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A Guide to the Biosolids Risk Assessments for the EPA Part 503 Rule

U.S. Environmental Protection Agency
Office of Wastewater Management
Washington, DC

Notice

Foreword

The U.S. Environmental Protection Agency's (EPA's) Part 503 rule provides comprehensive requirements for the use or disposal of biosolids generated during the process of treating municipal wastewater. Formulation of the final rule benefitted greatly from the input provided by the regulated and environmental communities, and especially the group of scientific experts who worked closely with EPA in revising the proposed rule. The final rule is the result of a very effective combination of public comment, scientific risk assessment, and informed risk management.

The Part 503 rule underwent an extensive multi-pathway risk assessment for evaluating and setting limits to manage pollutants in biosolids. The scientific approach used in developing the Part 503 requirements attempted to determine an acceptable level of pollutants that could be added to the environment in biosolids and differs from policy-based approaches used in some other countries.

This "Guide to the Part 503 Risk Assessment" has been prepared to help the public, wastewater treatment authorities, state regulators, and scientists better understand the risk assessment process. It helps explain many of the steps that were taken over a nine-year period to develop the rule, many of the issues that arose, how they were resolved, and how the risk assessment process was used in deriving the requirements in the final rule. The issues discussed in greater detail in the Guide are reflective of the questions that have been asked most often and are provided as examples to increase the reader's understanding of the nature and conservativeness of the Part 503's risk assessment process.

The Guide emphasizes the importance of collecting relevant data and using appropriate models and assumptions (field-verified whenever possible) in the establishment of pollutant limits and management practices that protect public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids. The Guide shows that the Part 503 rule is not only conservative and protective, but also realistically implementable.

Michael B. Cook, Director
Office of Wastewater Management

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This document represents the efforts of several individuals. Gratitude is extended to each person involved in preparing and reviewing this guide.

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Chapter 1

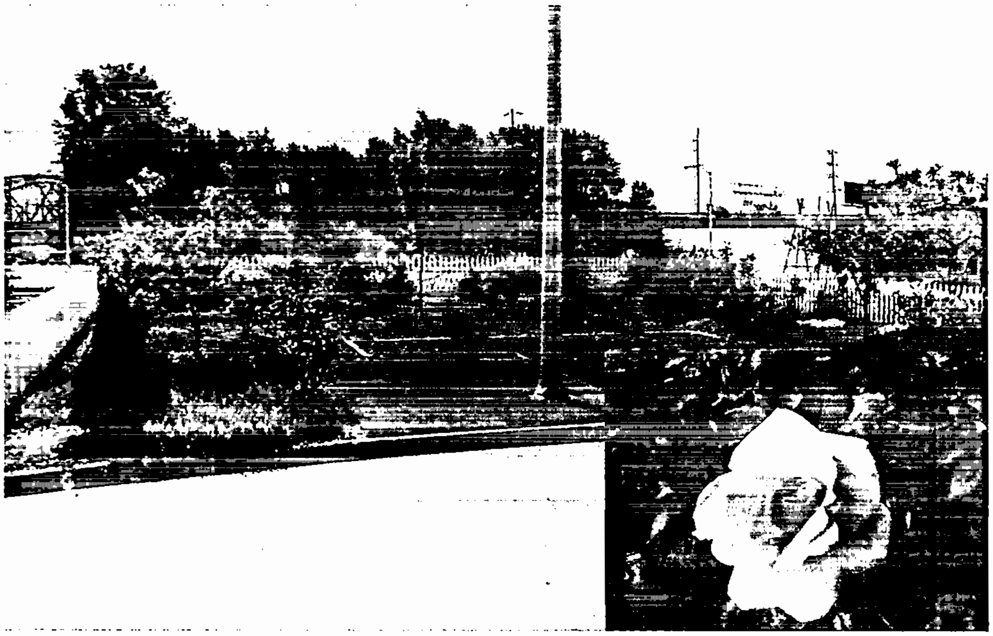
Overview

The U.S. Environmental Protection Agency (EPA) has developed a comprehensive, risk-based rule to protect public health and the environment from reasonably anticipated adverse effects of pollutants that may be present in biosolids (sewage sludge) that are used or disposed. Commonly known as the Part 503 rule, the regulation (40 CFR Part 503) was published in the *Federal Register* on February 19, 1993. Much of the rule was based on the results of risk assessments that were scientifically conducted to identify what, if any, risks were associated with the use or disposal of biosolids. Those parts of the rule that were not based on risk assessment were based on performance- or technology-based standards or on management, monitoring, and recordkeeping practices shown to protect human health and the environment.

This guide has been prepared to provide an understanding of the risk assessment process that was conducted as a basis for the Part 503 biosolids rule. The guide illustrates how extensive the process was and how it has resulted in a reasonable and protective rule. The document takes the reader through the multiple-step risk assessment process. Specifically, this guidance document:

- Describes the risk assessment procedures used to develop the Part 503 pollutant limits.
- Provides a historical accounting and discussion of the numerous steps taken to develop the risk assessments.
- Discusses the issues that arose during the risk assessment process and explains how these issues were resolved.
- Explains the assumptions and policy decisions involved in the selection and use of risk assessment data and models and the development of the Part 503 rule.
- Describes the conservativeness of the Part 503 rule and the risk assessment process on which it is based, providing reasons why the Agency believes that the pollutant limits set in the Part 503 rule are protective of public health and the environment and why more restrictive limits are not warranted.
- Addresses commonly asked questions about the risk assessments.

While this guide focuses primarily on the risk assessment conducted for land application of biosolids, it also highlights some of the key features of the biosolids



Safely recycled biosolids can result in healthy lawns and shrubbery, beautiful flowers, and nutritious food.

surface disposal and incineration risk assessments. The guide also briefly discusses the Part 503 non-risk-based requirements. For more detail on the Part 503 risk assessments, consult the appropriate *Technical Support Documents* (U.S. EPA, 1992a, 1992b, 1992c).

The reader will notice that throughout this document sewage sludge is referred to as biosolids. ***Biosolids*** are the primarily organic solid product yielded by municipal wastewater treatment processes that can be beneficially recycled (whether or not they are currently being recycled). The term biosolids is used in this document to emphasize the beneficial nature of this valuable, recyclable resource (i.e., the use of the nutrients and organic matter in biosolids as a fertilizer or soil conditioner). Also, it is important to point out that while many of the substances found in biosolids are called pollutants throughout this document, many also are beneficial elements that are essential for the growth of plants and animals. The term pollutants has been used as a result of language in the Clean Water Act.

Basis for the Part 503 Risk Assessments

Based on the best scientific data available, established EPA risk guidelines, and the scientific judgment of experts, an extensive risk assessment was conducted for each of the following biosolids use or disposal practices:

- Land application
- Surface disposal
- Incineration

The general process used for conducting the Part 503 risk assessments was based on well-established procedures described by the National Academy of Sciences (NAS, 1983). The procedures are listed in Box 1. Using this process, EPA analyzed risks to humans, animals, plants, and soil organisms from exposure to

Box 1
The Four Steps in the Part 503 Risk Assessments

The risk assessments for biosolids followed these four basic steps:

- ***Hazard identification:*** **Can this pollutant harm human health and/or the environment?** Scientists evaluated available studies on the toxicity (harmful effects) of the pollutant being assessed. For example, the hazard identification for biosolids indicated that cadmium does not appear to adversely impact the growth of plants (i.e., does not cause phytotoxicity) but could impact human health via adverse affects on the kidney and other systems if it is present in sufficiently high quantities.
- ***Exposure assessment*:** **Who is exposed, how do they become exposed, and how much exposure occurs?** Highly exposed individuals (HEI) were identified and their exposure to pollutants in biosolids were evaluated via relevant pathways of exposure. HEIs included humans, large and small animals, plants, and small organisms. A total of 14 pathways of exposure were evaluated for land-applied biosolids, 2 for surface disposed biosolids, and 1 for incinerated biosolids. The movement of biosolids pollutants through the environment was modeled (using mathematical equations). Many factors influence the actual exposure. For example, organisms often respond differently depending on whether they encounter a pollutant by inhaling it, eating or drinking it, or absorbing it through the skin, and also on where the pollutant goes after it enters the body (e.g., Does it enter the liver via the bloodstream, remaining there to cause liver damage? Or does it move from the liver to another, more sensitive organ where damage might occur?). In addition, an organism's response often differs depending on its nutritional status (e.g., levels of nutrients like iron, calcium, and magnesium can protect against cadmium absorption and retention in the human body), and whether it was exposed to a pollutant for long or short periods.
- ***Dose-response evaluation*:** **If a person, animal, or plant is exposed to this pollutant, what happens?** This part of the risk assessment is based on the likelihood of a person, animal, or plant developing a particular disease as the amount (dose) and exposure to a pollutant increases. Such dose-response relationships have been established based on years of carefully conducted toxicological experiments. The biosolids risk assessments used the following EPA toxicity factors, whenever available:

  Risk reference doses (RfDs)—daily intake of a chemical that, during an entire lifetime, appears to be without appreciable risk on the basis of all known facts at the time.

  Cancer potency values (q_1*s)—conservative indication of the likelihood of a chemical inducing or causing cancer during the lifetime of a continuously exposed individual.
- ***Risk characterization:*** **What is the likelihood of an adverse effect in the population exposed to a pollutant under the conditions studied?** This step involves putting the information together from the first three steps. Risk is calculated as:

  Risk = Hazard x Exposure

  Hazard refers to the toxicity of a substance determined during the hazard identification and dose-response evaluation, and exposure is determined through the exposure assessment.

  Generally, three types of risks are identified:

  – risks to individuals
  – risks to the general population
  – risks to highly exposed or highly sensitive subgroups

  In addition, risk characterization addresses uncertainties associated with some of the information used (e.g., if only studies of animals were available to assess risks to humans, a "safety factor" might be used that multiplies the results by a factor of 10, 100, or 1,000 to adequately protect humans).

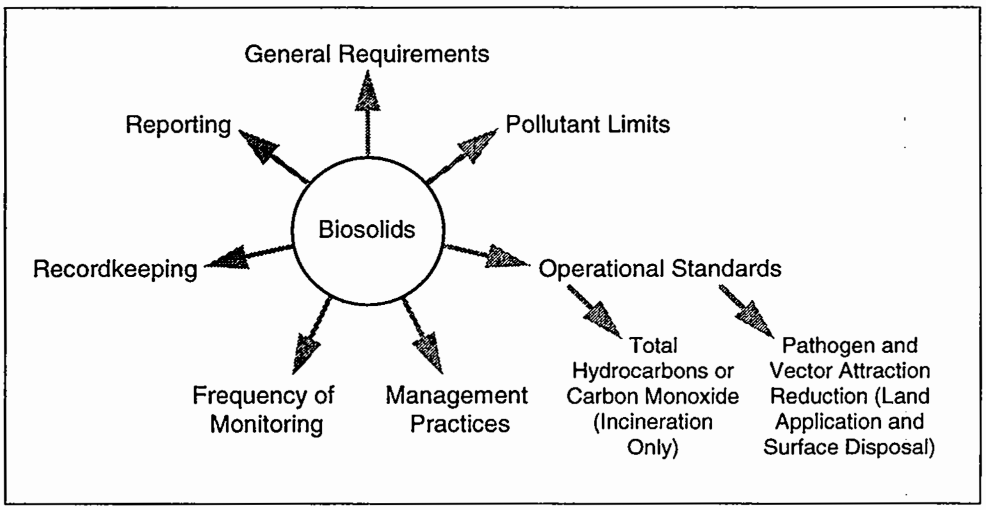
pollutants in biosolids through 14 different pathways (e.g., food, water, soil, air) for land-applied biosolids, 2 exposure pathways for surface disposal of biosolids, and 1 exposure pathway for incineration of biosolids. The process of selecting and managing the data, models, assumptions, and approaches used to conduct the risk assessments for the Part 503 rule underwent extensive refinement during the 7 years in which the final rule was formulated.

The Part 503 rule was developed with the realization that the use or disposal of biosolids may result in changes in the environment, as does the use of other fertilizers, the construction of buildings and other structures, and many other aspects of human activity. The biosolids risk assessment process provided a scientific basis for determining acceptable environmental change when biosolids are used or disposed. Acceptable change means that even though changes have occurred as a result of the use or disposal of biosolids (e.g., increases in nutrients and organic matter as well as pollutants), public health and the environment are still protected from reasonably anticipated adverse effects of pollutants in biosolids. This approach is quite different than the policy-driven approach followed by some European countries and Canadian provinces. Those policy-driven approaches allow only small, incremental increases of pollutants from the use or disposal of biosolids over background levels of pollutants already in the environment; for example, metal concentrations may not exceed either the 95th percentile of background soil concentrations, or a specified low concentration level assuming that 100 percent of a person's diet is consumed from biosolids-amended soils under poor management conditions. This latter approach often is not associated with an attempt to determine the extent or acceptability of environmental change.

In addition to using scientific risk assessment methods to identify acceptable environmental change, EPA made policy decisions when necessary to establish pollutant limits for biosolids that protect highly exposed individuals. EPA also relied on best professional judgment based on research and operational data to determine appropriate site restrictions (e.g., requiring waiting periods before harvesting crops grown on soils where biosolids have been applied) and other requirements necessary to ensure the safe use or disposal of biosolids. The end result was the Part 503 rule, which imposes general requirements; pollutant limits; management practices; opera-

Figure 1

Elements of the Part 503 Rule



tional standards (such as technology-based requirements for pathogen reduction and vector control); and frequency of monitoring, recordkeeping, and reporting requirements. These elements of the Part 503 rule are presented graphically in Figure 1.

The basic approach used in the biosolids risk assessments was to identify exposures to highly exposed individuals from pollutants of concern through specific exposure pathways. This approach involved using a combination of "high-end" (conservative) and "mid-range" (average) values to provide conservative protection for highly exposed individuals. This guide provides an explanation of this approach, including how the risk assessment defined highly exposed individuals, why "highly exposed" rather than "most exposed" individuals were ultimately used in the risk assessments, and how the risk-based pollutant limits protect these highly exposed individuals.

The choice of toxicity data, models, and approaches used; the key assumptions and policy decisions made; and the management of data all had important impacts on the risk assessment results. This guide addresses each of these elements, including discussions of science-based and policy-based decisions. Strengths and weaknesses of the risk assessment process also are indicated. One pollutant/pathway analysis is described in detail to illustrate how the various factors involved in the biosolids risk assessments were used to develop pollutant limits.

In conclusion, the best scientific data and talent were assembled and used for developing the final Part 503 rule to ensure that it was based on carefully reasoned science and policy decisions. This comprehensive process resulted in pollutant limits, management practices, and other provisions that protect public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids.

Document Organization

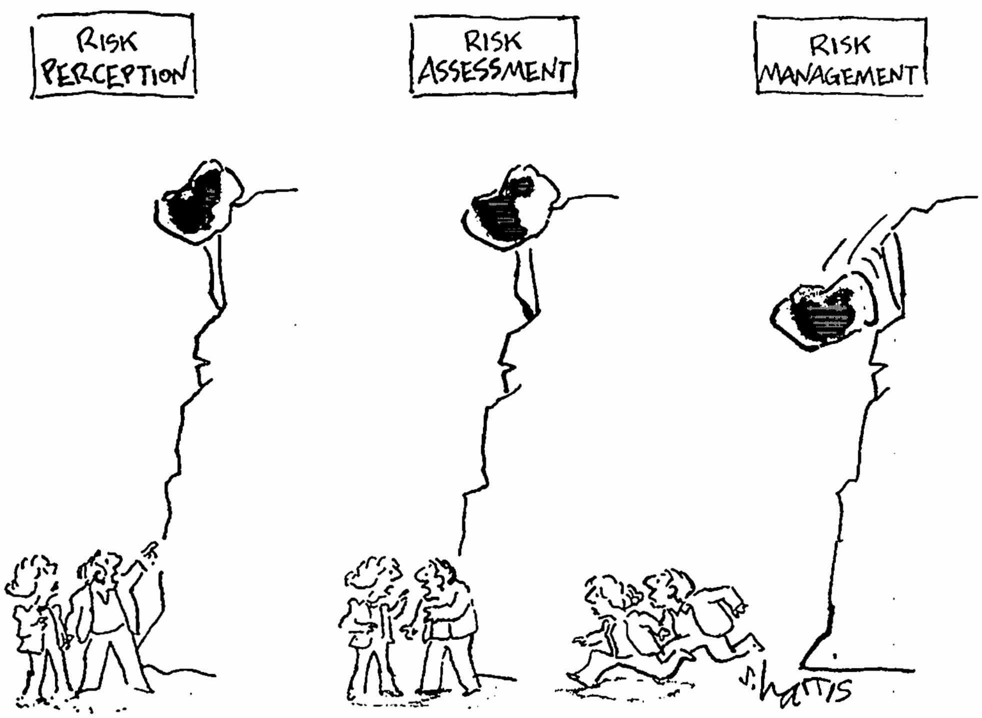
Several sections of this guide provide summaries of the biosolids risk assessment process or key aspects of the process for readers who may want to gain an overall perspective prior to delving into more detailed explanations, also included in this guide. These summary sections include: synopses of the risk assessment process at the beginning and end of Chapter 5; overviews of the many steps involved in the process in Table 1 and Figure 2 (see Chapter 2); a summary of the issues raised during the risk assessments and the resolution of these issues in Table 9 (see Chapter 3); a listing and description of all the parameters used in the risk assessment for land application in Appendices A and B; and a summary at the end of Chapter 4 on the high degree of protectiveness afforded by the Part 503 rule's pollutant limits. Greater detail on the issues raised, their resolution, the determination of pollutant limits, and the development of the Part 503 rule is provided in Chapters 2, 3, 4, and 5, while answers to commonly asked questions are given in Chapter 6.

