surface applied using good practices. In the Decker et al. (17) study, fluid sludge was sprayed on the pastures after mowing, and the crop grew for 21 days before cattle were allowed to graze; the study used four "rotation paddocks" so that each 7 days the cattle were moved to the next pasture which had grown for 21 days after sludge application. By analysis of the cattle feces after 7 days grazing on the treated pastures, they found that the animals ingested about 2.5% sludge in their diets. Metals served as a label for sludge; concentration of metals such as Fe, Pb, and Cu were much higher in treated forages and feces than in control forages and feces of control treatment cattle. Similar results were observed by Bertrand et al. (4). However, when sludge compost was applied the previous grazing season rather than during each "rotation", the cattle ingested only about 1.0% sludge (17).

Another possible consideration is the effect of having only part of a farm treated with sludge each year. The EPA (36) Methodology considered that for the rural farm family who consumed the greatest fraction of "home-grown" livestock (the MEI in Pathway 4), all grazing fields were treated with sludge each year for a 70 year lifetime. However, if sludge were applied intermittently, the fraction of sludge in the chronic grazing animal diet is lower because adhering sludge exceeded sludge ingested from the soil surface in season-long grazing studies with sludge (see 9). Based upon our experience and discussion with regulatory officials in several states, we estimate that in any one year, the normal maximum fraction of a farm treated with sludge may be 33% rather than 100%. If one presumes the cattle are rotated among several pasture fields, the actual fraction of the diet which is sludge will be lower than the 2.5% measured with continual exposure (this lifetime approach is necessary because the cancer endpoint protected against requires that exposure appropriate for a chronic lifetime model be estimated). To take this into account, the allowed RFC for sludge-treated forage should be adjusted for the fraction of livestock diet affected by sludge application. Using 1% sludge ingestion during non-application periods (2/3 of time), and 2.5% ingestion during sludge application periods (1/3 of time), the long term average would be 1.5% sludge in diet.

To estimate sludge PCB transfer from grazing livestock to humans, the lifetime average amounts of fat of meat and dairy products from grazing livestock ingested per day are needed. The US-EPA (36) "Methodology" estimated the amounts of fat in the human diet from each class of livestock, for a range of age and sex groups of the US population. The original data were described by Pennington (31). One can calculate a lifetime diet composition by assuming the number of years each age range of consumption covers. Table 4 shows the estimated average lifetime daily consumption of fat from meats from different livestock. Other foods considered in this paper are also included in Table 4.

The MEI for Pathway 4 is believed to be members of a rural farm family ingesting much of their lifetime meat consumption from home grown livestock (which consume sludge on forages or soil-sludge mixture) for their 70 year lifetime exposure. The calculation starts with estimation of the maximum allowed daily PCB intake to limit 70 year lifetime cancer risk:

$$RIA = \left[\frac{RL \cdot BW}{q_1^* \cdot RE} \right] \cdot 10^3 = \left[\frac{10^{-4} \cdot 70\ kg}{7.7 \cdot 1} \right] \cdot 10^3 = 0.909\ \mu g\ PCB/day$$

RIA = adjusted reference intake (μg/day)
q_1^* = human cancer potency ([mg/kg/day]$^{-1}$)
RL = risk level = 0.0001 for TSD
BW = body weight = 70 kg
RL = Relative Effectiveness or bioavailability.

After calculating the RIA, one calculates the maximum allowed feed concentration of PCBs (RFC) for Pathway 4 (see Table 5):

$$RFC = \frac{RIA}{\Sigma\ (UA_i \cdot DA_i \cdot FA_i)}$$

RFC = reference feed concentration of the pollutant (μg/g DW)
RIA = adjusted reference intake (μg/day)
UA_i = uptake response slope of pollutant in the animal tissue food group i, for organics, on a fat basis, = 2 (μg PCB/g fat)$\cdot$(μg PCB/g feed DW)$^{-1}$ for *sludge-borne* PCBs added to test diets.
DA_i = Daily dietary consumption of animal food/fat group i, g dry wt.
FA_i = fraction of the food group i assumed to be derived from amended soil (in this case, from fat in tissues of or milk from cattle consuming 1.5% sludge averaged over their lives). Assumes that a high fraction of the diet came from cattle raised on the sludge-treated pastures (44% for meat fat, and 40% for dairy fat for a 70 year lifetime).

