Chapter 6

Questions and Answers on the Part 503 Risk Assessments

A number of particular questions are often asked about the Part 503 risk assessments. This chapter poses many of these questions and provides answers to them. Additional discussion about many of these issues may be found elsewhere in this guide.

Risk Assessment

Q: What do the Part 503 risk assessments accomplish?

A: They assess the potential for risk to humans, other animals, and plants from pollutants in biosolids. The risk assessments evaluated exposure to selected pollutants in biosolids via 14 exposure pathways for land application, 2 for surface disposal, and 1 for incineration.

Risk Level of 1×10^{-4} or 1×10^{-6}

Q: What does a risk level of 1×10^{-4} mean?

A: For carcinogenic compounds (compounds that are capable of inducing or causing cancer), a 1×10^{-4} risk level means there is a 1 in 10,000 chance of the highly exposed individual getting cancer.

Q: Does this 1×10^{-4} risk level mean that as a result of the Part 503 biosolids rule, 2,500 of the 2.5 million persons living in the United States (1 person for each 10,000) could possibly get cancer because of exposure to a pollutant in biosolids?

A: No, the risk of getting cancer is related only to the population that is exposed to that risk. In the United States, the number of persons highly exposed to risks from biosolids is actually very small. If, for example, 10,000 individuals were in the highly exposed population, then there might potentially be one case of cancer arising in the United States from exposure to a particular pollutant in biosolids. If, however, the population of highly exposed individuals was 10, then there might potentially be 0.001 case of cancer arising in the United States from that pollutant.

Q: Were the limits for metals in the Part 503 rule established based on a 1×10^{-4} risk?

A: No, the Part 503 metals were considered noncarcinogens (they do not cause or induce cancer) for the exposure pathways evaluated.

Q: If metals were not regulated on a 1×10^{-4} risk basis, then on what basis?

A: The pollutant limits for each of the Part 503 metals in biosolids are based on threshold limits such as risk reference doses (RfDs), which represent the amount of daily intake of a particular noncancer-causing substance that is not expected to cause adverse effects; the RfD is a conservative determination of the upper level of acceptable intake. The RfD (or other threshold limit) was then combined with pollutant intake information (e.g., the amount of a pollutant in biosolids taken up by plants that are then ingested by humans; the amount of a particular food consumed) to derive a pollutant limit. Each pollutant limit is set to protect a highly exposed individual (plant or animal) from any reasonably anticipated adverse effects of a pollutant in biosolids.

Q: Understanding now that the limits for metal pollutants in biosolids used or disposed were not based on a 1×10^{-4} risk in the Part 503 rule, were any pollutant limits established on the basis of a 1×10^{-4} risk?

A: Yes and no. Yes, in that pollutant limit determinations based on a 1×10^{-4} cancer risk level were made for potentially toxic organic pollutants that could occur in biosolids. And, no, because the pollutant limits determined in this way were not included in the final rule, as described below.

Land Application: Thirteen pollutant limits were determined for organic pollutants using the 1×10^{-4} approach, but they were not included in the final Part 503 rule. The decision to drop these organic pollutants from the final Part 503 rule was made because: (i) the pollutant has been banned, restricted for use, or is no longer manufactured for use in the United States; (ii) the pollutant is not present in biosolids at significantly high frequencies of detection, based on data gathered from the National Sewage Sludge Survey (NSSS); or (iii) the limit for the pollutant identified in the biosolids risk assessments is not expected to be exceeded in biosolids that are used or disposed, based on data from the NSSS.

Surface Disposal: Pollutant limits also were determined for toxic organic pollutants in surface-disposed biosolids based on a 1×10^{-4} cancer risk. None of the organics were retained in the final Part 503 rule, and three inorganics were deleted from regulation because each of these organic and inorganic pollutants met one of the three criteria described in the previous paragraph.

Incineration: Pollutant limits were also determined for toxic organic pollutants associated with incinerated biosolids for which q_1^*s (cancer potency values) exist, based on a 1×10^{-4} cancer risk. Because of the limitations of the risk assessment process in reflecting all of the individual toxic organic pollutants emitted from biosolids incinerators, the EPA's Science Advisory Board recommended using an operational standard rather than pollutant limits. The recommended operational standard involves monitoring the emission of total hydrocarbons from biosolids incinerators to ensure the levels from stacks do not exceed 100 ppm. This standard is believed to be protective of public health for the spectrum of toxic organic pollutants that are emitted from biosolids incinerators.