To help the reader track discussions this guide, letters have been assigned to each individual step and issue listed, as shown in Tables 1 and 9 and in the text of Chapters 2 and 3.

The guide's additional chapters include:

- Chapter 2 describes the extensive process that EPA followed to develop and conduct the risk assessments for biosolids. This description includes a historical listing and discussion of each of the important steps in developing the risk assessments.
- Chapter 3 examines some of the key issues that were raised during the risk assessment process and development of the Part 503 rule and describes how EPA resolved these issues.

- Chapter 4 describes how the risk assessments were conducted, including how scientific data, assumptions, policy decisions, and methods were used. The process of developing the algorithms (i.e., the mathematical equations) used to calculate pollutant limits is discussed, including the different types of parameters used in the algorithms and the values assigned to these parameters. Several example calculations are given for various pollutants and exposure pathways, including a detailed example (for cadmium in Pathway 2 of the land application risk assessment) that explores how the parameters relate to each other and examines the influence of the parameters (both individually and collectively) on the biosolids pollutant limits.
- Chapter 5 summarizes the risk assessment process and discusses how the risk assessment results were used to develop pollutant limits in the final rule. This chapter also includes brief discussions of how different provisions of the Part 503 rule are based on, or support, the biosolids risk assessments. It also provides descriptions of Part 503 provisions that are not risk-based.
- Chapter 6 addresses commonly asked questions about the biosolids risk assessments.
- The Appendices provide additional information used in developing the biosolids risk assessments and Part 503 rule.



Chapter 2

The Risk Assessment Process for the Part 503 Biosolids Rule

The biosolids risk assessment process involved selecting representative pathways by which humans, animals, and plants could become exposed to pollutants of concern that can be present in biosolids. Data on exposures associated with each pathway were combined with data on allowable doses of a pollutant to develop a limit for that pollutant. The process by which pollutants of concern and appropriate exposure pathways were selected, as well as the key scientific analyses, deliberations, and policy decisions involved in the biosolids risk assessment process, are summarized in Table 1 and outlined in Figure 2. The large letters to the left of each section heading in the text indicate when in the risk assessment process the step occurred. These letters also are shown in Table 1 (this chapter) and throughout Chapter 3.

Initial List of Pollutants

Step A Biosolids Task Force Study

The biosolids risk assessment process began in 1982 when the Intra-Agency Biosolids Task Force was established to assess biosolids management approaches nationwide, evaluate existing regulatory activities, and identify data needs. In 1983 the task force recommended that a comprehensive regulatory program be developed by EPA under the authority of Section 405 of the Clean Water Act and other environmental statutes. The Agency identified several key components for such a program, including:

- Determining pollutants of concern
- Developing risk assessment methodologies
- Determining appropriate risk-based pollutant limits and management practices
- Issuing comprehensive, risk-based regulations (i.e., the Part 503 rule)

Table 1
The Biosolids Risk Assessment and Rule Development Process

Developmental Step	Mechanism Used	Key Features
Step A Intra-Agency Sludge (Biosolids) Task Force Study	Team within EPA worked directly under the Assistant Administrators to develop a biosolids management and regulatory plan	The Task Force worked intensively to develop a comprehensive plan with input from all impacted groups
Step B Identification of 200 pollutants	EPA list	Pollutants placed on list based on expected toxicity
Step C Selection of 50 pollutants from 200 for further study	Four panels of experts met to recommend pollutants for land application (LA), surface disposal (SD), incineration (I), and ocean disposal (OD) of biosolids	Selection based on best professional judgment; likelihood that environmental and human exposure will occur via LA, SD, I, or OD; known pollutant toxicity via relevant exposure pathways; and availability of exposure and toxicity data
Step D Initial identification of exposure pathways for each use or disposal practice	Expert panels identified appropriate exposure pathways for each pollutant	Selection based on best professional judgment
Step E Profile assessment and hazard indices developed for 50 pollutants	Hazard indices developed with the assistance of a contractor	Profile assessment and hazard indices based on: —pollutant toxicity —pollutant concentration in soil, water, air, food, and/or biosolids —worst-case data —extreme exposure for most exposed individual (MEI)
Step F Selection of pollutants for detailed risk assessment	Environmental profiles developed based on results of hazard indices	If hazard indices were 1 or greater, pollutants were considered for detailed risk assessment and regulation
Step G Risk assessment methodology review	Review by EPA Science Advisory Board (SAB)	Reviewed algorithms, exposure routes, assumptions
Step H Risk assessments for LA, SD, I, OD for proposed Part 503 rule	EPA with contractor assistance	—MEI —conservative models and assumptions —worst-case data—e.g., salt data for plant uptake, use of 98th percentile for non-agricultural (ag) LA
Step I Published proposed Part 503 rule for comment	Published in the *Federal Register*, February 6, 1989, for public comment and external review	5,500 pages of comments received; LA and SD peer review; incineration review by SAB
Step J Risk assessments for final Part 503 rule revised based on comments; expert advisors continue reviews	EPA/advisors met to review and modify data selection, models used, data management	—changed from MEI to highly exposed individual (HEI) —changed models —used field data —developed data management protocol —combined distributed-and-marketed, ag, and non-ag LA data

(Continued)

Table 1 (Continued)

Developmental Step	Mechanism Used	Key Features
Step K National Sewage Sludge Survey (NSSS)	$1.2 million study involving biosolids sample collection and analyses, and questionnaire	Statistically based groups of publicly owned treatment works (POTWs) (totaling 180) for biosolids sampling and analysis, and additional information from 475 POTWs for data on use and disposal practices, costs, impacts of the proposed rule, etc. Information used to evaluate: —current pollutant concentrations in biosolids (412 analytes) —current biosolids use or disposal practices —impact of rule on current practices
Step L Published NSSS results and proposed changes for final Part 503 rule for comment	Published in the *Federal Register*, November 9, 1990, for public comment and external review	Comments received from 153 respondents; Proposed alternate pollutant limit concept for "clean" biosolids
Step M Revised risk assessments for final Part 503 rule	EPA with assistance of team of experts and contractor	Areas of change included: —protecting HEI rather than MEI —greater emphasis on field study data —refined models, data, assumptions —use of NSSS results —revised pathways
Step N Internal EPA review of draft final Part 503 rule	All EPA offices reviewed rule and identified issues of concern	Major issues identified: —biosolids binding —phytotoxicity —concerns about ecological risk —nitrogen management issues Major risk management decisions: —use of 99th percentile concentrations from NSSS —use of agronomic rate for nitrogen —"clean" biosolids emphasis
Step O Published final Part 503 rule	Published final rule in *Federal Register*, February 19, 1993	40 CFR Part 503 with subparts on: general provisions, land application, surface disposal, pathogens and vector attraction reduction, and incineration
Step P Amendment to rule to address lawsuits and EPA revisions to the final Part 503 rule	Published in *Federal Register*, February 24, 1994	Issues: —land application: molybdenum, cadmium, chromium pollutant limits; annual pollutant loading rates (APLR); selenium —incineration: THC vs. carbon monoxide (CO) monitoring Amendments for: certain molybdenum pollutant limits for land application; THC/CO—continuous emission monitoring

(Continued)

Table 1 (Continued)

Developmental Step	Mechanism Used	Key Features
Step Q Rulings on court cases	Remanded portions of the Part 503 rule for modification or further justification; issues included: —land application chromium limits —99th-percentile land application limit for chromium and selenium —special land application limits for heat-dried biosolids —special selenium limits for land application on public contact sites with a low potential for occupancy	Undergoing review by EPA as of August 10, 1995

Step B Identification of 200 Pollutants

The process of identifying pollutants of concern began in 1984, when EPA developed for possible consideration a list of approximately 200 pollutants based on the following types of available data:

- Human exposure and health effects
- Plant uptake of pollutants
- Phytotoxicity (adverse effects on plants)
- Effects in domestic animals and wildlife
- Effects in aquatic organisms
- Frequency of pollutant occurrence in biosolids

Step C Selection of Pollutants by Scientific Experts for Further Consideration From the List of 200 Pollutants

In 1984 the Agency submitted its initial list of 200 pollutants for review by four panels of experts covering land application, surface disposal, incineration, and ocean disposal of biosolids. The panels recommended that approximately 50 of the 200 pollutants listed be studied further. The recommended list of pollutants was based on:

- The probability that the pollutant would be toxic when exposure occurred through use or disposal of biosolids.
- The likelihood that human and environmental exposure to the pollutant would occur via land application, surface disposal, incineration, or ocean disposal of biosolids.
- The availability of toxicity and exposure data for the pollutants.
- Best professional judgment.

Figure 2
Steps in the Development of the Part 503 Risk Assessment and Rule

1982	EPA establishes Intra-Agency Sludge (Biosolids) Task Force
1982	EPA publishes results of the "40 Cities Study"
1983	EPA Biosolids Task Force presents recommendations, including need for comprehensive regulatory program
March 1984	EPA develops list of 200 pollutants
May 1984	Experts select 50 pollutants for further study and identify exposure pathways
1984-85	EPA conducts worst-case hazard profile assessment
1985	Science Advisory Board approves general risk assessment methodology, including algorithms, exposure routes, and assumptions, but does not check data selection
1986-88	EPA conducts risk assessments protecting MEI, using worst-case data, assumptions, and models
1988	The ocean dumping option is dropped from the rule due to the Ocean Disposal Ban Act of 1988
Feb. 1989	EPA publishes proposed Part 503 rule for comment
July 1989	Peer review of Part 503 is conducted; report points out scientific reasons why pollutant limits in proposed rule are overly stringent and recommends that more realistic limits be developed
1988-89	EPA conducts National Sewage Sludge Survey (NSSS)
Jan. 1990	A team of experts is established to assist EPA with revision of rule
1990	EPA selects new data, assumptions, and models to use in revising risk assessments
Nov. 1990	EPA publishes NSSS results and possible changes to the proposed rule for public comment
1990-92	EPA conducts revised risk assessments protecting HEI, using field data, and modified assumptions and models; incorporates comments in NSSS notice
1992	Internal Agency-wide review of Part 503 rule by EPA completed
Nov. 1992	Administrator approves final Part 503 rule
Feb. 1993	EPA publishes final Part 503 rule and notices of availability of supporting documents
Feb. 1994	EPA publishes an amendment to Part 503 rule
1993-95	EPA identifies 32 additional biosolids pollutants for regulatory consideration by year 2000. Further analysis may narrow the focus for consideration primarily to dioxins, furans, and PCBs
1994-95	EPA considers 4 provisions of Part 503 rule remanded by court for modification or additional justification
1994-95	EPA begins ecological and field monitoring studies on specific issues identified for additional investigation during development of Part 503 rule
Nov. 1995	Additional ("Round 2") list of biosolids pollutants developed for regulatory consideration by the year 2000
Dec. 1999	Proposed "Round 2" amended regulation
Dec. 2001	Final "Round 2" amended regulation

Hazard Profiles of the 50 Pollutants Selected for Further Evaluation

Step D Initial Identification of Exposure Pathways for Hazard Assessment

A preliminary exposure assessment was conducted to develop "environmental profiles" for each of the 50 pollutants. The exposure assessments were based on "pathways" by which an individual (person, animal, or plant) could be exposed to a pollutant in biosolids. To determine appropriate exposure pathways, EPA adapted existing exposure models and developed new ones to represent the movement of pollutants in the environment and ultimately to an affected individual. Identification by experts of the exposure pathways for each use and disposal practice began in 1984 (conducted by a group that included the same experts that recommended further evaluation of 50 pollutants, see above). The exposure assessment was subsequently used to develop the risk assessments conducted for both the proposed and the final biosolids rule.

Step E Profile Assessments of 50 Pollutants

The environmental profile developed for each of the 50 pollutants included a compilation of data on toxicity, occurrence, and fate and effects of the pollutant. Information on occurrence (i.e., frequency and concentration of pollutants in biosolids) was obtained from the "40 Cities Study" (described below), which was considered the best source for such data at the time. Each environmental profile also evaluated hazards of pollutants associated with particular exposure pathways. Not all pollutants were evaluated for each pathway because some pathways were considered unlikely routes of exposure for certain pollutants.

Using a **hazard index** (Box 2), the environmental profiles evaluated the hazards for each of the 50 pollutants in biosolids by comparing a pollutant's concentration in the environment (in soil, plant or animal tissue, water, or air) with established human health and other regulatory criteria (e.g., acceptable daily intake for a noncarcinogen, or a cancer risk-specific intake). EPA assumed worst-case conditions in this initial assessment (i.e., maximum exposure of an individual to a pollutant in its most bioavailable form via the most sensitive route of exposure, assuming maximum toxic effect).

Step F Use of the Hazard Profile Process To Select Pollutants for Detailed Risk Assessment

Selection of pollutants for detailed risk assessment using the hazard indices evaluation involved a two-part process (EPA, 1985). First, all sources of exposure to a pollutant was considered, including biosolids and background levels of a pollutant from sources other than biosolids. A hazard index of less than 1 indicated that the concentration in the environment was lower than the concentration known to be toxic to the organism being evaluated. It also indicated that the pollutant was not a hazard to humans, animals, or plants via the pathway being evaluated, even when factoring in exposures to background concentrations of the pollutant in soil, water, air, and plants. Pollutant/pathway combinations with hazard indices of less than 1 were dropped from further consideration.

A hazard index value of 1 or greater indicated that a pollutant was potentially toxic. Each pollutant in this higher-value group was then further evaluated in the second part of the process, called **hazard ranking**, by adjusting the index so that it

Box 2
Calculation and Use of Hazard Index and Hazard Ranking for Biosolids

Hazard Index:

$$\text{Pollutant hazard index} = \frac{\text{Estimated concentration in soil, plant or animal tissue, water, or air}}{\text{Lowest concentration toxic to organism being evaluated}}$$

1. The hazard index for pollutants in biosolids was calculated by comparing:
   a.) the estimated concentration of the pollutant in soil, plant or animal tissue, ground water, surface water, or air (based on the "40 Cities Study" data on pollutant concentrations in biosolids and on pollutant transport and fate data) to:
   b.) the lowest concentration of a pollutant shown to be toxic to the organism being evaluated (as indicated by available scientific data) via the most sensitive route of exposure (i.e., ingestion, inhalation, or injection) while assuming maximum toxic effect.
2. Pollutants with hazard index values of less than 1 for "worst-case" conditions via certain pathways were not analyzed further for that pathway because a value of less than 1 indicated that the pollutant was not toxic to the organism. For example:

Lindane (Soil Biota Predator Toxicity):

$$Index = \frac{I_1 x\ UB}{TR} = \frac{0.129950x1.05}{50} = 0.002728$$

where: I_1 = Concentration of pollutant in biosolids-amended soil (μg/g dry weight [DW])
UB = Uptake factor of pollutant in soil biota (μg pollutant/g tissue DW [μg pollutant/g soil DW]$^{-1}$)
TR = Feed concentration toxic to predator (μg pollutant/g tissue DW)

3. Pollutants with hazard index values of 1 or greater for certain pathways were considered to be potentially toxic and were further evaluated (unless the circumstances did not warrant further study, predominantly because the data were insufficient). For example:

Lindane (Human Cancer Risk Resulting from Soil Ingestion [toddler]):

$$Index = \frac{(I_1 x\ DS) + DI}{RSI} = \frac{0.129950 + 2.71}{0.053} = 63.39152$$

where: I_1 = Concentration of pollutant in sludge-amended soil (μg/g DW)
DS = Assumed amount of soil in human diet (g/day)
DI = Average daily human dietary intake of pollutant (ug/day)
RSI = Cancer risk-specific intake (ug/day)
DW = Dry weight

Hazard Ranking:

4. Pollutants with hazard index values of 1 or greater were then evaluated to determine what portion of the hazard associated with a pollutant was attributable to its presence in biosolids. After adjustment (i.e., subtraction of background values so that pollutant exposure from sources other than biosolids were excluded from the rankings), indices for each of the pollutants were ranked (i.e., less than 1; 1 to 100; 100 to 1,000; and greater than 1,000). Higher rankings indicated greater potential risk from pollutants in biosolids. Ultimately, all hazard index rankings of 1 or greater received addditional evaluation. (Note: Background pollutant concentrations were considered in the exposure calculations for organisms during the risk assessments for both the proposed and the final Part 503 rule.)
5. If the portion of a pollutant's hazard attributable to biosolids resulted in a hazard ranking of less than 1, the pollutant was not analyzed further.
6. Pollutants with hazard rankings of greater than 1 were evaluated in the risk asessments conducted for biosolids use or disposal practices, with the exception of fluoride, iron, and pollutants deferred due to insifficient data (see text).

reflected only the pollutant's hazard attributable to biosolids. This adjustment was made by excluding background exposures to the pollutant from sources other than biosolids. The remaining value indicated impacts from pollutants in biosolids only.