Table 4. Human consumption of selected foods (fat from meats derived from several classes of livestock; garden crops) (g dry weight/day) for different age groups, and estimated lifetime average food intakes for 70 kg US adult citizens. The child age group (not reported by Pennington [31]) was assumed to consume the average of that consumed by toddlers and teen-agers. Meats in mixed foods assigned to source by US-EPA (36).

Food Group	Age Grouping						
	Baby	Toddler	Child	Teen-Agers	Adult	Older Adult	Estimated Lifetime
Age:	0-1	1-6	6-14	14-20	20-45	45-70	0-70
Grazing Livestock:							
Beef Fat	2.45	6.48	11.34	16.22	20.40	14.07	15.50
Beef Liver Fat	0.05	0.07	0.08	0.10	0.29	0.33	0.25
Lamb Fat	0.14	0.08	0.07	0.06	0.31	0.22	0.21
Dairy Fat	38.99	16.48	20.46	24.43	18.97	14.51	18.13
Non-Grazing Livestock:							
PorkFat	2.01	8.19	10.47	12.75	14.48	13.04	12.73
PoultFat	1.10	0.83	1.12	1.41	1.54	1.31	1.34
EggFat							0.96
Garden Food Crops:							
Potatoes	5.67	10.03	14.72	19.40	17.28	14.79	15.60
Leafy Veg.	0.84	0.49	0.85	1.22	2.16	2.65	1.97
Legume Veg.	3.81	4.56	6.51	8.45	9.81	9.50	8.75
Root Veg.	3.04	0.67	1.20	1.73	1.77	1.64	1.60
Garden Fruit	0.66	1.67	2.57	3.47	4.75	4.86	4.15

For Teen, Adult, and Older Adult categories, FDA (31) intakes of females and males were averaged; for other groups, no separation of data by sex was reported. Child intake was set equal to the average of Toddler and Teen.

The best value for UA for PCB transfer from feed to fat has been discussed by Fries (19). Based on his own and other research, Fries concluded that the UA was 4 for beef fat and 4.8 for dairy products. However, this was for pure PCB added to cattle diets or provided in corn oil. Baxter et al. (3) tested the bioaccumulation ratio for PCB in a dried anaerobically digested sludge containing 24 mg PCBs/kg DW. Because sludge adsorbs PCBs strongly, the UA for sludge-borne PCB was only 1.9. This value was the average for beef cows and steers fed 10% sludge in their complete diet for 270 days. It should not be unexpected that sludge PCB adsorption properties and oils could reduce the bioavailability of sludge PCBs. Rozman et al. (33) found adding mineral oils to feeds increased the excretion of hexachlorobenzene from cattle. Fairbanks and O'Connor (16) found soil organic matter strongly adsorbed PCBs, and the adsorbed PCBs showed strong hysterisis (limited release) of PCBs in sludge.

$$RFC = \frac{RIA}{\Sigma(UA_i \cdot DA_i \cdot FA_i)} \quad = \quad \text{or } RFC = \frac{0.909}{27.13} = 0.0335\ \mu g/g\ DW$$

The fraction of sludge in the diet enters into the calculation so the maximum amount of PCB allowed in the sludge can be estimated for *Pathway 4-Surface Application*. Reference Sludge Concentration (RSC) can be calculated as specified in the Methodology:

Table 5. Calculation of $\Sigma(UA_i \cdot DA_i \cdot FA_i)$ needed to estimate human exposure to PCB in fat of meat from grazing livestock. UA value from Baxter et al. (3), based on feeding cattle 10% sludge for 270 days at which time equilibrium of PCB in fat with the diet would have been reached according to Fries (19). DA is the lifetime daily average intake of fat from grazing livestock. FA is the fraction of total lifetime ingestion of these meats by the MEIs (members of a rural farm family.

	Sludge PCB in Diet of Grazing Livestock			
Food Group	DA g/day	UA	FA	$(UA_i \cdot DA_i \cdot FA_i)$ Estimated Lifetime
Beef fat	15.50	1.9	0.44	12.96
Beef liver fat	0.25	1.9	0.44	0.21
Lamb fat	0.21	1.9	0.44	0.18
Dairy fat	18.13	1.9	0.40	13.78
ΣFat from grazing livestock	34.09			27.13

RSC = RFC/FS

RSC = Reference Sludge Concentration
RFC = Reference Feed Concentration
FS = Fraction of livestock diet comprised of sludge (chronic lifetime exposure = 0.015 according to discussion above.)

RSC = RFC/FS = 0.0335/0.015 = 2.23 μg PCB/g DW in applied sludge.