Q: Why was a risk limit of 1 x 10^{-4} chosen as a basis for the pollutant limits for carcinogens instead of a 1 x 10^{-6} risk (a 1 in 1 million chance of potentially getting cancer)?

A: The less restrictive 1 x 10^{-4} risk limit was chosen as a policy decision. The aggregate (overall) risk from biosolids use or disposal in the United States is especially low (i.e., ranging from only a fraction of a person to several persons being at risk out of the total U.S. population). Because the risk is especially low, the less restrictive risk limit still provides adequate protection.

Q: If a risk limit of 1 x 10^{-4} is sufficient, then why not apply a more protective risk limit just to be more safe? After all, a 1 x 10^{-6} risk limit is only 100 times more restrictive than the 1 x 10^{-4} risk limit.

A: In addition to the fact that cancer risk from the use of biosolids is very low, a 1 x 10^{-6} cancer risk level was not chosen to be more protective because:

- Use of more conservative levels in risk assessment calculations has sometimes led to predictions that the levels of certain substances in the environment are more hazardous than relevant research indicates. A good discussion of how risk assessment methodology can predict erroneously that the levels of certain substances in the environment are too high can be found in a paper by Ryan and Chaney (1995).
- Although not used as a determining factor during the development of the Part 503 rule, use of a more stringent risk level would require thousands of facilities to achieve the stricter limit of 1 x 10^{-6} for a given substance rather than 1 x 10^{-4}, even though the limit is only one hundred times more stringent. It is difficult to justify such an expense for little or no actual difference in risk to the highly exposed organism.

Selection of the Part 503 Pollutant Limits

Q: How were the pollutant limits chosen for the Part 503 rule?

A: For all pollutants evaluated, first the highly exposed individual was identified for each of the applicable pathways of exposure. For example, for land application practices, a different highly exposed individual was identified for each of the 14 different exposure pathways that were applicable. The risk assessment limit for each pollutant was selected from the pathway with the highest exposure and lowest permitted dose. For example, the pollutant limit for copper was set at 1,500 kg copper/hectare of land based on the Pathway 8 pollutant limit being the most stringent (lowest) at 1,500 kg-copper/ha-land; for all the other copper exposure pathways, the pollutant limits were greater. For land application, additional pollutant limits were derived from these values and incorporated into the rule.

Q: Were all pathways evaluated for each pollutant?

A: No. Risk assessments were not conducted for all pathways for each pollutant. Risk assessment is made up of several components, including hazard identification and exposure assessment. Where the exposure assessment indicated that exposure to the pollutant was not significant via a certain pathway, or where EPA lacked data, that pathway was not evaluated for a particular pollutant.

Most Exposed Individual (MEI) vs. Highly Exposed Individual (HEI)

Q: Was the final Part 503 rule designed to protect the MEI or the HEI?

A: The HEI.

Q: Why not the MEI?

A: The MEI is a hypothetical (imaginary) individual that experts did not believe could exist. Protecting an individual that does not even exist was believed to be unrealistic. The Agency's risk assessment policy states that the individual that should be protected is an HEI. In contrast to the MEI, the HEI may exist, although in small numbers.

The MEI was used as the target organism to be protected in the proposed Part 503 rule, and was developed with very conservative assumptions and overly stringent models. As an example, one of the MEIs in the proposed Part 503 rule (for land application exposure pathway 1F [later exposure Pathway 2]) was the hypothetical home gardener:

- Who produced and consumed essentially all of his or her own food for 70 years in a home garden amended with biosolids.
- Whose biosolids-amended garden soil contained the maximum cumulative permitted application of each of the evaluated pollutants for that 70-year period.
- Whose food harvested from the garden had the highest plant uptake rate for the 70-year period for each of the pollutants, as calculated using data from pot/salt studies.
- Who for 70 years consumed foods that were grown in that garden, with the gardener always at the age, sex, and physiological state for maximum absorption and/or ingestion (e.g., simultaneously male and female, pregnant, an infant, and a teen-age male).