The adjusted hazard indices then were ranked into one of the four hazard ranking groups—ranging from less than 1, 1 to 100, 100 to 1,000, and greater than 1,000—for the purpose of evaluating those pollutant indices with the highest score first. The weighted scores, however, were not used. Instead, all pollutant/pathway combinations with hazard rankings of 1 or more were evaluated in more detail (as discussed below and in Box 2), while pollutant/pathway combinations with indices of less than 1 were eliminated from further consideration.

All pollutant/pathway combinations assigned a hazard ranking of 1 or greater in the environmental profile process were selected for evaluation in the detailed risk assessments for biosolids, with the exception of fluoride and iron (discussed in Chapter 3) and pollutants for which further evaluation was deferred because of insufficient data. This process resulted in narrowing the list of pollutants to 22 for assessing risks from land application of biosolids, 16 for surface disposal, and 14 for incineration (see Table 2). Several additional pollutants were added or deleted from further analysis, as indicated in Table 3.

Some pollutants were not evaluated for all use or disposal practices (i.e., land application, surface disposal, incineration) because different practices may result in different routes of exposure and different potential risks from the same pollutant. For example, a pollutant might be toxic if a person inhales it from the air near a biosolids incinerator, but not be toxic if consumed in a crop grown on soil where biosolids were used as a fertilizer.

Risk Assessments Conducted for the Proposed Part 503 Rule

Step G EPA Science Advisory Board Review of Risk Assessment Methodology for the Proposed Rule

The methodologies used for the risk assessments conducted as a basis for the Part 503 proposed rule were reviewed and approved by EPA's Science Advisory Board (SAB). It is important to note that the review of the risk assessment methodologies by the SAB did not include the data used for the ***algorithms*** because this information was not available at that time. Algorithms are mathematical equations used in a risk assessment model to relate various relevant parameters (e.g., of exposure and dose response) for pollutants in applicable pathways. For the biosolids risk assessments, the algorithms ultimately were used to identify pollutant limits. Algorithms are discussed in detail in Chapter 4.

Step H Risk Assessments for Proposed Part 503 Pollutant Limits

Based on the SAB's favorable review of the risk assessment methodologies, EPA conducted separate risk assessments for land application, monofilling, and incineration of biosolids using toxicity and exposure data available at that time. Although a risk assessment methodology for ocean disposal of biosolids was developed and reviewed by the SAB, a risk assessment for this biosolids disposal practice was not conducted once the Ocean Disposal Ban Act of 1988 prohibited this disposal practice.

EPA conducted the initial biosolids risk assessments using highly conservative assumptions and worst-case exposure data in an attempt to ensure protection of public health and the environment. The conservative approach was adopted because a court-ordered schedule limited the time available to conduct the risk assessments and then develop the rule.

Factors of Importance in the Risk Assessments for the Proposed Part 503 Rule: Some of the key factors and conservative assumptions and approaches used in the biosolids risk assessments conducted for the proposed Part 503 rule are presented below. Many of these factors were the subject of lengthy scientific and policy deliberations (as discussed in Chapter 3) and, subsequently, were reevaluated and revised in the risk assessments conducted for the final Part 503 rule (as discussed later in this chapter). The key factors in the risk assessments for the proposed Part 503 rule included:

- ***How Organisms Are Exposed:*** Different exposure pathways (the ways in which people, animals, and plants can become exposed to pollutants in biosolids) were evaluated for agricultural land application, non-agricultural land application (i.e., forests and reclamation sites), distribution and marketing, surface disposal, and incineration of biosolids. All use or disposal practices except for non-agricultural land application and surface disposal (monofills) were evaluated by formal scientific exposure assessments (use of algorithms). (Much of the data, assumptions, models, and endpoints used in the risk assessments for the proposed rule were refined or changed for the final Part 503 risk assessments.)
- ***98th-Percentile Approach:*** A 98th-percentile (policy-based) approach was used by EPA to develop pollutant limits for biosolids applied to non-agricultural land and placed on a surface disposal site. The 98th-percentile pollutant concentrations were calculated based on data from the "40 Cities Study" and were used as "ceilings" for allowable pollutant concentrations in biosolids for the proposed regulation. (Changed to the 99th-percentile for the final rule risk assessments.)
- ***Who Is at Risk:*** Two types of risk were chosen for evaluation—individual and aggregate risks:
  - ***Individual risks*** were evaluated for the "most exposed individual" (MEI) for each pollutant and pathway. For humans, this MEI was the most sensitive individual being continuously exposed over a 70-year lifetime to a pollutant at its maximum concentration in a given pathway. For plants and animals, the MEI was the most exposed or most sensitive species exposed over its critical life period to the maximum pollutant solubility, bioavailability, and/or concentration. (Changed to the highly exposed individual [HEI] for the final rule risk assessments.)
  - ***An aggregate risk assessment*** was conducted to determine the benefits of the regulation in terms of numbers of cancer cases avoided in the population nationally, as required in the Regulatory Impact Analysis for the Part 503 rule. The aggregate risk assessment multiplied the risks to individuals (as described above) by the estimated number of individuals exposed to determine the number of cases avoided. The aggregate risk assessment was not used as a basis for determining pollutant limits or management practices in the final Part 503 rule.
- ***Quantifying Health Effects:*** Conservative criteria, such as risk reference doses (RfDs) and cancer potency values (q_1*s), among others, were used in algorithms for calculating pollutant exposure limits (see Box 3). (Retained for the final rule risk assessments.)

Table 2
Pollutants Remaining After Hazard Index, Hazard Ranking, or Deferral

	Land Application[a]			Surface Disposal[b]			Incineration		
Pollutants Evaluated	Hazard Index	Hazard Ranking[c]	Deferral (yes = not deferred)[d]	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)
Aldrin/Dieldrin	yes	yes	yes	—[e]	—	—	yes	yes	yes
Arsenic	yes	yes	yes	yes	no	NA[f]	yes	yes	yes
Benzene	—	—	—	yes	yes	yes	yes	no	NA
Benzo(a)anthracene	no	no	deferred	—	—	—	yes	no	deferred
Benzo(a)pyrene	yes	yes	yes	yes	yes	yes	yes	yes	yes
Bis(2-ethylhexyl) phthalate	yes	no	deferred	yes	yes	yes	yes	yes	yes
Beryllium	—	—	—	—	—	—	yes	yes	yes
Cadmium	yes	yes	yes	yes	no	NA	yes	yes	yes
Carbon tetrachloride	—	—	—	—	—	—	yes	yes	yes
Chlordane	yes	yes	yes	yes	yes	yes	yes	yes	yes
Chloroform	—	—	—	—	—	—	yes	yes	yes
Chromium	yes	yes	yes	yes	no	NA	yes	yes	yes
Cobalt	yes	no	deferred	yes	no	deferred	—	—	—
Copper	yes	yes	yes	yes	yes	yes	—	—	—
Cyanide	no	no	NA	yes	yes	yes	no	no	NA
DDT/DDE/DDD	yes	yes	yes	yes	yes	yes	yes	no	NA
2,4-Dichloro-phenoxyacetic acid	—	—	—	yes	no	NA	no	no	NA
Dioxins	—	—	deferred	—	—	deferred	no	no	deferred
Fluoride	yes	yes	yes	—	—	—	—	—	—
Furans	—	—	deferred	—	—	deferred	no	no	deferred
Heptachlor	yes	yes	yes	—	—	—	yes	no	NA
Hexachlorobenzene	yes	yes	yes	—	—	—	—	—	—
Hexachlorobutadiene	yes	yes	—	—	—	—	—	—	—
Iron	yes	yes	yes	—	—	—	—	—	—
Lead	yes	yes	yes	yes	yes	yes	yes	yes	yes
Lindane	yes	yes	yes	yes	yes	yes	yes	no	NA
Malathion	—	—	—	yes	no	NA	no	no	NA
Mercury	yes	yes	yes	yes	yes	yes	yes	no	NA
Methyl ethyl ketone	—	—	—	no	no	deferred	—	—	—
Methylenebis(2-chloro-) aniline	yes	no	deferred	—	—	—	—	—	—
Methylene chloride		no	deferred	yes	no	deferred	yes	no	NA
Molybdenum	yes	yes	yes	yes	no	no	—	—	—

(Continued)

Table 2 (Continued)

Pollutants Evaluated	Land Application[a]			Surface Disposal[b]			Incineration		
	Hazard Index	Hazard Ranking[c]	Deferral (yes = not deferred)[d]	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)
Nickel	yes	yes	yes	yes	yes	yes	yes	yes	yes
n-Nitroso-dimethylamine[g]	yes	no	NA	yes	yes	yes	—	—	—
Polychlorinated biphenyls (PCBs)	yes	yes	yes	yes	yes	yes	yes	yes	yes
Pentachlorophenol	yes	no	deferred	—	—	—	no	no	NA
Phenanthrene	—	—	—	yes	no	deferred	yes	no	deferred
Phenol	—	—	—	—	—	—	no	no	NA
Selenium	yes	yes	yes	—	—	—	—	—	—
Tetrachloroethylene	—	—	—	—	—	—	yes	no	NA
Toxaphene	yes	yes	yes	yes	yes	yes	yes	yes	yes
Trichloroethylene	no	no	NA	—	—	—	no	no	NA
Tricresyl phosphate	yes	no	deferred	—	—	—	—	—	—
Vinyl chloride	no	no	NA	no	no	NA	yes	no	deferred
Zinc	yes	yes	yes	yes	no	NA	yes	no	NA

[a]Includes land application and distribution and marketing; for later risk assessment, these two categories were combined.

[b]Surface disposal was evaluated as "Landfilling" in the Hazard Index/Ranking.

[c]Pollutants remaining after the hazard ranking had a hazard index/ranking ≥1 and were included in the Part 503 risk assessment. Pollutants with a hazard index/ranking of <1 were excluded from further analysis, except as discussed in Table 3.

[d]Some pollutants were deferred after the hazard index/hazard ranking process due to lack of data; pollutants marked "yes" remained for further analysis.

[e]— = not evaluated for that use or disposal practice.

[f]NA = deferral not applicable because hazard ranking indicated that pollutant did not pose a hazard (for exceptions, see Table 3).

[g]Also known as dimethyl nitrosamine.

- ***Acceptable Level of Cancer Risk From Potentially Toxic Organic Pollutants:*** Risks at 1×10^{-4} (1 case of cancer in a population of 10,000), 1×10^{-5} (1 case in 100,000), and 1×10^{-6} (1 case in 1,000,000) were evaluated. For the proposed Part 503 regulation, EPA made a policy decision to regulate risk at 1×10^{-4} for land application and surface disposal and at 1×10^{-5} for incineration. (The cancer risk level for incineration was changed to 1×10^{-4} for the final rule risk assessments.)
- ***Type of Data Used:*** Worst-case plant uptake data were used in the risk assessments for the proposed rule. The worst-case data came predominantly from greenhouse pot studies and studies using metal salts. The use of data from biosolids field studies was limited. (This was changed to the use of predominantly field study data for the final rule risk assessments.)
- ***Linearity Assumption for Plant Uptake of Inorganic Pollutants:*** EPA used the conservative assumption that plant uptake of inorganic pollutants is linear (i.e., that crops take up a pollutant in a manner that is directly proportional to the amount of pollutant in biosolids applied to land). (Retained for the final rule risk assessments.)

Table 3

Pollutants Added or Deleted From Evaluation After Hazard Index/Ranking Completed

Pollutant	Added or Deleted	Reason
Benzene	Added for: land application	Evaluated with additional exposure pathways
	incineration	Regulated as total hydrocarbon (THC) operational standard
Bis(2-ethylhexyl) phthalate	Added for land application	Evaluated with additional exposure pathways
Cadmium	Added for surface disposal	Additional data available, and for consistency with land application risk assessment
Chromium	Added for surface disposal	Additional data available, and for consistency with land application risk assessment
DDT/DDE/DDD	Added for incineration	Regulated as THC operational standard
Dioxins	Added for incineration	Regulated as THC operational standard
Fluoride	Deleted for land application	Limited data indicating toxicity
Furans	Added for incineration	Regulated as THC operational standard
Heptachlor	Added for incineration	Regulated as THC operational standard
Iron	Deleted for land application	Limited data indicating toxicity
Lindane	Added for incineration	Regulated as THC operational standard
Mercury	Added for incineration	Regulated through NESHAPS[a] standard
n-Nitroso-dimethylamine	Added for land application	Evaluated with additional exposure pathways
Trichloroethylene	Added for land application	Evaluated with additional exposure pathways

[a]NESHAPS = National Emissions Standards for Hazardous Air Pollutants

- ***Food Consumption:*** EPA used conservative dietary data to determine human exposure to pollutants in biosolids through food consumption. The risk assessment used the highest daily consumption rate of each of eight food groups (e.g., consumption of dairy products by the teen-age male) to calculate risk to humans from consuming plant or animal products grown or raised on soils to which biosolids were applied. (Refined for the final rule risk assessments.)
- ***Pollutant Transport:*** Particularly conservative models were used for predicting pollutant transport into ground water, surface water, and air. (Refined for the final rule risk assessments.)
- ***Organic and Inorganic Pollutants:*** Potential risks from both organic and inorganic pollutants were assessed. (Retained for the final rule risk assessments.)
- ***The "40 Cities Study":*** During the initial risk assessment process, the primary source of information on the presence and concentration of pollutants in biosolids evaluated in the risk assessments for the proposed Part 503 rule was the "40 Cities Study," published in 1982 (U.S. EPA, 1982). This study did not reflect the quality of biosolids used or disposed at the time of the proposed rule (1989) because:
  - The study included primarily data on biosolids in various stages of treatment at publicly owned treatment works (POTWs) prior to final processing, rather than data on final, processed biosolids leaving POTWs that were used or disposed.

Box 3
Quantifying Cancer and Noncancer Effects: Q_1*s and RfDs

For many analyses conducted for the biosolids risk assessments, EPA used cancer potency values (q_1*s) or risk reference doses/concentrations (RfDs/RfCs) to measure toxic human effects, as described below. Both q_1*s and RfDs/RfCs are conservative measures because they predict greater impacts on human health than are likely to actually occur and because both values assume exposure for an entire lifetime (70 years). Q_1*s or RfDs were used in the biosolids risk assessments to calculate the concentration of pollutant in biosolids that is reasonably protective against adverse impacts.