This same number is used for estimating allowed sludge PCB applications under *Pathway 4-Mixed With Soil*, only now it is 2.23 μg PCB/g dry soil-sludge mixture which is chronically ingested by the grazing livestock at 1.5% of diet (annual average basis; see also [9, 19, 21]). In the case of sludge mixed into soils, however, the regulatory approach is quite different because PCBs can volatilize or be biodegraded over time after application. The 2.23 μg PCB/g dry soil-sludge mixture which must not be exceeded is considered to be the equilibrium reached when PCB dissipation during one year equals the annual PCB application. Persistent higher chlorinated PCBs have about a 6-10 year half-life; for these calculations, the $T_{0.5}$ is presumed to be 10 yr ($k = 0.693/T_{0.5} = 0.0693$/yr).

An equilibrium PCB concentration is reached after about 5.6/k = 81 years (36), and the formula used to calculate the annual PCB application mixed into the soil (RP_a) needed to reach this equilibrium RSC after 81 continuous annual applications is:

$$RP_a = RLC \cdot (2000 \text{ Mg soil/ha}) \cdot 10^{-3} \cdot [1e^{0 \cdot 0.0693} + 1e^{-1 \cdot 0.0693} + \ldots + 1e^{-81 \cdot 0.0693}]^{-1}$$
$$= 2.23 \cdot 2 \cdot [14.9]^{-1} = 0.299 \text{ kg PCB/ha/yr.}$$

This could be applied by 10 Mg/ha/yr of a sludge containing 29.9 mg PCB/kg:

$$\frac{0.299 \text{ kg PCB}}{\text{ha} \cdot \text{yr}} \cdot \frac{1 \text{ ha} \cdot \text{yr}}{10 \text{ Mg sludge DW}} = \frac{0.0299 \text{ kg PCB}}{\text{Mg sludge}} = 29.9 \text{ mg PCB/kg sludge DW.}$$

Thus, Pathway 4-Surface Application comprises significantly greater potential for PCB transfer to humans than does Pathway 4-Mixed. Pathway 4 risk assessment remains a very conservative estimation of allowable toxic organic concentrations in sewage sludge. The exposure scenario, a rural farm family ingesting, for a 70 year lifetime, a high proportion of home grown meat and dairy products from livestock which often graze sludge-amended pastures, is conservative. In *Pathway 4-Surface Application*, the sludge is assumed to remain on the surface of pastures continuously for 70 years in contrast with known agronomic practices which require that the surface be intermittently tilled with the plow layer soil to incorporate pH-modifying agents, fertilizers, and organic matter into the surface soil. The MEI is conservatively assumed to consume 44% of meat of grazing livestock and 40% of dairy products from livestock raised on sludge-using farms, but few farms raise both lamb and beef, and dairy cattle are fed feed supplements to improve production efficiency (21). Further, it is likely that current data on food consumption by rural farm families would show that a lower fraction of locally grown livestock is consumed by the highest consuming families.

The alternatives to surface application of sludge on pastures include use of sludge injection, and mixing sludge with the soil before forage crops are established. These would all lead to much lower estimations of risk than found with Surface Application. *Pathway 4-Mixed With Soil* calculations indicate that much greater protection of humans from sludge-applied PCBs can be achieved by avoiding surface application of sludge on pastures. The use of sludge injection minimizes sludge ingestion by grazing livestock, conserves sludge nutrients, and prevents malodors and unsightliness of surface applied sludge. In any case, the MEI is well protected against chronic health effects of sludge PCBs by limitations appropriate for the method of application.

Assessing Risk From Uptake of Soil PCB Residues by Forage and Feed Crops For Livestock Used as Food by Humans (Pathway 3; Sludge→Soil→Plant→Animal→Human)

For Pathway 3, sludge is presumed to be uniformly mixed with the plow layer soil, and forage and feed crops are grown on the sludge-treated soil. As in Pathway 4, the MEIs are rural farm families assumed to consume a high proportion of their lifetime meat and dairy products from livestock which eat only crops grown on sludge-treated soils. This Pathway is similar in approach to Pathway 4-Mixed, but all meats and dairy products are considered. Fat from non-grazing livestock classes (poultry, swine) are included in Pathway 3 because feed grains can be harvested from sludge-amended soils in addition to hay and silage harvested for ruminant livestock. Transfer of PCBs from sludge-amended soil to edible parts of crops is quite low (28, 40) and annual sludge applications are limited by the N fertilizer supplied by the sludge, resulting in the steady state concentration of PCB in soil being quite low compared sludge lying on the soil surface in Pathway 4. Pathway 3 therefore, would always be expected to provide lower transfer of persistent PCBs to humans via animal fat.