In contrast, the use of an HEI combines high-end and mid-range assumptions in models and algorithms (descriptive mathematical equations). The HEI attempts to be representative of a real individual. This is indicated by the data, models, and assumptions used for protecting the highly exposed home gardener again via Pathway 2 during the revised risk assessment and development of the final Part 503 rule. In this risk assessment:

- The home gardener HEI produced and consumed up to 59 percent of his or her own food (depending on the food group) for a 70-year period in a biosolids-amended garden.
- The biosolids-amended garden soil contained the maximum cumulative permitted application of each of the evaluated pollutants for the 70-year period.
- The food that was harvested from the garden had plant uptake slopes for biosolids pollutants determined using the geometric mean of relevant data from field studies, with both acid and neutral biosolids-amended soils.
- The food consumption was apportioned among several different age periods during the 70-year life of the HEI gardener.

What If?

Q: Do we know everything about the use or disposal of biosolids?

A: No.

Q: Then, how can the Agency determine that it is all right to use or dispose of biosolids? What if we find that some other pollutant in biosolids is hazardous? Or what if we find there is a "time-bomb" effect and all the pollutants we now think are being held in an unavailable form by the biosolids, even after they are added to soils, later become available?

A: The use of biosolids has been one of the most extensively studied waste management practices in the United States. Some public uses have occurred in the United States for 70 years. Throughout this long history of use, biosolids have repeatedly been shown to be a valuable soil conditioning and fertilizing product. While there can be no absolute guarantees, the past use of biosolids has been very reassuring when biosolids have been used in accordance with practices known to be acceptable.

In the few instances in the past where problems occurred from biosolids use, the implementation of various commonly used management practices has rectified most situations, as is the case with any farming practice where stewardship of the land is management-based (i.e., managing soil pH, insect pests and plant disease, weeds, water, levels of macro- and micronutrients, crops, microclimate, and harvesting methods).

The use of biosolids also can be valuable where lands have been mismanaged. It is commonly known that lands disturbed by mining can be reclaimed through effective use of biosolids. More recently, it has been determined that arid lands "devastated by overgrazing" can be recovered considerably with the use of biosolids. Also, studies now underway suggest that lead in soils from paint and automotive exhausts can be bound by the application of biosolids, making the lead less available to children who eat soil.

Science continues to show new uses for waste resources such as biosolids. All field research to date leads to the conclusion that the agronomic use of high-quality biosolids is sustainable and safe. Thus, it seems prudent to make informed use of biosolids as a highly recyclable resource.

Soil pH

Q: Why wasn't soil pH management included as a biosolids land application requirement in the Part 503 rule, especially given that it was a requirement in the former Part 257 rule?

A: The Part 503 rule was designed to be self-implementing and to cover all practices that involve the use of biosolids. Hence, the plant uptake values used to establish the regulatory limits for land application pathways in the Part 503 rule included data from acidic, neutral, and alkaline soils (i.e., pH <6.0 to >7.0).

It is possible that some sensitive plant species may exhibit symptoms of phytotoxicity when grown in soils amended with biosolids containing high concentrations of zinc, nickel, or copper at low soil pH and near the cumulative pollutant loading rates. At the recommendation of experts who assisted EPA, however, the Agency decided that it would be ill-advised to require pH control. The rationale is that many other factors offer protection against harmful effects from metals, such as the soil-plant barrier and other elements present in biosolids that bind pollutants (as discussed more fully in Chapter 3). In addition, in soils where the pH is below 5.5, not only do high levels of biosolids pollutants have the potential to become toxic to plants, but so do the naturally occurring soil metals, such as aluminum and manganese. Given the potential toxicity from these widespread soil metals, most agronomic plants do not grow well at very low pH. Under these conditions, farmers and home gardeners would need to add lime to soils to obtain a reasonable yield of edible food, regardless of whether biosolids are being used for their soil conditioning and fertilizing value.

"Time-Bomb" Theory

Q: What is the so-called time-bomb theory?

A: The time-bomb theory involves the belief that the organic matter present in biosolids is primarily what binds metals and thus reduces their bioavailability. The basic premise of the theory is that as soon as the organic matter degrades, the metals will become more bioavailable.

Q: Do pollutants in biosolids become more bioavailable after having been added to soil and after the organic matter in biosolids has decayed?

A: Evidence does not support this claim. Biosolids are typically about 50 percent organic and 50 percent inorganic. The experts who assisted EPA in the risk assessments cited evidence that much of the binding that occurs is attributable to the inorganic part of biosolids, namely from oxides of iron, aluminum, and manganese, and also from phosphate compounds. This binding effect is so strong that it persists after the biosolids have been applied to soils, except in very low pH situations as described in the soil pH Question and Answer section above. Examination of field data, gathered as many as 60 to 100 years after the use of irrigation wastewater and/or biosolids on soils, supports the concept of binding by the inorganic fraction of the biosolids and indicates that binding of the metals persists when the biosolids organic matter has had time to degrade.