*Cancer Effects: Q_1*s*

Cancer potency values (q_1*s) were used to quantify human cancer in the risk assessments for biosolids. A q_1* represents the dose at which an exposed individual would be expected to get cancer (i.e., the relationship between a specific dose of a carcinogenic [cancer-causing] substance and its associated degree of risk). The degree of risk (i.e., 1×10^{-4}) is a policy decision made by the Agency that indicates an acceptable degree of cancer risk for the most exposed person, based on that person's continual exposure at that dose for a lifetime (e.g., 70 years). In evaluating cancer risks, EPA conservatively assumes that any exposure to a carcinogen produces a measurable risk. The q_1* is a "bounding" (upper-limit) estimate; the true risk to humans is not likely to exceed the q_1*, and probably is lower. Q_1*s are based on data for the most sensitive animal as well as on conservative (i.e., linear) extrapolation from high doses (used in laboratory experiments) to low doses (representative of actual human exposure). Q_1*s for specific pollutants are listed in EPA's computerized Integrated Risk Information System (IRIS) data base, which can be accessed through the National Library of Medicine.

Noncancer Risks: RfDs/RfCs

Reference dose (RfD) or ***reference concentration (RfC)*** values were used in the biosolids risk assessments to indicate health effects other than cancer from exposure to inorganic pollutants in biosolids. RfDs/RfCs are conservative estimates of the amount of a chemical that can be consumed daily without appreciable risk of ill effects during a lifetime. Thus, these values identify "thresholds" for noncancer health effects; no such threshold was identified for cancer risks discussed above because any dose of a carcinogen is assumed to be capable of producing a carcinogenic effect. Conservative safety factors ranging from 10 to 10,000 are incorporated into RfDs/RfCs to address areas of uncertainty, such as extrapolation from short-term to long-term exposure, interspecies sensitivity, and variation in sensitivity in humans. Like q_1*s, RfDs/RfCs are listed in EPA's IRIS data base. The Clean Water Act requires that EPA protect against reasonably anticipated adverse effects of each regulated pollutant in biosolids. For example, the chosen RfD for cadmium protects against renal tubular proteinuria.

- The study was designed to trace the fate of toxics in POTWs that had received significant volumes of industrial wastewater discharge (and thus potentially high concentrations of pollutants in resulting biosolids).
- Many POTWs have initiated pretreatment programs since 1978, resulting in cleaner biosolids.
- Wastewater treatment processes have changed over time.
- Advances in analytical procedures since the "40 Cities Study" allow for more accurate analyses of pollutants in biosolids.

Realizing the limitations of the "40 City Study," EPA conducted a much more representative evaluation of biosolids from POTWs across the United States (and pollutants in those biosolids) via a National Sewage Sludge Survey (NSSS). (NSSS data were used to help develop the final rule.)

Based on the results of the initial risk assessments and numerous policy decisions described above, EPA developed and published the proposed Part 503 rule for public comment in the February 6, 1989, issue of the *Federal Register*.

Comments on the Proposed Part 503 Rule and EPA's Response

Step I — Public Review and Comment on the Proposed Part 503 Rule

EPA proposed the Part 503 rule on February 6, 1989 (54 FR 5746), seeking comment and additional data for improving the rule. Many different types of reviews were undertaken that resulted in more than 5,500 pages of comments received by the Agency. Some of the most extensive comments were received from expert peer review groups established by the Agency that included representatives from academia; federal, state, and local government agencies and research centers; and environmental organizations.

One of the expert peer review groups was organized by the U.S. Department of Agriculture's (USDA's) Cooperative State Research Service Technical Committee W-170 to assess the technical basis of the proposed rule for land application, distribution and marketing, monofilling, and surface disposal. This review group, called the Peer Review Committee (PRC), identified a number of deficiencies and recommended changes in the data, assumptions, and models used for the risk assessments. The PRC recommendations (USDA/CSRS, 1989) are listed in Table 4.

A second expert peer review group was assembled by the SAB to review the technical basis for the proposed incineration rule. This group's recommendations and findings (U.S. EPA, 1989a) are listed in Table 5.

Step J — EPA Analysis of Comments on the Proposed Rule and Revision of the Risk Assessments

EPA performed an extensive analysis of the comments received and undertook a series of actions in response to the comments. Perhaps one of EPA's most important actions was to assemble a team of experts (Appendix C) with extensive research and experience related to the issues raised by the PRC and a number of the other commentors.

The team of experts met a number of times over 3 years to provide EPA with recommendations for improving the risk assessments, including the data, models, and assumptions that should be used. The team helped assemble and tabulate the available relevant data, advised EPA on the proper use of these data, and helped revise the models and assumptions used in the risk assessments. The experts recommended a number of significant changes to the proposed Part 503 rule. These changes were announced along with the results of the NSSS, both of which are described in the following section. EPA has continued to benefit from the assistance provided by members of this team during internal review and promulgation of the final rule and in explaining the risk assessment process at numerous meetings both in the United States and abroad.

Step K — The National Sewage Sludge Survey

EPA conducted the NSSS in 1988 and 1989 to obtain a current and reliable data base on biosolids quality and management that could be used to help develop the final Part 503 rule. The NSSS included an analysis of 412 analytes in samples of biosolids from 180 POTWs as well as analysis of questionnaire information on use or disposal practices from 475 POTWs with secondary or more advanced wastewater treatment. The resulting national estimates of pollutant concentrations in biosolids, quantities of biosolids generated, and biosolids treatment, practices, and related costs permitted a more accurate assessment of the level of risk posed by current biosolids quality and use or disposal practices.

Step L Publication of the NSSS Results and Proposed Changes for the Final Part 503 Rule

Upon completion of its analysis of review comments on the proposed Part 503 rule and the NSSS findings, EPA considered making a number of changes to the Part 503 rule. These changes were published along with the results of the NSSS in the November 9, 1990, issue of the *Federal Register* (55 FR 47210-47283) and entitled *National Sewage Sludge Survey: Availability of Information and Data, and Anticipated Impacts on Proposed Regulations*. The NSSS results indicated that pollutants exist at relatively low levels in today's biosolids, and the proposed changes to the rule reflect these results. The findings in that publication are discussed in more detail below.

NSSS Results: The NSSS results were significantly different from previous estimates of pollutant concentrations in biosolids. Concentrations of heavy metals, including cadmium, chromium, lead, nickel, zinc, beryllium, and mercury, were found to be substantially lower than previous estimates. In particular, lead concentrations were found to be only about 40 percent as high as previously estimated. Concentrations of most chlorinated organic pollutants also were confirmed to be low. Problems with limits of detection in the NSSS were overcome for the most part via a statistical procedure called maximum likelihood estimation for multiple censored points.

Biosolids samples also were analyzed for polychlorinated biphenyl (PCB) congeners. No detectable levels of PCB congeners 1016, 1221, 1232, or 1242 were found in any of the 198 tested samples. The remaining congeners—PCB 1248, 1254, and 1260—were found to be above the minimum detectible level in about 10 percent of the biosolids samples.

The national estimates of pollutant concentrations from the NSSS are considered appropriate and essentially unbiased statistically (except for PCBs, which differ from other pollutants in that they do not show a log normal distribution). The estimates were found to be statistically sound for several reasons:

- The surveyed POTWs were selected from all POTWs with secondary treatment identified by the 1986 Needs Survey, the most complete listing available.
- The POTWs included in the NSSS were selected to equally represent each of four representative POTW size ranges.
- Analytical protocols used to measure the concentration of pollutants in NSSS samples were specifically adapted for the biosolids matrix.
- While the wide differences in percent solids in the different biosolids samples analyzed resulted in detection limit problems, the statistical method used to incorporate sample results that were below the detection limit (known as the maximum likelihood estimation for multiple censored points technique) reduced the bias associated with more commonly used estimation procedures.

The NSSS results, particularly those indicating that concentrations of metals in biosolids were lower than estimated by the "40 Cities Study," were used in important ways to revise the final Part 503 rule. For example, the results provided a basis for (1) excluding organic pollutants from the final Part 503 rule, (2) developing low pollutant concentration limits for minimally regulated biosolids, and (3) establishing 99th-percentile ceiling concentration limits, as discussed later in this chapter.

Table 4

Peer Review Committee Recommendations Concerning the Part 503 Proposed Rule Risk Assessment (USDA/CSRS, 1989)

The Peer Review Committee (PRC) recommended that EPA revise and repropose the Part 503 rule after revision and correction of the risk assessment methodology. The recommended revisions included more realistic most exposed individuals (MEIs) and models, inclusion of "clean" biosolids, site-specific considerations, and careful selection and use of relevant data. The PRC recommended specifically that EPA should:

- Enlist working groups consisting of experts in biosolids, risk assessment, and modeling to help review the data, revise the scenarios and models, and obtain more realistic pollutant limits.
- Use risk assessment procedures that lead to best estimates and uncertainty bounds rather than calculating upper bound estimates. At a minimum, the MEI should be replaced with an approach that considers exposure situations that are reasonable and that may exist in the United States.
- 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 in biosolids to humans.
- Use sensitivity analysis to identify the most critical parameters in risk/exposure computations 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 when making calculations.
- Use results of field studies involving additions of biosolids rather than results of green house or pot studies involving additions of metal salts or pure organic compounds.
- Use field data to establish Lowest Observed Adverse Effect Levels (LOAELs) or No Observed Adverse Effect Levels (NOAELs) as a basis for calculating pollutant limits.
- Expand the proposed rule to include consideration of potential iron and fluoride toxicity.
- Develop the concept of a "clean" biosolids that allows for minimal regulation.
- Avoid regulating all distributed and marketed (D&M) products as biosolids.
- Require labeling of D&M products to provide consumer information on proper use of the products.
- Drop the MEI scenario for D&M products, a concept that assumes a rural nonfarm family grows 60 percent of their fruit and vegetables in a D&M biosolids-amended home garden for a 70-year lifetime.
- Prepare and address different categories for non-agricultural and D&M practices.
- Exempt from the rule compounds banned from use in the United States that have been shown to pose insignificant risk (e.g., 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 biosolids-applied PCB, and perform detailed reevaluation and analyses of the PCB pathways.
- Use two distinct frameworks to assess risk for non-agricultural land:
  - Exposure and significant future conversion very low
  - Exposure more likely or conversion more probable
- Allow for exception to the 5-year conversion period in non-agricultural land application on a case-by-case basis.
- Drop 98th-percentile approach.

Table 4 (Continued)

- Continue the approach of separating the vector attraction reduction requirements from the pathogen reduction requirements in the proposed regulation.
- Regulate pathogens on a risk-based approach. In the interim, the existing requirements in 40 CFR 257 should be maintained.
- Replace the air dispersion model with a more realistic model, such as that used for the EPA solid waste incineration program.
- Adopt a consistent approach for including volatile compounds (e.g., benzene and trichloroethylene) in models used to predict air and ground-water transport.
- Exclude from the rule chemicals that the Agency assumes to be lost from biosolids during processing and that are not present in the biosolids 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.
- Convert output from the unsaturated zone transport model to input for the AT123D saturated zone transport model in such a manner that satisfies conservation of mass.
- Use realistic, site-specific geologic, hydraulic, and chemical parameters as inputs to computer simulations of contaminant transport.
- Differentiate between trench and area monofills because of the different 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 biosolids management scheme.
- Avoid requiring methane monitoring at surface disposal sites where biosolids are applied at high rates to the soil surface.
- Establish acceptable analytical methodologies and limits of detection for regulated biosolids 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 are 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 pollutant limit derived from that limit of detection.
- Allow the use of zero concentrations from biosolids pollutant data below the limit of detection for laboratories meeting the Agency's analytical standards.

Proposed Changes to the Part 503 Rule:

Some of the changes listed in the *Federal Register* notice were:

- ***Domestic Septage:*** A less complex and more easily implementable regulatory approach that would remain protective of public health and the environment.
- ***Organic Emissions From Biosolids Incinerators:*** An operational (i.e., technology-based) standard rather than risk-based limits.

Table 5

Science Advisory Board Recommendations Concerning the Part 503 Regulatory Approach for Incineration of Biosolids (U.S. EPA, 1989a)

Based on its review of the proposed Part 503 rule's approach for regulating incineration of biosolids, the Science Advisory Board (SAB) recommended:

- EPA has the scientific basis for developing enforceable operational standards (rather than risk-based standards) for organic pollutants that would provide incentives for improving incineration technology and pollution control equipment. Risk-based standards are not recommended because of the wide range of uncertainties in the risk analysis used for biosolids incineration.
- EPA should undertake and support epidemiological research to determine the incidence of adverse health effects in populations residing near existing incineration facilities.

Further, the SAB commended EPA's Office of Water in attempting to develop a risk-based regulation for sewage sludge incinerators. Based on its review of the proposed Part 503 rule's approach to regulating incineration of biosolids, however, the SAB identified several uncertainties associated with the risk analysis that precluded risk-based regulation, including:

- Numerous safety factors were used in the analysis. While each individual factor appears reasonable, the multiplicative use of a series of such factors made the final number unreasonable.
- The methodology did not explicitly assign a measure of uncertainty or confidence to the calculations, but rather a single risk number was used.
- Use of total hydrocarbons (THCs) as a direct indicator of risk is not possible due to the uncertainties associated with field implementation of hot flame-ionization detector (FID) systems and the lack of a direct link between THCs, as measured by FID, and the total spectrum of organics that might be emitted from sewage sludge incinerators. In addition, it has not been demonstrated that hot FID systems can operate continuously in the stack gas environment of sewage sludge incinerators. Thus, it is not appropriate to propose regulations that will demand such operation for compliance.
- THC measurements may at best indicate the combined performance of combustion and air quality control devices, but how these measured concentrations at the stack relate to environmental concentrations of carcinogens remains unknown.

- ***Non-agricultural Land Application of Biosolids:*** Use of exposure pathway analyses rather than a 98th-percentile approach to establish numerical pollutant limits for all non-agricultural land application practices, including forest and range lands, soil reclamation sites, and public contact sites (e.g., parks, golf courses).
- ***Surface Disposal of Biosolids:*** Use of a risk-based exposure assessment approach, similar to the one used for monofills in the proposed rule, rather than a 98th-percentile approach.
- ***Agricultural Land Application of Biosolids:*** Numerous revisions were considered regarding selection of appropriate target organisms, exposure pathways, transport models, and data, including use of:
  - More realistic assumptions that would protect an HEI rather than an MEI for each pathway.
  - New models for aquatic pathways.
  - More plausible dietary data.
  - Updated and more relevant plant uptake and phytotoxicity data from field studies of biosolids-amended soils.
  - "No effect" and non-detection data to establish pollutant limits based on No Observed Adverse Effect Levels (NOAELs) or Lowest Observed Ad-

verse Effect Levels (LOAELs) where appropriate, based on results from numerous studies on phytotoxicity and bioavailability.

- New calculations for the fraction of food derived from biosolids-amended soils.
- Field measurements for the consumption of biosolids or soils by grazing livestock.
- Revised rate of soil consumption by children.

- ***50 Metric Tonnes per Hectare Limit:*** Proposed dropping of the requirement to limit the land application rate to 50 metric tonnes per hectare (mt/ha) in the proposed rule because the use of newer models allowed higher than 50 mt/ha application rates to be calculated in the risk assessments.
- ***Combining Land Application Pollutant Limits:*** Use of only one set of pollutant limits for biosolids that were distributed and marketed or applied to agricultural or non-agricultural land.
- ***Use of the Most Limiting Pathway To Set Pollutant Limits:*** Selection of the most limiting exposure pathway to set the limit for each pollutant.

Step M Revised Risk Assessments Conducted for the Final Part 503 Rule

In response to the extensive public and scientific peer review comments received on the proposed rule and the information obtained from the NSSS, EPA (working closely with internationally recognized experts) revised some of the data, models, and assumptions used in the risk assessments for biosolids. Some of the key revisions, summarized in Table 1 and discussed in more detail in Chapter 3, included:

- ***Reassessment of Who Is at Risk:*** EPA used the highly exposed individual (HEI) instead of the most exposed individual (MEI) as the target organism in the revised risk assessment because use of the MEI was criticized as being too conservative, reflecting highly unlikely or unusual circumstances rather than realistic exposure conditions. The HEI reflects more reasonable risks to exposed individuals, while remaining a conservative measure (Habicht, 1992).
- ***Revised Health and Environmental Criteria:*** EPA reviewed and revised its use of health and environmental criteria. As a result, the Agency used a new model for risks associated with lead exposure; developed refined ecological criteria; and used Recommended Daily Allowances (RDAs) when RfDs/RfCs were unavailable.
- ***Reconsideration of Risk Levels:*** EPA reassessed the cancer risk levels of 1×10^{-5} for incineration and 1×10^{-4} for all other use or disposal practices based on new information obtained after the initial risk assessment was conducted. This reassessment indicated minimal risk from all current biosolids use or disposal practices, including incineration. The reassessment resulted in the EPA policy decision to regulate cancer risks for all biosolids use or disposal practices at 1×10^{-4} in the final Part 503 rule.
- ***Revision and Reevaluation of Exposure Pathways,*** including:
  - ***Replacement of the 98th-percentile approach with formal exposure pathway assessments*** for all non-agricultural land application and surface disposal practices, based on new data and modeling techniques. The number of exposure pathways evaluated for non-agricultural land application (e.g., forest lands, soil reclamation sites, and public contact sites) was increased.
  - ***Use of the most stringent of the pollutant limits for each pollutant from all pathways of exposure for land application*** based on revised

risk assessments that predicted similar pollutant limits for agricultural and non-agricultural land application and distribution and marketing.