For Pathway 3 (uptake of PCBs by forage/feed plants, or contamination with PCB independent of sludge or soil ingestion), the EPA (36) Methodology presumed that the PCB uptake slope for forage crops was the appropriate transfer slope to feeds for all livestock. However, in calculating the estimate of toxic organic compound transfer to humans by this Pathway, we believe it is important to also discriminate between grain crops fed to some classes of livestock and forage crops fed to ruminant livestock. Further, milk cows are supplied grains and other "concentrates" to provide nutrients and energy for high production rates, and it is inappropriate to presume 100% forage diet for dairy products (21). A modified approach to calculating this limitation is shown below which allows correction of this error in the risk assessment Pathways.

For 70 year lifetime exposure, the EPA (36) algorithm to calculate RIA for Pathway 3 is the same as in Pathway 4). After calculating the RIA, one calculates the RFC for the feed as under Pathway 4, but adds the fat from other foods as shown in Table 6:

$$RFC = \frac{RIA}{\Sigma\ (UA_i \cdot DA_i \cdot FA_i)}$$

RFC = reference feed concentration of the pollutant (μg/g DW)
RIA = adjusted reference intake (μg/day)
UA_i = uptake response slope of pollutant in the animal tissue food group i for organics, on a fat basis, = 4 for PCB mixtures added to test diets; does not use the data from Baxter et al. used for Pathway 4 because sludge is not present to adsorb PCB during transit through the gut.
DA_i = Daily dietary consumption of the animal tissue food group i
FA_i = fraction of the food group i assumed to be derived from amended soil (in this case, from fat in tissues of or milk from cattle consuming feeds which were all grown on soils which received sludge annually.

The RLC is calculated from the RFC by dividing by the uptake slope for the compound for the crop used to estimate uptake (UC):

$$RLC = (RFC \div UC) + BS$$

where:
RLC = Reference Soil Concentration (μg/g DW)
UC = linear response slope of forage crop [μg/g crop DW (μg/g soil DW)$^{-1}$]
BS = background soil concentration of pollutant (μg/g DW) (assumed to be 0 since the cancer risk to be estimated is the incremental risk, not the absolute risk.

Our method of calculation sums a new product of UC_i and DF_i (Diet Fraction) times the old product (Table 6) to directly calculate RLC from RIA:

$$RLC = \frac{RIA}{\Sigma((UC_i \cdot DF_i \cdot UA_i \cdot DA_i \cdot FA_i)} = \frac{0.909}{0.04954} = 18.3 \text{ mg/kg soil-sludge mixture DW}$$

The Methodology calculation then estimates an annual sludge PCB application rate taking into account the rate of dissipation (volatilization or degradation) of PCBs ($T_{0.5}$ = 10 yr) so that the RLC is reached at steady state between application and dissipation.

The formula was introduced above.

$$RP_a = RLC \cdot (2000/1000) \cdot (14.9)^{-1} = 2.46 \text{ kg PCB/ha/yr.}$$

Table 6. New approach to estimate PCB limitation for Pathway 3; $\Sigma(UC_i \cdot UA_i \cdot DA_i \cdot FA_i)$ is calculated to allow discrimination between PCB transfer to livestock which consume grain and those consuming forage.

Animal Tissue Group	Feed Type	Diet Fraction	Uptake(UC_i) Slope	UA	DA	FA	Σ
Beef Fat	Forage	1.00	0.001	4.0	15.50	0.44	0.02728
Beef Liver Fat	Forage	1.00	0.001	4.0	0.25	0.44	0.00044
Lamb Fat	Forage	1.00	0.001	4.0	0.21	0.44	0.00036
Pork Fat	Grain	1.00	0.0001	4.0	12.73	0.44	0.00224
Poultry Fat	Grain	1.00	0.0001	4.0	1.34	0.34	0.00018
Dairy Fat	Forage	0.50	0.001	4.8	18.13	0.40	0.01740
Dairy Fat	Grain	0.50	0.0001	4.8	18.13	0.40	0.00146
Eggs Fat	Grain	1.00	0.0001	4.0	0.96	0.48	0.00018
Total				-	-	-	0.04954

Uptake slopes (UC_i) from [28].