A few scientists question this belief, but experimental data exist to support this inorganic binding concept, and experimental data do not exist to refute it. A leading proponent (Beckett et al., 1979) of the time-bomb theory who attempted to prove it, dropped his advocacy of the theory after conducting a series of experiments that failed to provide support (Johnson et al., 1983).

Q: Is there a direct relationship between the amount of biosolids metals that have been applied to soil and the amount of metals absorbed by plants?

A: No. Metals are bound by the biosolids matrix, which reduces their phytoavailability. As an example, assume that the total amount of a metal in biosolids does not change. As more of the biosolids are added to soils, the total amount of that metal pollutant present in the soil/biosolids mixture increases. However, the metal phytoavailability (plant uptake of that metal) does not proportionately increase due to the simultaneous increase of the inorganic part of the biosolids matrix in the soil/biosolids mixture. This increasing inorganic matrix strongly binds the metal, and competes with and limits the ability of a plant to absorb the metal. This issue is discussed more fully in Chapter 3.

Q: Does the Part 503 rule take into account that reduced bioavailability is associated with the use of biosolids?

A: No and yes. No, because EPA did not adjust Part 503 pollutant limits based on bioavailability. Yes, because the Agency did, however, use biosolids field data on plant uptake of pollutants to the extent possible, which invariably showed there to be less uptake (i.e., a reduced uptake slope) than if only metal salts were added to soils. Nonetheless, in the Part 503 risk assessments the Agency assumed that the plant uptake slope was linear. Given that in fact the uptake slope is less than linear, the final rule overestimates the phytoavailability of biosolids metals.

Q: In the risk assessments for the final rule, why weren't more plant uptake data used from experiments in which metals salts were added to soils?

A: Experts determined that metal salt data are not relevant to biosolids because metals are bound by the biosolids matrix during generation and processing of the biosolids. This binding does not occur when metal salts are added to soils. Data from metal salt studies were used only when no other data were available.

Phytotoxicity

Q: What is phytotoxicity as it relates to the Part 503 biosolids rule?

A: Phytotoxicity refers to the retardation in plant growth that can be caused by plant toxicity from metal pollutants in biosolids. The Part 503 pollutant limits were set to preclude phytotoxicity.

Q: Is it true that the risk assessments assumed that phytotoxicity has not occurred unless there is a 50 percent reduction in plant growth?

A: No. EPA used several procedures to determine the concentration of the potentially phytotoxic metals (zinc, copper, nickel, and chromium) in plants that result in phytotoxicity. A 50-percent retardation in plant growth of young corn and bean seedling was involved in only one of the alternative approaches used to establish phytotoxicity limits. Even in this approach, other levels of growth retardation were evaluated (i.e., 8-, 10-, and 25-percent plant growth retardation), although the 50-percent level was used. In another approach, data on plant tissue concentrations associated with yield reduction were taken from the available literature to define phytotoxic effects for sensitive crops, such as lettuce. These sensitive plant species are more susceptible than corn to metal-induced inhibition of growth (phytotoxicity). These data were used to develop plant tissue levels of metals associated with first detectable yield reductions, which were identified as phytotoxicity thresholds. These data, in turn, were used, in conjunction with data on plant uptake of metals, to identify metals application rates that would exceed the phytotoxicity threshold. The more restrictive of the values determined by these approaches was chosen as the pollutant limit for phytotoxicity in the risk assessment. These procedures are described in more detail in Chapters 3 and 4.

Q: Why is it difficult to set a phytotoxicity limit?

A: The problem facing the experts who assisted EPA with the phytotoxicity risk assessment was that many things can cause phytotoxicity, as well as apparent phytotoxicity, during the growth of seedlings. Furthermore, the retardations in early vegetative growth that often occur may or may not be associated with harvestable crop yield reduction. Factors that can cause phytotoxicity or apparent phytotoxicity include: cold weather; insoluble salts, low nutrients, high nutrients, and high metals in soils; pesticides and herbicides; and ozone and other impurities in the air. In carefully conducted field tests, yields commonly vary by as much as 15 to 25 percent with good fertility and management. An ultimate yield reduction of at least that much must be attained to support a determination that the reduction was significant, especially over several seasons and with various crops being grown.