- ***Use of one risk assessment for all biosolids surface disposal practices,*** including biosolids-only landfilling (monofilling), permanent lagooning, dedicated high-rate surface application for disposal, and dedicated beneficial use. Although there was one risk assessment, two exposure routes were evaluated and the more stringent of the two pollutant limits was chosen as the Part 503 pollutant limit.
- ***Revision of the exposure pathways for ground water, surface water, and air*** in the land application and surface disposal risk assessments to incorporate better fate and transport models and assumptions and to correct techniques used to calculate how much of a pollutant is lost to ground water, surface water, and air. The risk assessments for the proposed rule had used the assumption that 100 percent of any evaluated pollutant could be simultaneously transferred to ground water, surface water, and air. This overly conservative approach was changed. The revised risk assessments used a "mass balance" approach, which more realistically assessed the portion of the pollutant that is transferred to ground water, surface water, and air.
- The exposure pathways used in the revised risk assessments for biosolids are shown in Tables 6 and 7.

Potential risks to people, plants, and animals from applying biosolids to cropland, as well as numerous other "exposure pathways," were evaluated in the biosolids risk assessment (Tables 6 and 7)

Table 6

Summary of Exposure Pathways Used in Risk Assessment for Land Application of Biosolids

Pathway	Description of HEI[a]
1. Biosolids → Soil → Plant → Human	Human (except home gardener) lifetime ingestion of plants grown in biosolids-amended soil
2. Biosolids → Soil → Plant → Human	Human (home gardener) lifetime ingestion of plants grown in biosolids-amended soil
3. Biosolids → Human	Human (child) ingesting biosolids
4. Biosolids → Soil → Plant → Animal → Human	Human lifetime ingestion of animal products (animals raised on forage grown on biosolids-amended soil)
5. Biosolids → Soil → Animal → Human	Human lifetime ingestion of animal products (animals ingest biosolids directly)
6. Biosolids → Soil → Plant → Animal	Animal lifetime ingestion of plants grown on biosolids-amended soil
7. Biosolids → Soil → Animal	Animal lifetime ingestion of biosolids
8. Biosolids → Soil → Plant	Plant toxicity due to taking up biosolids pollutants when grown in biosolids-amended soils
9. Biosolids → Soil → Soil → Organism	Soil organism ingesting biosolids/soil mixture
10. Biosolids → Soil → Soil → Organism → Soil → Organism → Predator	Predator of soil organisms that have been exposed to biosolids-amended soils
11. Biosolids → Soil → Airborne Dust → Human	Adult human lifetime inhalation of particles (dust) (e.g., tractor driver tilling a field)
12. Biosolids → Soil → Surface Water → Human	Human lifetime drinking surface water and ingesting fish containing pollutants in biosolids
13. Biosolids → Soil → Air → Human	Human lifetime inhalation of pollutants in biosolids that volatilized to air
14. Biosolids → Soil → Ground Water → Human	Human lifetime drinking well water containing pollutants from biosolids that leached from soil to ground water

[a] HEI = highly exposed individual

Table 7

Summary of Exposure Pathways Used in Risk Assessments for Surface Disposal and Incineration of Biosolids

Surface Disposal	
Pathway	Description of HEI[a] Exposure for a 70-Year Lifetime
1. Biosolids → Soil → Air → Human	Adult human breathing volatile pollutants from biosolids disposed at a surface disposal site
2. Biosolids → Soil → Ground Water → Human	Adult human drinking water obtained from ground water beneath a surface disposal site
Incineration	
1. Biosolids → Incineration → Particulate → Air → Human	Adult human breathing pollutants in the emissions from a biosolids incinerator

[a]HEI = higly exposed individual

- ***Deletion of Organic Pollutants:*** Based on comments received on the proposed Part 503 rule, EPA reevaluated the organic pollutants regulated by the proposed rule to determine whether any should be deleted from the final regulation. This reevaluation resulted in EPA's policy decision to delete all organic pollutants from land application and surface disposal sections of the final Part 503 rule because these pollutants met one of the following criteria: (1) the pollutant has been banned or restricted for use in the United States or it is no longer manufactured for use in the United States; (2) the pollutant is not present in biosolids at significant frequencies of detection based on data gathered in the NSSS; or (3) the limit for a pollutant from the biosolids exposure assessment is not expected to be exceeded in biosolids that are used or disposed based on data from the NSSS.
- ***Food Consumption Revisited:*** The methodology and data used to calculate dietary exposure to pollutants in biosolids were reviewed and revised to reflect more realistic values representing average lifetime food consumption.
- ***Greater Reliance on Results of Field Studies:*** Field study data were used in the revised risk assessment whenever available (rather than greenhouse pot or metal salt-addition studies) to determine plant uptake of metals and phytotoxicity. New data provided during the public comment and scientific review period indicated that field studies provide a much more realistic basis on which to set biosolids pollutant limits than pot/salt study data, with limits that are more representative of real-world conditions. These new data showed that plants in the field take up metal pollutants at lower rates than predicted based on greenhouse pot/salt addition studies (see photographs, next page), and that these rates remain low over time.
- ***Revised Evaluation of Biosolids Incineration,*** including:
  - Use of an ***updated model*** of incineration of biosolids to evaluate exposure to metal emissions.
  - Determination that ***site-specific modeling and performance testing*** to calculate air dispersion factors and control efficiencies (required in the final rule) are more appropriate than establishing absolute values for those parameters, as was done in the proposed Part 503 rule.
  - Determination that it was infeasible to establish a risk-based numerical limit for total hydrocarbon (THC) emissions from biosolids incinerators, as was included in the proposed rule. Instead, a technology-based ***operational standard for THC*** was included in the final rule.
- ***A New Aggregate (Population) Risk Assessment:*** The aggregate (population) risk assessment conducted for the final Part 503 rule indicated that current use or disposal practices for biosolids pose minimal risk to public health and the environment.

Many of the revisions summarized above are discussed in more detail in Chapter 3.

Step N EPA Review of Science and Policy Decisions Used in the Biosolids Risk Assessments Prior to Issuance of the Final Part 503 Rule

During the review of the final Part 503 rule, several EPA offices raised a number of issues that needed resolution prior to publication of the final rule. These issues are summarized in Table 8. Many of these issues and EPA's resolution of them are discussed in greater detail in Chapter 3.

Table 8

Questions Raised During Internal EPA Review

Topic	Question	Where Addressed in this Document
Pathogens	How should pathogens (e.g., bacteria, viruses) in biosolids be regulated?	Chapter 5
Phytotoxicity	How should phytotoxicity (adverse effects on plants) be defined?	Chapter 3; Chapter 4, Box 10
Lead risks	What methodology should be used to determine risks from exposure to lead in land-applied biosolids?	Chapter 3
Biosolids binding of pollutants	Does "biosolids binding" (the ability of biosolids to strongly react with pollutants, resulting in less pollutant being taken up by plants) persist over time?	Chapter 3
Soil pH	Should soil pH be regulated?	Chapter 5
Ecological risks	Is the ecological risk assessment adequate?	Chapter 3
Margin of safety	Can a 98th- or 99th-percentile approach used as an additional margin of safety be justified?	Chapters 3 and 5
Incineration monitoring	How should incineration monitoring be regulated?	Chapters 2 and 5
Nitrogen in ground water	How should nitrogen that migrates into ground water from biosolids be regulated?	Chapter 3
"Clean" biosolids	Should special provisions to encourage the production of "clean" biosolids (i.e., biosolids containing low levels of pollutants) be included in the final rule?	Chapters 3 and 5

Step O — Publication of the Final Part 503 Rule in the *Federal Register*

The final Part 503 rule was published in the *Federal Register* on February 19, 1993 (58 FR 9248). The rule set limits for pollutants that may be present in biosolids that are land applied, surface disposed, or incinerated, as well as other requirements, including management practices, operational standards (i.e., pathogen and vector attraction reduction requirements for land application and surface disposal; THC emissions testing for incinerators), general requirements, and frequency of monitoring, reporting, and recordkeeping requirements (see also Figure 1 in Chapter 1). In addition to the rule itself, the preamble included informative discussions regarding differences between the proposed and final rule pertaining to public and scientific comments, EPA responses to comments, and final actions taken to revise the proposed rule.

Step P — Comments, Lawsuits, and Amendments Regarding the Published Final Part 503 Rule

Comments: EPA received comments on the published final Part 503 rule from 89 respondents in response to a request for comments in the Preamble. The comments raised issues regarding the pollutant limits set for cadmium, selenium, and chromium; the use of "annual pollutant loading rates"; use of a percentage of the Maximum Contaminant Level (MCL) for nitrate-nitrogen allowance; and the need for additional ecological field research (see further discussions in Chapter 3). The comments also questioned the need for pollutant limits for molybdenum and the requirements for monitoring emissions from biosolids incinerators, as discussed below.

Lawsuits Regarding Pollutant Limits for Molybdenum and Chromium: Several POTWs and industry groups as well as the USDA noted errors in the calculation of the uptake slope for molybdenum that caused an underestimation of allowed biosolids molybdenum applications to farmland. Several organizations sued, referring to the error and stating that the limit would significantly restrict the use of biosolids as fertilizer or impose severe restrictions on molybdenum discharge to POTWs without need or benefit. In addition, several industry groups and POTWs initiated lawsuits in which they contended that the land application pollutant limits set for chromium are overly stringent. In particular, plaintiffs argued that because the limits set for chromium were based on a risk assessment that did not identify a limit that would cause harm to public health or the environment, the limits would be unnecessarily detrimental to their industrial practice. On this basis, plaintiffs contended that the limits should be deleted from the rule.

Lawsuits Regarding Biosolids Incinerator Monitoring: Lawsuits also were filed regarding continuous emission monitoring requirements for measuring total hydrocarbons in emissions from biosolids incinerators. The incineration lawsuits questioned the requirement for continuous monitoring of THC emissions from certain incinerators that already had continuous emission monitoring systems for carbon monoxide (CO) in place, which plaintiffs claimed achieved the same results. In addition, arguments were made that EPA was not allowing sufficient time nor providing adequate instruction for installation, start-up, continuous operation, and calibration of continuous emission monitoring systems for THC.

Part 503 Amendment: In response to the public comments received and lawsuits filed, EPA published an amendment to the rule in the Federal Register on February 25, 1994 (59 FR 9095). The amendment states that the Agency is reconsidering the land application pollutant limits for molybdenum. During the period of reconsideration, only the ceiling concentration limit (Part 503, Table 1) must be met for molybdenum. The other pollutant limits (i.e., cumulative pollutant loading rates [Part 503, Table 2], pollutant concentration limits [Part 503, Table 3], and annual pollutant loading rates [Part 503, Table 4]) for molybdenum have been suspended pending additional study by EPA.

In addition, the February 25, 1994, amendment allows continuous CO monitoring to be used as a surrogate for THC monitoring for incinerators that do not exceed 100 ppm_v (parts per million, volume basis) of CO in the exhaust gas. Also, operators of biosolids incinerators are not out of compliance if not monitoring for THC or CO until either a permit has been issued or other federal action has been taken (e.g., Federal Register notification).

Step Q Court Remand of Specific Portions of the Rule

The court remanded certain provisions of the rule to EPA for modification or further justification as a basis for their continued inclusion in the Part 503 rule. These provisions continue to be in effect pending the Agency's review of the remanded portions of the rule.

The remanded portions of the rule include:

- The ***chromium*** pollutant limits
- The ***99th-percentile cap*** used as a pollutant concentration limit for selenium
- Pollutant concentration limits for ***heat-dried biosolids*** (currently not included in Part 503)

These issues are discussed in more detail in Chapter 3.

Chapter 3

Identification and Resolution of Risk Assessment Issues

Determining the risks associated with pollutants in biosolids was a challenging process. Numerous factors had to be considered, many of which had not been fully explored previously. This chapter presents some of the key issues raised during the risk assessment process for biosolids and discusses how EPA resolved them. These issues are summarized in Table 9 and addressed in more detail throughout this chapter. The large letters to the left of each section heading in the text and in the left-hand column of Table 9 refer to the same risk assessment steps discussed in Table 1 in Chapter 2 and indicate when in the risk assessment process the issue was raised. Not all letters are shown because not all of the risk assessment steps discussed in Chapter 2 involved issues that required further resolution.

Step H — Evaluation of Iron and Fluoride

Although the initial biosolids hazard index and ranking process (described in Chapter 2) identified both iron and fluoride as potentially toxic, EPA decided not to evaluate these two pollutants in the risk assessments for biosolids. EPA made this decision because toxic effects have only been observed under atypical conditions—in experiments with unusually high concentrations of iron and fluoride and single high volume applications of biosolids.

For example, cattle in which iron toxicity resulted were grazed on land to which, in an experiment, high iron content biosolids were land applied a day before grazing. These cattle received no supplemental feed and were continually rotated to new fields week after week immediately after the fields had been treated with high iron-content liquid biosolids.

Such an occurrence of elevated iron toxicity in cattle is highly unlikely other than in a similar experimental setting. The Part 503 rule requires at least a 30-day waiting period after application of Class B biosolids (those meeting certain pathogen reduction requirements) before allowing grazing. Possibly, Class A biosolids (virtually pathogen free) could be applied just before grazing; however, Class A biosolids are usually in a dry state and initially do not tend to stick to the forage, as do liquid Class B biosolids. Also, it is highly unlikely that biosolids in any form would continue to be applied week after week to pastures immediately before cattle graze.

Table 9
Issues Raised During the Biosolids Risk Assessment Process

Issue Raised During	Issue	Resolution of Issue
Step E Profile assessment	Retain or drop ocean disposal	Dropped—policy decision because of Ocean Disposal Ban Act
Step H Risk assessments for proposed rule	Drop iron and fluoride, which had high hazard indices	Iron is ubiquitous and an essential element; two studies showing high levels (Fe and F) considered to be unrepresentative; iron and fluoride not regulated
Step J Expert reviews	(1) Target organism	Replaced most exposed individual with highly exposed individual
	(2) Use of 1 x $10^{-4, -5, \text{or} -6}$ cancer risk level	Used 1 x 10^{-4} for all use or disposal practices (policy decision)
	(3) Salt/pot vs. biosolids/pot vs. field data	Used field data to accurately reflect biosolids pollutant concentrations in plants because salt data greatly overestimate actual uptake
	(4) Megaeater model	Replaced with better data and model
	(5) Drop organics from Part 503 rule	Policy decision—NSSS showed organics not present in sufficiently high levels in biosolids to exceed risk-based limits; infrequently detected; or no longer used or manufactured for use in the United States
Step L NSSS results, rule changes	Add concept for land application of biosolids containing low pollutant levels that require less regulatory control. If such biosolids meet pollutant concentration limits and certain pathogen and vector attraction reduction requirements, they would be minimally regulated	"Clean" biosolids concept shown to be viable by risk assessment for low pollutant concentrations; field data confirmed that land-applied biosolids containing low pollutant levels have no observed adverse effects on public health and the environment; NOAEL biosolids concept included in final Part 503 rule
Step N Internal EPA review	(1) Lead risk evaluation not properly conducted	Explained how animal data were used to show no impact on body burden; used EPA IEUBK model; risk management decision to use 300 ppm from animal data vs. 500 ppm from IEUBK model as land application pollutant concentration limit
	(2) Whether biosolids binding of metals is long-term	Detailed evaluation of data showed a valid basis for long-term binding of pollutants by biosolids components
	(3) Whether ecological risks, especially phytotoxicity, were properly assessed	Reviewed and explained EPA procedures for ecological risk assessment; specifically described how risks to animals, plants (phytotoxicity), and microbes were determined; policy decision to add ceiling concentration limits to prevent worst-case exposure, partly in response to phytotoxicity concerns (see Step N-6 in text); made plans for additional future ecological and biosolids metal binding studies
	(4) Allow use of PSRP and PFRP	Policy decision to use both; made vector attraction reduction a separate requirement; added monitoring requirement to preclude regrowth for Class A PFRP
	(5) Non-agricultural and surface disposal pollutant limits	Changed from 98th percentile to risk-based limits