At an annual application rate of 10 Mg dry sludge/ha, the sludge could contain as much as 246 mg PCBs/kg.

$$\frac{2.46 \text{ kg PCBs}}{\text{ha}\cdot\text{yr}} \cdot \frac{1 \text{ ha}\cdot\text{yr}}{10 \text{ Mg sludge DW}} = \frac{0.246 \text{ kg PCBs}}{\text{Mg sludge DW}} = \frac{246 \text{ mg PCBs}}{\text{kg sludge DW}}.$$

This high allowed annual application of sludge PCBs will not practically limit sludge application because modern sludges contain low levels of PCBs, with median levels < 0.1 mg/kg DW.

Another way to view this high annual allowed PCB application and equilibrium soil PCB concentration under Pathway 3 is that Pathway 4 would estimate unacceptable risk levels for the same soils. During periods of sludge use on pastures, the limitations of Pathway 4 must limit sludge PCB application. These considerations confirm the summary of relative risk from Pathways 3 and 4 noted in the introduction.

Calculations for Pathway 3 also remain very protective for the presumed MEIs. Sources of protection include: 1) the assumption that the rural farm family consumes a large portion of "home-grown meats" for their 70 year lifetime exposure; and 2) that sludge is applied annually to 100% of the farmland used to produce forage and grain crops used as animal feed.

Assessing Risk From Food Crops (Pathway 1F; Sludge→Soil→Plant→Human):

The production of food crops for humans on sludge-amended soils will transfer some sludge constituents into human diets. The MEI for this Pathway is the home gardener who grows a large fraction of his diet on sludge amended soil, for 70 years. Sludge is presumed to be applied and mixed into the soil annually until the PCB concentration reaches an equilibrium with PCB loss (81 years as noted above). The exposure is assumed to be at the equilibrium level for the whole 70 year consumption of garden crops grown on the treated soil. Pathway 1F-D&M could be estimated by assuming a D&M product is applied annually, so no waiting period is allowed. In the Agricultural Use Pathway 1F, a five year waiting period is assumed before crops are grown on the treated soil, presuming a waiting period followed by conversion of the site to residential use. Because

Pathway 1-D&M estimates the highest possible exposure under Pathway 1, it is used for an example. Exposure from Pathway 1F-D&M is much lower than from Pathway 2-D&M or Pathway 4-Surface. Pathway 1F-D&M will not practically limit utilization of sludges with low PCB concentrations presently available.

The method of calculation of food chain transfer of toxic organics according to the Methodology (36) (home garden scenario) uses several steps to complete the calculation. The first step is the calculation of daily allowed TO intake (RIA) based on the cancer potency value. One then sums the amount of each food group consumed times the slope of plant uptake for the compound times the fraction of food group grown on sludge amended soil. This value is divided into the RIA to produce the RLC, the soil PCB concentration which sludge application may not be allowed to exceed.

From calculations above, we know the RIA is 0.909 µg PCB/day. The next step sums the amount of PCB ingested if FC (fraction of the diet) were grown on sludge amended soil, if DC (g DW of foods) were consumed daily on average for 70 years, and if UC were the transfer coefficient from soil to each food group (µg PCB/g dry crop per µg PCB/g dry soil) grown in the garden.

Calculation of the $\Sigma(UC_i \cdot DC_i \cdot FC_i)$ for PCBs relies on the values in Table 7. The DC for garden vegetables lifetime ingestion estimates were shown in Table 4. Table 7 combines the new food intakes, corrected crop PCB uptake slopes, and fraction of diet from the US-EPA Proposed 503 Rule (US-EPA, 1990a) to calculate the $\Sigma(UC_i \cdot DC_i \cdot FC_i)$ for PCBs. Carrot accounts for 53% of the dry matter of the root vegetable grouping according to Chaney et al. (9). Thus, the overall root vegetable group is shown as equal to 53% of the uptake slope of carrot. Although most people peel carrots before consuming them, there is no assurance that carrots will be peeled. Therefore, the uptake slope for unpeeled carrots was used. O'Connor et al. (29) found little PCB entry to carrot deeper than the normal peel depth.

Table 7. Using corrected UC slopes, food intakes (DC), etc., for the calculations for Pathway 1F home garden analysis for PCBs. The absolute slope used for **unpeeled carrot** was (0.075 µg/g DW carrot)•[µg PCB/g soil DW]$^{-1}$; from O'Connor et al. (29), after review of PCB uptake by carrot and lettuce from sludge-PCB treated soil. Other data are best judgement values because slopes are not generally available from properly conducted field experiments with sludge-applied PCBs.