Synergistic Effects of Biosolids Metals

Q: Is there evidence of any synergistic (additive or more than additive) negative effects associated with metals in soils amended with biosolids?

A: The only evidence of synergy has been observed in soils freshly amended with metal salts (not biosolids). EPA is not aware of any evidence to suggest that synergy has occurred even in pot studies where metal-rich biosolids were used as the soil amendment.

Q: Is there any evidence of positive interactive effects from biosolids metals?

A: Yes. When biosolids are used as a source of fertilizer, there is a built-in protection for people who eat crops that may accumulate metals, including cadmium. This is because invariably biosolids also contain iron, calcium, and zinc, which are absorbed into the edible portion of the plant. The presence of these other three substances in the crop consumed reduces the potential for cadmium absorption into a person's intestines and body, and hence reduces the potential health risk from cadmium.

Use of Data With Zero or Negative Plant Uptake Slopes

Q: Were data used from experiments that had a zero or negative plant uptake slope?

A: Yes, but such data were given a protective minimum value; that is, when the slope was negative or zero, a minimum, slightly positive value of 0.001 was used. This procedure allowed such data to be used in determining plant uptake slopes. This minimum value, however, overestimates uptake to some degree.

Pathogens

Q: Is the pathogen operational standard risk-based?

A: No. Risk assessment methodologies had not been developed sufficiently to make such calculations. Instead, the pathogen operational standard, which is technology-based, requires that pathogens in biosolids be reduced to below detectable levels or to levels that, when coupled with crop harvesting and site access restrictions, have been demonstrated to be protective of public health and the environment.

Determining "Acceptable" Concentrations of Biosolids Pollutants in Soils

Q: The biosolids risk assessments were designed to determine acceptable pollutant application rates or pollutant concentrations in biosolids. Based on the risk assessment results and the Part 503 pollutant limits, what are the "acceptable" concentrations of biosolids pollutants in soils? How are these soil concentrations derived?

A: Table 18 presents acceptable concentrations of biosolids pollutants in soils (Column 6). The following equation shows how soil concentrations (RLC) can be derived from the biosolids risk assessment pollutant limits (RPs), which are equivalent to the Part 503 cumulative pollutant loading rate (CPLR) limits.

$$\frac{RP}{MS \times 10^{-9}} = RLC\ (in\ \mu g/g) \times 10 = RLC\ (in\ mg/kg)$$

where:

RP = cumulative application rate of pollutant in biosolids (kg/ha)

MS = 2×10^9 g/ha (assumed mass of soil in upper 15 cm)

10^{-9} = conversion factor (kg/μg)

10 = conversion of RLC from μg/g to mg/kg

RLC = allowed soil concentration of pollutant from biosolids (μg/g, or mg/kg)

For copper, the soil concentration RLC would be:

$$\frac{RP}{MS \times 10^{-9}} = \frac{1{,}500}{20} = 75\ (RLC,\ in\ \mu g/g) \times 10 = 750\ (RLC,\ in\ mg/kg)$$

The copper pollutant concentration in soil from biosolids (RLC) calculated from the above equation is further adjusted by adding in the background median (50th percentile) soil concentration for the pollutant in question, in this case for copper (Holmgren et al., 1993), to determine the "acceptable" concentration for biosolids pollutants in soils:

RLC for copper of 750 mg/kg in biosolids + median background soil concentration for copper of 19 mg/kg = an "acceptable" concentration for copper of 769 mg/kg in the soil-biosolids mixture

Table 18

Acceptable Soil Concentrations for Metals Derived from the Biosolids Risk Assessment

(1)	(2)	(3)	(4)	(5)	(6)
Pollutant	Table 3 in Part 503	Table 2 in Part 503	CPLRs as Soil Concentration Limits (mg/kg-soil)[a]	50th Percentile Background Soil Concentration (mg/kg-soil)	Risk Assessment Acceptable Soil Concentration (mg/kg-soil)
	Pollutant Concentration Limits (mg/kg-biosolids)	Cumulative Loading Rates (CPLRs) (kg/ha-land)			
Arsenic	41	41	20.5	3[b]	23.5
Cadmium		39	19.5	0.2[c]	19.7
Chromium[d]					
Copper	1,500	1,500	750	19[c]	769
Lead	300	300	150	11[c]	161
Mercury	17	17	8.5	0.1[e]	8.6
Molybdenum[f]					
Nickel	420	420	210	18[c]	228
Selenium	100	100	50	0.21[g]	50.21
Zinc	2,800	2,800	1,400	54[c]	1,454

[a]Assumes a final 1:1 ratio of biosolids:soil in the upper 15 cm (6 in.) plow layer.