(Continued)

Table 9 (Continued)

Issue Raised During	Issue	Resolution of Issue
Step N Internal EPA review (cont.)	(6) Ceiling concentration limits for land application and caps for pollutant concentration limits	Policy decision to use 99th percentile as a ceiling concentration if less stringent than risk-based cumulative pollutant loading rate; used NSSS to assess impact on 1% (99th percentile) of POTWs for final rule (vs. 10%, or 98th percentile, in initial proposed rule); 99th percentile still limits use or disposal of biosolids with highest concentrations of metals
	(7) Assign fraction of ground-water nitrate MCL (10 mg NO_3-N) to biosolids nitrogen	Policy decision not to fractionate but to assign entire 10 mg NO_3-N to biosolids; no other EPA rule had fractionated the MCL for nitrogen, and no agreed upon basis for fractionization has been established
	(8) Use biosolids as model for nutrient management	Policy decision—too complex an issue for unilateral decision by EPA; involves all sources of nutrients from chemical fertilizer, animal manure, and other wastes, as well as biosolids
Step P Comments, lawsuits, EPA revisions	(1) USDA issues, e.g., cadmium ceiling concentration limit; APLR approach	Considering whether to make changes or develop guidances
	(2) Regulation of chromium and molybdenum	Science basis questioned—need for more definitive data; land application pollutant limits for molybdenum deleted except for Part 503 Table 1 ceiling concentration limits
	(3) THC-CO monitoring	Allow either CO or THC monitoring for biosolids incinerators
Step Q Court remand of specific provisions of rule	(1) Chromium land application	Considering deleting chromium as a regulated metal for land application because the risk assessment did not show chromium to be a risk
	(2) 99th-percentile caps for selenium and chromium	Considering deleting chromium from the rule and changing the capped selenium pollutant concentration limit from 36 mg/kg (99th-percentile, policy-based) to 100 mg/kg (risk-based)
	(3) Special land application pollutant limits for heat-dried biosolids	At the time this document was prepared, no final decision had been made
	(4) Different ceiling concentration limits for selenium	At the time this document was prepared, no final decision had been made

Step J-1 Who Is at Risk? The "Highly" Versus "Most Exposed" Individual

Proposed Rule: For the proposed rule EPA focused its risk assessments on the ***most exposed individual*** (MEI) as the ***target organism*** (the individual at risk) to be protected from pollutants in biosolids. The MEI was defined as the individual that is most exposed to a pollutant in biosolids for a lifetime (e.g., 70 years, if the MEI was an adult person; or the critical life period of a plant or animal). Worst-case estimates of the potential for exposure were assigned to the MEI, resulting in very stringent pollutant limits in the proposed rule.

As discussed in Chapter 2, experts were critical of the risk assessments EPA used as a basis for developing the proposed Part 503 rule's pollutant limits. They criticized the use of the MEI as the target organism to be protected, the very conservative assumptions, and the overly stringent models. Some reviewers showed that the use of the MEI was so unrealistic that such an individual would not exist; hence, an assessment of risk to a nonexistent organism would not be meaningful. For example, the MEI used in developing the proposed Part 503 rule for exposure Pathway 1F (exposure Pathway 2 in the final rule's risk assessment) was a hypothetical home gardener:

- Who for 70 years produced essentially all of his or her own food grown 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 salt and pot studies.
- Who consumed foods grown in that garden for 70 years (the gardener's food consumption represented both male and female diets simultaneously, and the gardener was always at the age and physiological state for maximum ingestion for each of the food groups [e.g., pregnant, an infant, and a teen-age male]).

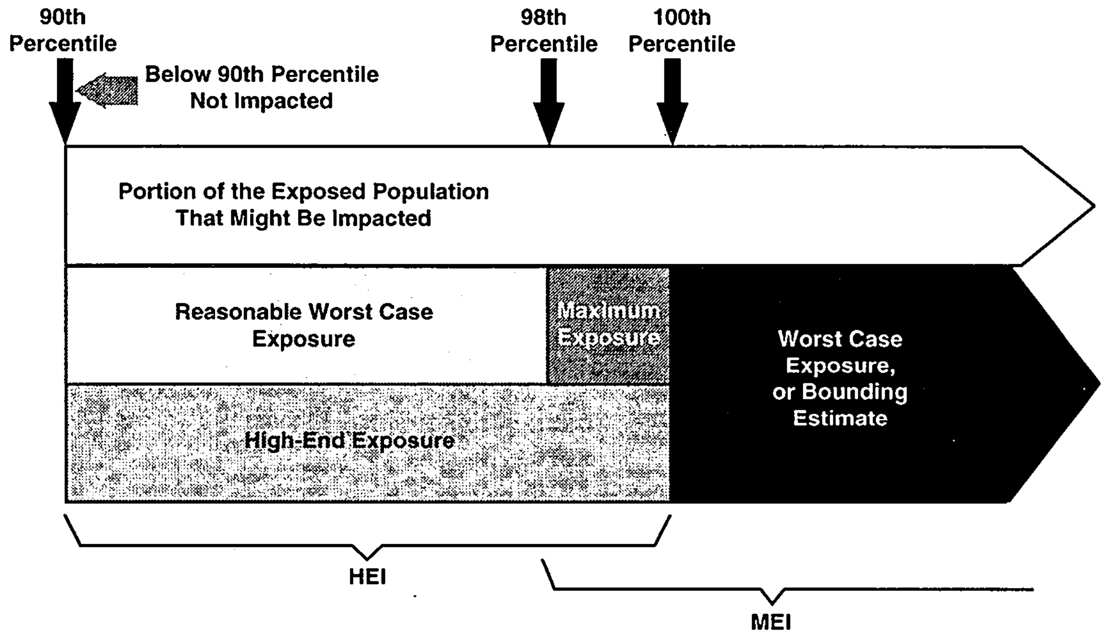
This MEI is illustrated in Figure 3. Because of the highly unlikely combination of all these conservative assumptions, this MEI very likely represents the ***worst case*** exposure (Ryan and Chaney, 1993).

Final Rule: Because of the many difficulties experienced with the MEI approach, EPA developed a new paradigm for conducting risk assessments (Habicht, 1992). This paradigm, which was used to conduct the risk assessments for the final Part 503 rule, involved the protection of a ***highly exposed individual*** (HEI) and the use of a combination of high-end and mid-range assumptions in models and algorithms. The HEI also is depicted in Figure 3. In contrast to the MEI, EPA considers the HEI to be more representative of that subset of the population of actual individuals at higher risk than the general population because the HEI models an individual who has high exposure and can exist. Contrast the data, models, and assumptions used for protecting the highly exposed home gardener (Pathway 2) during the revised risk assessments and development of the final Part 503 rule with those previously described for the most exposed home gardener (Pathway 1F). In the revised risk assessment:

- For 70 years, the home gardener HEI produced up to 59 percent of his or her own food (depending on the food group) grown in a home garden amended with biosolids.
- The biosolids-amended garden soil contained the maximum cumulative permitted application of each of the evaluated pollutants for the 70-year period.
- The food 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.
- Food consumption was apportioned among several different age groups during the 70-year life of the HEI gardener.

Figure 3

Comparisons of the Highly Exposed Individual (HEI) and the Most Exposed Individual (MEI) (adapted from U.S. EPA, 1991)



Step J-2 Cancer Risk Level Used

Risks from cancer are typically expressed as a "cancer risk level," such as 1×10^{-4} (meaning that the chance of getting cancer is 1 in 10,000) or 1×10^{-6} (meaning that the chance of getting cancer is 1 in 1 million). This number indicates the probability that one additional cancer case (over and above the background cancer risk in individuals not exposed to the pollutant source being evaluated) could be expected to occur in a population of a certain size exposed for 70 years. This level is not a scientific estimate of actual risk but a criterion designed to guide choices among regulatory alternatives. It is an estimate of the upper limits of actual risk that could exist given certain assumptions; the actual risk level is likely to be significantly less than the estimated cancer risk level, and may be zero.

Proposed Rule: EPA's initial biosolids risk assessments conducted for the proposed Part 503 rule evaluated cancer risks associated with pollutants in biosolids at risk levels of 1×10^{-4} (1 cancer case in a population of 10,000 MEIs), 1×10^{-5} (1 cancer case in a population of 100,000 MEIs), and 1×10^{-6} (1 cancer case in a population of 1,000,000 MEIs). The pollutant limits in the proposed Part 503 rule were based on risk levels of 1×10^{-4} for all use or disposal practices except incineration, which was proposed to be regulated at 1×10^{-5} because the aggregate (population) risk assessment indicated that incineration posed a higher risk than other use or disposal practices.

Final Rule: Cancer risks were reevaluated in the revised risk assessments conducted for the final Part 503 rule based on new information obtained after the initial risk assessments were conducted. The new results indicated that minimal risk exists from all current biosolids use or disposal practices, including incineration. Thus, EPA made a policy decision to regulate risks for all biosolids use or disposal practices in the final Part 503 rule at 1×10^{-4}. This risk level is the lifetime cancer risk to a highly exposed individual. EPA believes that a 1×10^{-4} risk level for cancer risks from pollutants in biosolids provides adequate protection of human health because the latest analyses did not indicate a significant carcinogenic risk to the population as a whole for any biosolids use or disposal practice. EPA estimated that biosolids use or disposal practices prior to promulgation of the final Part 503 rule could have contributed 0.9 to 5 cancer cases annually and that the rule reduces cancer cases by 0.09 to 0.7 annually (see also the questions and answers on this subject in Chapter 6.)

Step J-3 Plant Uptake of Metals: Pot/Salt Vs. Field Studies

Pot/Salt Studies Overestimate Risk

Proposed Rule: For the initial risk assessments conducted for the proposed rule, EPA relied primarily on the results of greenhouse studies in which soluble metal salts were added to soil in pots, rather than on the results of studies conducted in fields, to determine plant uptake of pollutants and phytotoxicity from pollutants in biosolids. This approach was taken in part based on the assumption that it was necessary to obtain adverse effect levels associated with uptake, otherwise the data would not be suitable for use in the risk assessment. In many cases such adverse effects data were found only in pot/salt studies and not in pot/biosolids or field/biosolids studies. Many of the field studies showed no adverse effects because of the binding of pollutants by components of the biosolids matrix. (See photographs on facing page.)

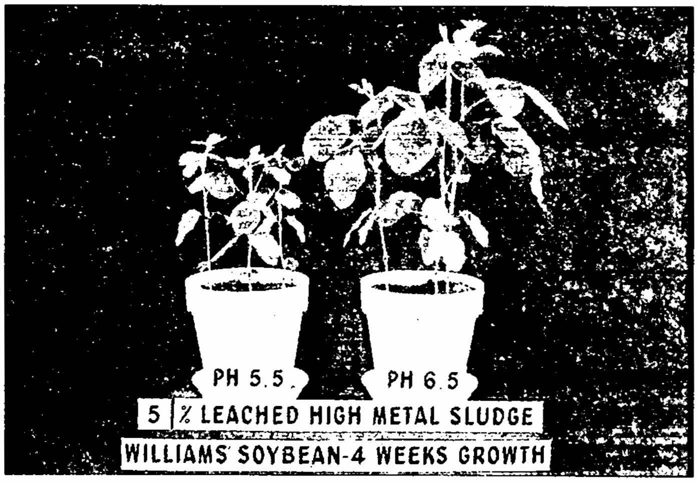
Final Rule: Careful evaluation of the data and new research conducted since the initial Part 503 risk assessments indicated that the results of metal salt and pot studies greatly overestimated phytotoxicity and the bioavailability of pollutants in biosolids (USDA/CSRS, 1989). This is because certain components in biosolids (e.g., ferric hydrous oxides, organic matter, phosphates) bind pollutants to the biosolids, making the pollutants less available to plants, animals, and humans (Corey et al., 1987; Chaney and Ryan, 1994; Mahler et al., 1987). This biosolids binding effect is not present when pure metal salts (rather than metals in biosolids) are added to soil. In addition, conditions of pot studies (e.g., plant root confinement, elevated soil temperature, rapidly changing water environment due to evaporation and transpiration) tend to increase the uptake of pollutants by plants compared to uptake under field conditions.

Plant Response to Metals

The differences between plant uptake of metals in field soils amended with biosolids versus plant uptake of metal salts added to soils in pots or in the field is also illustrated in Figure 4. When pure metal salts are added to soils, a ***linear response*** occurs (i.e., as the concentration of metal salts increases in the soil, the concentration of metal increases in plants). This is because the added metal salts are not bound as tightly by the soil as are metals in biosolids-amended soils (see description below) and therefore are taken up more freely by plant roots.

In contrast, a ***plateau response*** in plant uptake occurs when plants are grown in soil-biosolids mixtures (see Figure 4). This plateau response has been observed repeatedly in numerous field studies. With the plateau effect, the rate of pollutant uptake by plants in the soil-biosolids mixture decreases with increased biosolids-metal loadings (Chaney et al., 1982). The plateau effect occurs because the adsorptive materials in the biosolids become as important or more important than the adsorptive materials initially in the soil. Hence, the uptake slope for the pollutant levels off because more of the stronger biosolids adsorptive capacity is added for each unit of the pollutant that is added. More specifically, when soils are first amended with initial amounts of biosolids, which generally contain low levels of metals, plants and soils compete for the biosolids-bound metals and uptake of

1



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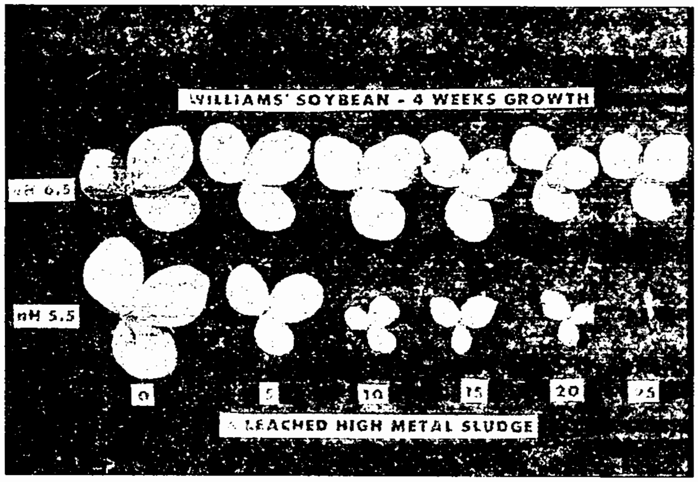

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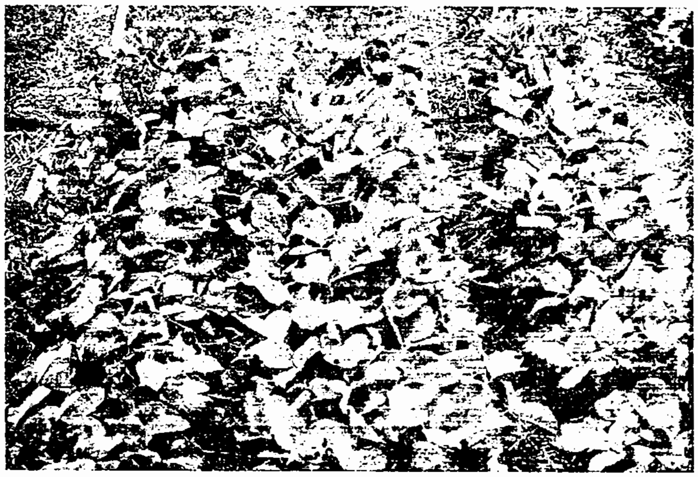
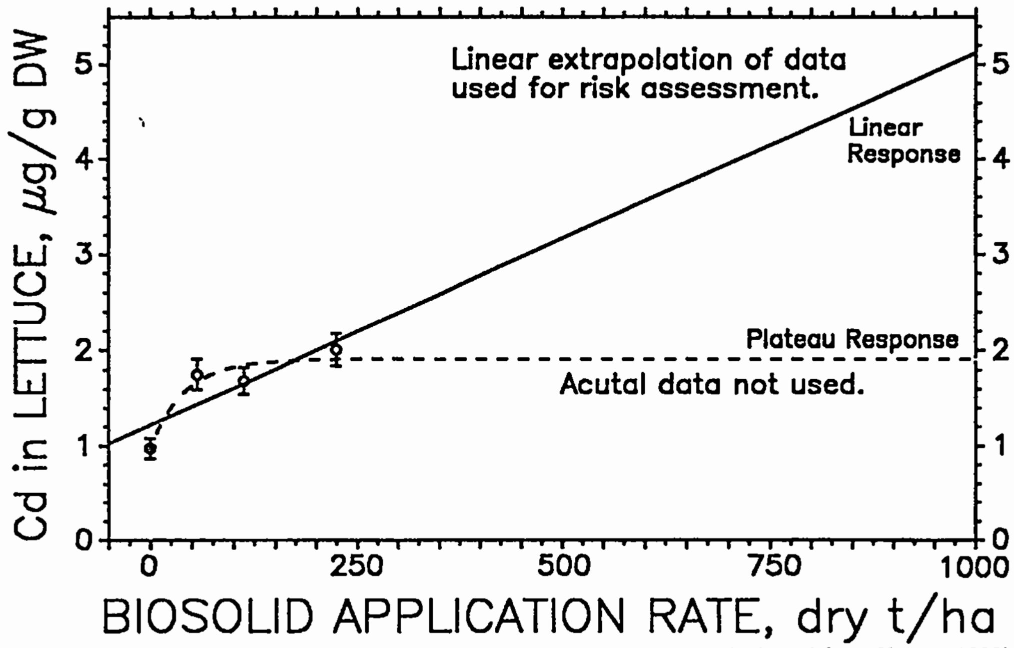


(Photographs by Rufus Chaney, USDA)

Plants respond very differently in pot studies vs. field studies. Photograph 1 shows plants grown in pot studies. The plant on the left was grown in low pH soil; the plant on the right was grown at pH 6.5. Photograph 2 is a close-up of leaves taken from the plants shown in Photograph 1, with the low pH leaves shown at the bottom. Photograph 3 shows plants thriving in the field, even though they are being grown in low pH soil. Documented field study research and operational experience were used in the biosolids risk assessment for land application for the final Part 503 rule whenever possible because these data are much more representative of real-world conditions.