Food Group	Food Intakes DC	Uptake Slope UC	Fraction home-grown. FC	$(UC_i \cdot DC_i \cdot FC_i)$ $\frac{\mu g/day}{\mu g/g \text{ soil DW}}$	
	g DW/day	$\mu g/g(\mu g/g)^{-1}$			%Total
Potatoes	15.60	0.025Carrot=0.00188	0.45	0.0132	24.9
Leafy Veg.	1.97	≤0.0010	0.60	0.00118	2.2
Legume Veg.	8.752	0.001Carrot=0.000075	0.29*	0.00019	0.4
Root Veg.	1.60	0.53Carrot =0.03975	0.60	0.03816	72.1
Garden Fruit	4.15	0.001Carrot=0.000075	0.60	0.00019	0.4
				Σ = 0.05292	100.0

*0.17 for dried legume vegetables (8.412 g DW/day) and 0.60 for fresh legume vegetables (3.340 g DW/day) gives 0.29 for weighted total legume vegetables.

Using the corrected $(UC_i \cdot DC_i \cdot FC_i)$, the estimated RLC is:

$$RLC = \frac{0.909\ \mu g\ PCB/day}{0.05292\ \mu g\ PCB/day\ (\mu g\ PCB/g\ soil\ DW)^{-1}} = 17.2\ \mu g\ PCB/g\ dry\ soil$$

This is the maximum allowed concentration of PCB in soil at any time that garden vegetables are grown on the soil. This can be converted to an annual sludge-PCB application as done above in Pathway 4-Mixed With Soil, and Pathway 3. The RP_a would be 17.2 • 2 ÷ 14.9 = 2.31 kg PCB/ha/yr. A sludge applied at 10 Mg/ha/yr could contain 231 mg PCB/kg DW.

Table 8 compares the original calculated limitations for the Proposed 503 Regulation (38), and the estimated limitations if the appropriate algorithms and transfer coefficients shown in this paper were used (28, 8).

Table 8. Comparison of PCB application limits for each pathway for data from the 503 Proposed Rule and the corrected versions reported in this document. The last column lists concentrations of PCBs which could exist in sludges applied as N fertilizer annually at 10 Mg/ha.

	Original EPA Estimate		Corrected Approach		Sludge Limit,
mg/kg Pathway	Limit Units	Limit value	Limit Units	Limit value	@ 10 Mg/ha/yr
1	kg/ha•yr	4.1			
1D&M	kg/ha•yr	0.264	mg/kg Soil Max.	17.2	
1D&M	kg/ha/yr	2.31		231.	
2D&M	kg/ha•yr	7.3	mg/kg sludge DW	9.09	9.09
3	kg/ha•yr	0.0056	mg/kg Soil Max.	18.3	
			kg/ha/yr	2.46	246.
4-Surface Application	kg/ha•yr	0.019	mg/kg sludge DW	2.23	2.23
4-Mixed With Soil	kg/ha/yr	0.019	mg/kg Soil Max.	2.23	
4-Mixed With Soil	kg/ha/yr	0.019	kg/ha/yr	0.299	299.

FUTURE

The effort to complete development of the Clean Water Act 503 Regulations for sewage sludge is continuing. Final regulations are expected to be issued in 1992, and all 28 contaminants being considered in the present regulation will undergo risk assessment for all Pathways.

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16. ABSTRACT

Basic research and monitoring of sludge utilization programs have identified specific Pathways by which potentially toxic constituents of sewage sludge can reach and cause toxicity to livestock, humans, plants, soil biota, wildlife, etc. In the process of preparing a new regulation for land application of sewage sludge in the US, a Pathway approach to risk assessment was undertaken. Two Pathways were found to comprise the greatest risk from persistent lipophilic organic compounds such as PCBs: 1) direct ingestion of sludge by children; and 2) adherence of sludge to forage/pasture crops from surface application of fluid sludge, followed by grazing and ingestion of sludge by livestock used as human food. Each Pathway considers risk to Most Exposed Individuals (MEIs) who have high exposure to sludge. Because 1990 sewage sludges contain very low levels of PCBs, the estimated risk level to MEIs was less 10^{-4}; low sludge PCBs and low probability of simultaneously meeting all the constraints of the MEI indicate that MEIs are at less 10^{-7} lifetime risk. We conclude that quantitative risk assessment for potentially toxic constituents in sewage sludge can be meaningfully conducted because research has provided transfer coefficients from sludges and sludge-amended soils to plants and animals needed for many organic compounds.

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17. KEY WORDS AND DOCUMENT ANALYSIS

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