[b]Baxter et al., 1983

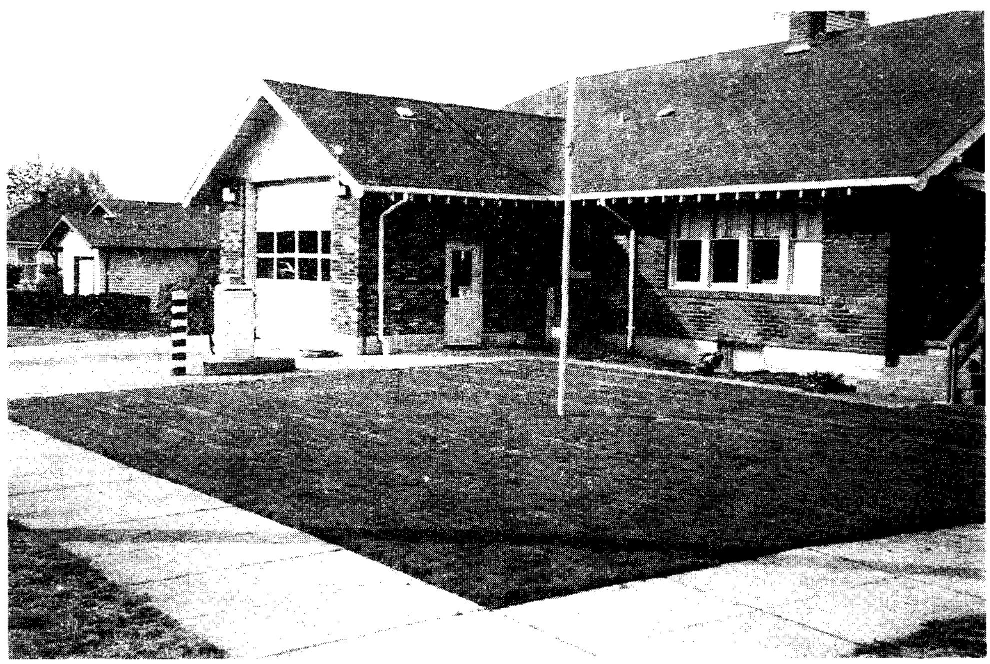
[c]Holmgren et al., 1993

[d]To be deleted from the Part 503 rule based on a court decision (see Section Q, Chapter 3).

[e]U.S.G.S., 1970

[f]Currently not in the Part 503 rule; subject to re-evaluation (see Section P, Chapter 2).

[g]Cappon, 1984



The top photograph shows biosolids being used as a fertilizer and soil conditioner on a residential lawn. The lush lawn achieved as a result of using biosolids is shown in the bottom photograph. The benefits of using biosolids can be substantial. The results of the biosolids risk assessment process tell us how to recycle biosolids safely.

Q: Should people compare soil cleanup standards with Part 503 CPLR limits (Column 3 in Table 18) or Part 503 pollutant concentration limits (Column 2 in Table 18)? (Note that the relationship between Part 503 CPLRs and pollutant concentration limits is discussed in Chapter 5.)

A: No. Instead, soil cleanup standards should be compared with "acceptable" soil concentration values, as derived from the biosolids risk assessments (Column 6 in Table 18).

Q: How do these acceptable soil concentrations compare with state and other EPA cleanup standards for soils?

A: In most cases, the acceptable soil concentrations calculated from the Part 503 risk assessments are greater than those for state and other federal EPA programs; however, some of the state and other federal acceptable soil concentrations are greater. Almost no set of soil concentrations agree. Furthermore, most of the other sets of numbers are only preliminary (numbers are not finalized) and have been calculated for other purposes (e.g., in connection with efforts to cleanup soils contaminated by hazardous wastes). Some of the concentration levels have been calculated based on best available technology and others are based on risk assessments using different data sets, approaches, assumptions, models, and/or pathways than were used in the Part 503 risk assessments.