Figure 4

Comparisons of the Plateau and Linear Plant Uptake Responses to Metals



(Adapted from Chaney, 1993)

metals may increase in plants (e.g., uptake appears to be linear). As more biosolids are added to the soil, the strong binding sites of the biosolids matrix become dominant over the weaker binding sites in the soil. Consequently, phytoavailability (the ability of plants to take up metals) no longer increases with further additions of biosolids, resulting in the plateauing effect. For some elements, interactions between several pollutants also hinder uptake by plants (e.g., zinc inhibits cadmium uptake).

Nevertheless, EPA continued to use the conservative linear response assumption for land application Pathways 1, 2, 4, 6, and 8 in the risk assessment for the final Part 503 rule, even though it significantly overestimates pollutant uptake by plants. Plateau regression could not be fully estimated because data were not available from field studies using different rates of application over many years. Hence, linear response was retained in the final rule. This conservative assumption of linearity was used in combination with less conservative assumptions, such as using the geometric mean (rather than the more conservative arithmetic mean) from a large number of studies to determine input values used in calculating plant uptake slopes, as described below.

Calculating Plant Uptake Slopes

Prior to calculating plant uptake slopes for pollutants in the revised risk assessment, EPA reviewed, corrected, expanded, and ranked the data from numerous studies on plant uptake (see Box 4).

Data from Type A (field) studies were used whenever available for the revised risk assessment because they best represent conditions being regulated. Nonetheless, for certain categories of studies other types of data were used. Data from Type B biosolids pot studies were used for mercury and selenium. Type C data were used for arsenic for all but "leafy vegetables," for which Type A data were used.

Box 4
EPA Plant Uptake Data Ranking Classification

Type A:	Data from studies conducted in fields where biosolids had been applied.
Type B:	Data from all other studies conducted with biosolids (i.e., field studies using biosolids spiked with additional metals; greenhouse studies using plants grown in biosolids in pots).
Type C:	Data from all other non-biosolids metals studies in the field or greenhouse (e.g., studies using metal salts or soils contaminated or geochemically enriched from sources other than biosolids).

The plant uptake slope, or response, for each study was then calculated. For studies with multiple application rates and tissue concentrations, the linear regression statistical method was used to calculate the plant uptake slope. For studies with one metal application rate and one plant tissue concentration, the uptake slope was calculated as shown in Box 5.

If the calculated uptake slope was negative or zero, a default slope of 0.001 was used. It is quite reasonable that the uptake slope of metals may be negative (i.e., that lower amounts of metals are obtained from soil by plants after biosolids are added to soils, even though the biosolids also contain the same metals). A negative slope would result from the strong binding surfaces in the biosolids matrix, which hold metals already present in soils and reduce their availability for plant uptake. The use of a minimum plant uptake slope was required for calculating geometric means. Therefore, the conservative assumption of a 0.001 minimum uptake slope allowed negative uptake data to be included in the risk assessment data set, even though that assumption caused the uptake slopes for the pollutants analyzed to be overestimated and the pollutant limits to be conservative.

Plant types were assigned to food groups (garden fruits, grains and cereals, leafy vegetables, legumes, potatoes, and root vegetables), and the uptake slope for each food group was calculated for each pollutant using the geometric mean ("average") of the uptake slopes already calculated for individual studies in the food group. Box 6 provides an example calculation.

Box 5
Sample Plant Uptake Calculation for a Study With One Observation

Algorithm:

$$Plant\ Uptake\ (UC) = \frac{Tissue\ Concentration\ (\mu g\text{–}pollutant/g\text{–}plant\ tissue,\ DW)}{Metal\ Application\ Rate\ (kg\text{–}pollutant/hectare\ of\ land,\ DW)}$$

Variables (for cadmium, swiss chard, pH 6.2 [Chaney and Hornick, 1978; CAST, 1980]):

$$Tissue\ Concentration = 1.675\ (\mu g/g\ DW)$$

$$Metal\ Application\ Rate = 4.43\ (kg/ha)$$

Calculation:

$$UC = \frac{1.675}{4.43} = 0.378\ (\mu g/g\ DW)(kg/ha)^{-1}$$

Box 6
Sample Plant Uptake Slope Calculation for a Food Group

Algorithm:

$$(UC_1 \cdot UC_2 \cdot \ldots \cdot UC_n)^{-n} = \textit{geometric mean of slopes, where:}$$

UC_n = plant uptake slope calculated in Study 1, 2, etc. for a plant species

Variables (hypothetical):

	Study 1	Study 2	Study 3
UC	0.005	0.023	0.005

Calculation:

$$(0.005 \cdot 0.023 \cdot 0.005)^{-3} = 0.0185\ (\mu g\text{–}pollutant/g\text{–}plant\ tissue\ DW)(kg\text{–}pollutant/hectare\ of\ land\ DW)^{-1}$$

Step J-4 Food Consumption

The assumptions used in the biosolids risk assessments regarding the amounts of food from different types of food groups that people consume influenced risk calculations in important ways.

Proposed Rule: For the land application risk assessment conducted for the proposed Part 503 rule, EPA used conservative dietary data to determine human exposure to pollutants in biosolids through food consumption. The risk assessment used the highest daily consumption rate of each of eight food groups (e.g., consumption of dairy products by teen-age males, consumption of leafy vegetables by adult females, milk fat consumption of infants for polychlorinated biphenyl [PCB] uptake). These assumption rates were used to calculate risks to people from consuming plants grown on soils to which biosolids were land applied or animal products from animals that had consumed such plants.

Further evaluation showed that such an approach resulted in an unrealistic "megaeater"—a person who is always of the age and physiological state for maximum ingestion of the pollutant (e.g, simultaneously pregnant, an infant, and a teen-age male, who ingests maximum rates for an entire 70-year life span). Such an approach would have overestimated exposure through dietary consumption by 3- to 10-fold.

Final Rule: EPA used an updated methodology and new data to calculate human dietary exposure to pollutants in biosolids for the final Part 503 rule (see Appendix B). This approach involved the derivation of more realistic values for dietary exposure by apportioning food consumption among several different age periods during the 70-year life of the HEI. Consistent with the new EPA paradigm for risk assessment, this less conservative but more realistic approach to assessing dietary intake was combined with both mid-range values (e.g., geometric mean of pollutant concentrations in food) and high-end, more conservative assumptions (e.g., regarding pollutant toxicity and linearity of pollutant uptake by plants) in calculations used to determine pollutant loading limits.

Step J-5 Pollutants Deleted

Organic Pollutants

Biosolids are known to contain synthetic organic chemicals (e.g., PCBs and polycyclic aromatic hydrocarbons [PAHs]).

Proposed Rule: Comments on the proposed Part 503 rule included recommendations that some of the organic pollutants proposed for regulation be deleted because the pollutants are either banned or restricted for use in the United States.

Final Rule: In response, EPA decided to reevaluate all organic pollutants proposed for regulation in the Part 503 rule. The results of this evaluation, as well as numerous research studies and the National Sewage Sludge Survey (NSSS), showed that organic pollutants occurred in biosolids in the United States at low levels that do not pose significant risks to public health or the environment. Thus, EPA decided to delete regulation of organic pollutants in the final Part 503 rule because organic pollutants met at least one of the following three criteria:

- The pollutant has been banned or restricted for use in the United States, or is no longer manufactured for use in the United States.
- The pollutant is not present in biosolids at significant frequencies of detection (i.e., 5 percent) based on data gathered in the NSSS in biosolids.
- 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.

The limits that might have been used based on the risk assessments if the organic chemical pollutants were included in the rule are listed in Table 11 (in Chapter 4).

Inorganic Pollutants

Final Rule: For surface disposal sites without a liner and leachate collection system, in addition to organics, the inorganics cadmium, copper, lead, mercury, and chromium met one of the three criteria discussed above (i.e., were not expected to exceed the levels identified in the risk assessment). Thus, EPA determined that risks from these inorganics in surface-disposed biosolids were negligible. The Agency believed that meeting these criteria protected human health and the environment from reasonably anticipated adverse effects of these pollutants in biosolids without establishing pollutant limits for them in the Part 503 rule. All pollutants, both inorganic and organic, were deleted from Part 503 regulation for surface disposal sites with a liner and leachate collection system based on the assumption that any potential migration of pollutants to ground or surface water would be precluded.

Step L Inclusion of "Pollutant Concentration Limits" (for Low-Metal Biosolids) for Land Application in the Part 503 Rule

Experts who assisted EPA in revising the biosolids risk assessments and the proposed Part 503 rule recommended including a provision that would identify biosolids containing low levels of pollutants which could be used with minimal regulatory oversight. These experts proposed levels of pollutants that, based on the risk assessment and data from field investigations, showed very low risk from land application of biosolids, even when soils were poorly managed. After reviewing these recommendations, along with results of the NSSS, which showed that pollutant levels in biosolids had dropped, EPA proposed the concept for comment. Known as the "clean" biosolids concept, this provision was adopted as part of the final Part 503 rule as "pollutant concentration limits."

Research conducted over the past decade (Chaney, 1993; Chaney and Ryan, 1991, 1993; Chang et al., 1992; Korcak and Fanning, 1985; USDA/CSRS, 1989) has clearly demonstrated that biosolids with low levels of pollutants, such as those designated by the Part 503 pollutant concentration limits, are associated with no observed adverse effects in the field. Thus, these biosolids are also known as "no observed adverse effect level (NOAEL)" biosolids. Chapter 5 discusses how the pollutant concentration limits for NOAEL biosolids were determined.

Part 503 allows NOAEL biosolids to be used with minimal regulatory oversight (i.e., additional cumulative amounts of pollutants added to land are not required to be tracked). In addition, if certain pathogen and vector attraction reduction requirements also are met, these biosolids do not have to meet Part 503 general requirements and management practices for land application. These simplified land application provisions provide an incentive to biosolids generators to improve the quality of biosolids and recycle them. EPA's ***A Plain English Guide to the EPA Part 503 Biosolids Rule*** (U.S. EPA, 1994) provides additional details on these provisions.

Step N-1 Risk From Exposure to Lead in Land-Applied Biosolids

Prior to Internal EPA Review: The critical exposure pathway for lead was Pathway 3—children ingesting biosolids that contain lead. Experts assisting EPA with the Part 503 rule initially recommended a lead limit of 300 milligrams per kilogram (mg/kg). This level was determined based on observations of absorbed and retained lead in the bodies of cows, sheep, pigs, and chickens whose diets consisted of up to 10 percent biosolids. In these studies, body burdens of lead (i.e., the content of lead in blood and bone) did not increase unless the lead concentration of biosolids fed as part of the animals' diet exceeded 300 mg/kg. It should be pointed out that if there is no increase in the blood and bone tissue, there can be no increase in any meat or milk from the ingesting animal. Hence, not only are the ingesting animals protected; individuals who might consume the meat or milk from these animals are also protected.

After Internal EPA Review: Prior to promulgation of the final Part 503 rule, there was an extended period during which an internal Agency review took place. EPA reviewers argued that the Agency should be using the ***Integrated Exposure Uptake Biokinetic*** (IEUBK) model to estimate soil/biosolids lead concentration limits that would protect against potential risks to children who ingest biosolids-amended soils. The IEUBK model is used by EPA's Office of Research and Development (ORD) to calculate protective limits against lead risks. The IEUBK model, as used for this calculation, assumed that:

- The lead blood level did not exceed 7.0 micrograms of lead per deciliter of blood (10 micrograms of lead per deciliter is the current critical level that should not be exceeded).
- The portion of the lead that is bioavailable is 60 percent as high as lead absorbed by children if they were to ingest lead from soluble lead salt sources.
- The percentage of the population that could exceed the designated blood level was 5 percent.

Using these IEUBK values, EPA calculated an allowable lead concentration in biosolids of 500 parts per million (ppm). EPA made a conservative policy decision to use the lower of the two sets of lead data—300 ppm—as the pollutant concentration limit in the final Part 503 regulation, thus providing an additional margin of safety for growing children. Studies on rats fed biosolids that contained up to 300 ppm lead per kilogram of biosolids as part of their diet (about 10 percent) have shown that the bioavailability of the biosolids-bound lead is only 5 percent as compared with the 60 percent bioavailability assumed in the IEUBK model calculations. This 12-fold overestimation of the actual bioavailability adds even more conservatism to the calculated pollutant limit.

Step N-2 "Biosolids Binding" of Pollutants: Biosolids Decrease Pollutant Phytoavailability and Bioavailability

Biosolids Binding Is Long Lasting and Reduces Risk

As previously discussed in this chapter, certain components in biosolids (e.g., iron, manganese, and aluminum oxides; organic matter; and phosphates) cause pollutants to be tightly adsorbed to the biosolids, making them less available to plants, animals, and people. This binding property of biosolids is a key reason why research studies have revealed no adverse effects when biosolids containg low levels of pollutants are land applied. Also, risks associated with phytotoxicity and bioavailability of pollutants in biosolids are relatively low when biosolids are land applied at rates commonly used in agriculture and good management practices are followed (Chaney and Ryan, 1993). For example, phytotoxicity from metals in biosolids has not occurred when biosolids have been applied to neutral, alkaline, or acidic soils in accordance with the conditions now required by the Part 503 rule. Phytotoxicity has only occurred when biosolids with high metals concentrations were land applied at high rates or when very low soil pH existed (below 5.0, near 4.5). The nutrient imbalance and phytotoxicity resulting from these two extreme conditions is readily revealed when soils are limed. These conditions are discussed later in this chapter in the section on "Ecological Risks".

A number of studies have shown that the binding properties of biosolids are environmentally stable (long term). Research has shown that biosolids continue binding metals after being added to soils and that the persistence of binding continues in the field for decades after biosolids addition ceases, even when the organic matter added to the soil with the biosolids decreases. This persistence of the increased metal-binding capacity of biosolids-amended soils also has been determined by studies of soils amended with biosolids over long periods that were collected from farmers' fields and laboratory and greenhouse studies of control soils (the same soils not amended with biosolids) (as discussed in Chaney and Ryan, 1993).

First-Year Biosolids Field Data Overestimate Risk

Not only is the binding of metals in biosolids stable, but binding increases and plant uptake of pollutants decreases over time following the last biosolids application. The highest uptake slope often occurs in the first year after biosolids application. This slope is artificially high during the first year because of metal solubilization, which results from anaerobic biodegradation byproducts and salts associated with the freshly applied biosolids (Chang et al., 1987). Thus, using first-year or short-term data on plant uptake overestimates long-term plant uptake responses. The biosolids risk assessments used long-term plant uptake data when available. Most field studies of biosolids, however, were conducted over a short period (i.e., 5 years or less) and thus the risk assessments yielded estimates of plant uptake that are somewhat conservative.

Additional Conditions That Reduce Risk

Soil-Plant Barrier: The soil-plant barrier concept (described by Chaney, 1980) indicates that plants and/or animals are protected against toxicity from biosolids-applied metals by natural processes in soils, plants, and animals. At least two different protective mechanisms are involved:

- First, some metals are so insoluble or so strongly adsorbed in biosolids-amended soil (e.g., chromium) or plant roots (e.g., lead) that they are not transferred into edible plant parts even when their concentrations are greatly increased in the biosolids/soil mixture.
- Second, when soils are strongly acidic (below pH 5.5) and when the available metal concentration is high, metals such as copper and nickel can be taken up by plants at levels that can cause phytotoxicity, in addition to the metal cadmium, which may cause harm to animals if ingested in sufficient quantity. The edible parts of these plants would be very stunted (small), or the plants would exhibit visible symptoms of phytotoxicity from high levels of metals. As a result, the quantities of such plants, and plant consumption by animals, would be reduced.

Biosolids Elemental Balance Protectiveness: Under some conditions, the soil-plant barrier protection described above does not apply (i.e., risks from excessive selenium, molybdenum, and cadmium in soils would not be prevented by the soil-plant barrier). If present in sufficient quantity in soils, these metals can be taken up by plants at high levels that do not cause toxicity to plants (if available levels of other potentially phytotoxic metals are not excessively high). Metals such as selenium, molybdenum, and cadmium are, however, potentially toxic to animals ingesting the plants if the level of these metals is sufficiently high. Fortunately, another kind of protection is available to the ingesting animals. This protection arises from the significant levels of other substances commonly found in biosolids, such as zinc, calcium, and iron. These substances are taken up by the plant along with metals such as cadmium. Zinc, calcium, and iron are beneficial to the ingesting animal and provide protection by inhibiting absorption of selenium, molybdenum, and cadmium from the ingested food into the animal's intestines and blood stream (see Box 7).

Step N-3 Ecological Risk Assessment

EPA evaluated ecological risks (potential adverse effects on plants and animals) in its risk assessment for land application of biosolids. The risk assessment used the best available ecological data from the scientific literature. Where data were extensive (e.g., on the phytotoxicity of agricultural crops), a comprehensive risk assessment was possible. Where data were more limited, such as for small wildlife and non-agricultural plants in an unmanaged environment, a much more limited approach had to be used for estimating ecological risk. Another difficulty encountered was that currently there is no universally approved procedure for assessing ecological risks.

The general approach followed in conducting the ecological risk assessment for biosolids is outlined below.

Risks to Animals

For animals, risks were evaluated for:

- Agricultural livestock ingesting crops grown on biosolids-amended soil.
- Small herbivores (e.g., deer mice) that live their entire lives in a biosolids-amended area feeding on seeds and small plants close to the biosolids/soil layer in fields, forests, and public contact sites (e.g., parks).
- Animals grazing on forages grown on biosolids-amended forest land or reclamation sites.
- Animals ingesting biosolids (i.e., soil) directly while grazing.
- Soil organisms (e.g., earthworms) living in and consuming biosolids-amended soil.

Box 7
How Diet Alters the Bioavailability of Cadmium: Experience in Japan, the United States, and New Zealand

Rice Grown in Japan

Cadmium in soil and food has been a concern since 1969 when subsistence farmers in the Jinzu Valley, Japan, experienced adverse health effects from consuming rice containing high levels of cadmium (Cd). Women in these farm families developed *itai itai* (or osteomalacia), a painful bone disease, following exposure to excessive cadmium from rice grown in paddies contaminated with mining wastes (10 µg-Cd/g-soil). These families also experienced renal tubular dysfunction (Fanconi syndrome), a disease in which low molecular weight proteins are excreted in urine because of accumulation of cadmium in the kidney cortex. Scientists now know that several circumstances contributed to these health effects:

- *The properties of rice*—The bioavailability of cadmium depends on the presence of calcium, iron, and zinc (Zn) in the rice, which when present are known to interfere with (reduce) cadmium absorption in the human intestine. Milling of brown rice into white rice removes most of these elements but little of the cadmium, thus increasing the bioavailability of cadmium in rice.
- *The diet of the Jinzu Valley farm families*—Malnutrition among the farm families during the pre-war depression, the World War II period, and the post-war depression resulted in a low intake of iron, zinc, and calcium. In addition, the water in Japan is low in calcium. These dietary factors also contributed to increased cadmium absorption from the rice consumed.
- *Properties of flooded soils in rice paddies*—Although the soil in the Jinzu Valley rice paddies was high in zinc (1,200 µg-Cd/g-soil), the cadmium in the soil was more easily oxidized and more soluble than the zinc when the flooded soil was drained. The cadmium was translocated to rice grain at high levels, while zinc remained in the soil or leaves.

Crops in Western Diets

In contrast, Western diets more often consist of substantial quantities of wheat and lettuce, which are grown in nonflooded soils, and rice that is not consumed on a subsistence basis and generally comes from many sources. Zinc always accompanies the cadmium into the edible parts of crops such as wheat and lettuce, reducing absorption of cadmium in the intestine. Usually zinc concentrations are 100 times higher than cadmium levels. Therefore, scientists consider the rice exposure cases in Japan to have no relevance for biosolids risk assessments for Western diets.

This conclusion is borne out by experience in New Zealand, where families fished for and consumed large amounts of cadmium-rich oysters, ingesting a level of cadmium (250 µg Cd/day) similar to that ingested by the farm families in Japan who developed kidney disease. But because neither oysters nor the New Zealand diet were deficient in zinc, iron, or calcium, the New Zealand families experienced no adverse health effects from cadmium ingestion. They did not develop renal tubular dysfunction or accumulate high amounts of cadmium in their kidneys, as did the Jinzu Valley farm families.

Several studies of cadmium in vegetables also demonstrate the low risk from increased cadmium concentration in crops. Morgan and Simms (1988) evaluated a mining site in the United Kingdom where garden soil cadmium levels reached 360 mg Cd/kg dry weight, resulting in cadmium concentrations in vegetables 15 to 60 times higher than in those grown in ordinary soil. This study and others, such as a study by Strehlow and Barltrop (1988) in Shipham, England, found no evidence of adverse health effects in the population consuming these vegetables. The Ca:Zn ratio was 1:200 at the mining site gardens in Shipham, England. Similar findings of no increased cadmium-induced kidney dysfunction were found for soils containing 100 mg Cd/kg at a zinc smelter in Palmerton, Pennsylvania. This community included elderly residents who had ingested homegrown garden vegetables over long periods (ATSDR, 1994). The Ca:Zn ratio was 1:100. Also, Chaney and Ryan (1994) found that only if soil cadmium levels exceeded 100 mg Cd/kg dry weight would exposure represent a potential risk to the subsistence Western gardener, based on data from a zinc smelter site. However, since the site was also contaminated with up to 10,000 mg Zn/kg, the zinc prevented the production of high cadmium crops.

Crops Grown in Biosolids-Amended Soils

Soils amended with biosolids that may contain cadmium also may contain zinc (usually at a 1:100 ratio of Cd:Zn by weight), iron, and calcium. When an animal ingests plants grown in such biosolids-amended soils, the animal obtains sufficient quantities of zinc, iron, and calcium along with the cadmium so that the absorption of cadmium is reduced in the animal's intestine. This contrasts with the high absorption of cadmium in the intestine due to diets low in zinc, iron, and calcium, such as the rice-based subsistence Japanese diets described above.

- Animals that eat soil organisms living in biosolids-amended soil (i.e., soil organism predators). Animals that eat earthworms are more highly exposed to potential risks from pollutants in soils than animals that only ingest soils because earthworms bioconcentrate pollutants like cadmium and PCBs. The initial risk assessment, conducted for the proposed rule, identified ducks eating earthworms as a key ecological target organism to be protected (i.e., the MEI); in fact, however, ducks eat grain, aquatic vegetation, and fish rather than earthworms. This was corrected in the revised risk assessment for the final Part 503 rule, which identifies shrews eating earthworms (which had assimilated and bioconcentrated PCBs) as one of the highly exposed key ecological organisms to be protected (i.e., the ecological HEI).

Other important factors in the ecological risk assessment conducted for animals included:

- The rate at which animals accumulate pollutants in their organs from consuming plants grown on biosolids land application sites.
- The maximum intake of a pollutant that would not cause a toxic effect to a most sensitive/most exposed animal; or, alternatively, determination of threshold contaminant concentrations in organs.
- The fraction of the animal diet that is biosolids or plants grown on biosolids-amended sites.
- "Bioavailability" and "bioaccumulation" factors to account for: (1) the ability of animals (particularly earthworms) to accumulate pollutants from soils; (2) the potential for animals (particularly predators of earthworms) to accumulate pollutants from other animals lower in the food chain; and (3) the binding of pollutants within the biosolids/soil mixture, which makes the pollutant less available to plants and animals (see also earlier discussions in this chapter regarding biosolids binding).

Risks to Plants (Phytotoxicity)

Pathway 8 in the biosolids land application risk assessment involves the exposure of plants to pollutants in biosolids added to soils. Adverse effects of these pollutants on plant growth and development are known as ***phytotoxic*** effects. EPA used a comprehensive approach to establish pollutant limits that would protect plants from the potentially phytotoxic metals in biosolids (zinc, copper, nickel, and chromium). Alternative procedures were used to establish these limits, and the procedure yielding the most stringent limit for a given metal was chosen as the pollutant limit for Pathway 8, the phytotoxicity pathway.

First Procedure for Determining Plant Metal Concentrations That Characterize Phytotoxicity (the Probability Approach)

Step 1: EPA searched the literature to identify plant tissue concentrations of metals associated with amount of growth. In the experiments analyzed, different species of plants were grown in nutrient solution or pots of soil with and without additions of different test metal salts for 2- to 6-week periods. The studies determined the concentrations of different metals in the vegetative tissues of various plant species associated with 8, 10, 25, and 50 percent retardation of vegetative growth, measured as shoot growth. The leaf concentration associated with ***50 percent growth reduction*** was selected as the phytotoxicity threshold (PT_{50}) for use in the risk assessment for the phytotoxicity pathway.

The PT_{50} was used because EPA determined that relatively severe initial effects (50 percent or greater growth reductions) would be necessary to correspond to later yield reductions, given that short-term growth effects do not necessarily translate into longer term yield reductions at maturity (the actual criterion used to define phytotoxicity). Exceeding the phytotoxicity threshold 1 out of every 100 times was considered acceptable. Even if the Agency had chosen a ***25 percent reduction in growth*** (PT_{25}) as the phytotoxicity threshold, the maximum loading rate (i.e., that would not exceed the threshold leaf concentrations) would not have been meaningfully different from that calculated using the PT_{50}. For example, at PT_{25} for zinc, the probability that this threshold would be exceeded at a 3,500 kilograms per hectare (kg/ha) loading rate would be 0.0011. This probability is equivalent to 1.1 chances in 1,000 (much less than 1 in 100). The probability of exceeding the PT_{50} at this same loading rate of 3,500 kg/ha would be <0.0001, or 0.1 chance in 1,000 (again much less than 1 in 100), as shown in Chart C of Box 10 (in Chapter 4). Thus, the results using PT_{25} and PT_{50} thresholds are not meaningfully different: 3,500 kg/ha would be the maximum loading rate for zinc determined using the probability approach under either threshold assumption. It is important to note that detection of significant growth reduction in the field (across seasons for any crop) of less than 25 percent—from any cause—is very difficult.

Step 2: Next, EPA used data from biosolids field experiments in which corn or soybeans had been grown. Because EPA had previously determined that uptake of metals by plants grown on biosolids-amended soils in the field cannot be simulated by plants grown in pots (see "Pot/Salt Studies Overestimate Risk," earlier in this chapter), EPA limited uptake data strictly to that obtained from field studies. EPA calculated geometric means and standard deviations of metal concentrations in plant tissues corresponding to various soil metal loadings. These data were then used to determine probabilities of reaching the PT_{50} for each metal in each plant species. ***Corn*** was selected as the focus of the analysis because more field data were available for corn than for any other plant species. A value of 0.01 was selected as an acceptable level of tolerable risk for exceeding the PT_{50} (i.e., exceeding the PT_{50} 1 out of every 100 times was considered acceptable). The probabilities of the pollutants in field-grown corn meeting or exceeding the PT_{50} threshold were significantly less than 0.01 at all biosolids loading rates analyzed, the highest of which were 3,500 kg/ha for zinc and 1,500 kg/ha for copper. An example of how the probabilities were used to select the limit for zinc is shown in Chapter 4, Box 10 (see Approach 1 and Chart C).

For chromium and nickel, the probabilities that these metal concentrations in corn leaf would exceed their PT_{50}s decreased as the cumulative loadings increased. This might be caused by dilution or by reactions of other biosolids constituents with chromium and nickel, rendering these metals less bioavailable. Because plant yields in field experiments did not show any negative effects from biosolids application (i.e., in all cases, there was no yield suppression, and in many cases yields increased), it is probable that phytotoxicity does not occur from chromium or nickel. Based on maximum loadings used in the evaluated scientific research, EPA determined that 3,000 kg/ha chromium and 420 kg/ha nickel can be safety applied without affecting corn yields.

Second Procedure for Determining Plant Metal Concentrations That Characterize Phytotoxicity (the Calculation Approach)

A problem inherent in the Probability Approach discussed above is that corn is not very sensitive to phytotoxicity from metals; thus, a second procedure also was used to characterize phytotoxicity. In EPA's second procedure, plant tissue concentrations associated with yield reduction were obtained from the literature to define an upper bound on phytotoxic effects for sensitive plant species (e.g., ***lettuce***). 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***. These concentrations were identified as the phytotoxicity threshold for each of four metals.

More specifically, using a linear response slope assumption (which is highly conservative given the plateau response actually seen for biosolids—see "Plant Response to Metals," earlier in this chapter), EPA calculated the geometric and arithmetic means for plant response to each metal, which were used to calculate the metal loading projected to result in plant tissue concentration associated with the first detectable yield reduction. The average of these geometric and arithmetic means were individually calculated for each metal as cumulative load applications in kg/ha (the phytotoxicity thresholds) (see Chapter 4, Box 10, Approach 2).

Selection of the Most Conservative Loading Rate From the First and Second Approaches as the Phytotoxicity Limit

For zinc, a mean of 2,800 kg/ha was calculated as the loading rate using the second procedure described above (the Calculation Approach; also see Chapter 4, Box 10), which was compared to the value determined using the Probability Approach (first procedure, described above). A limit was never actually reached for zinc using the Probability Approach (i.e., no phytotoxicity was observed even at the highest loading rate, so the highest loading rate analyzed, 3,500 kg/ha, was identified as a "limit"). The 2,800 kg/ha value identified by the Calculation Approach was within the upper loading range (2,500-3,500 kg/ha) of the Probability Approach, and thus 2,800 kg/ha, the more conservative rate, was chosen as an appropriate pollutant loading rate for zinc.

For copper, a mean of 2,500 kg/ha was calculated as the pollutant loading rate using the Calculation Approach, which was compared to the value identified in the Probability Approach (cumulative loading rates up to 1,500 kg/ha). The more conservative of these two values—the 1,500 kg/ha—was chosen as the appropriate limit for copper.

Similarly, for nickel, a limit of 2,400 kg/ha was calculated using the Calculation Approach as compared to 420 kg/ha for the Probability Approach. The more conservative value of the two, 420 kg/ha, was chosen as an appropriate limit for nickel.

Finally, for chromium, a limit could not be identified using the Calculation Approach. Thus, the maximum loading rate used in any experiment using the Probability Approach, 3,000 kg/ha, was used as an appropriate limit for chromium even though no yield reduction was observed using this procedure either. It should be noted that chromium will likely be dropped from the Part 503 rule due to the lack of adverse effects and a recent court action (see also the discussions on chromium in Steps P and Q of this chapter).

Holistic Review of Field Data To Determine If Phytotoxicity Limits Were Protective

A comprehensive review was made of plant metal concentration data and yields from all available biosolids field studies (U.S. EPA, 1992a), including all data reflecting various soil types and biosolids sources. This review found no instances of phytotoxicity concentration limits being exceeded nor yield reductions, even in crops that tend to accumulate metals and exhibit phytotoxicity symptoms, such as Swiss chard, lettuce, and soybeans, unless the biosolids contained very high concentrations of metals (above Part 503 ceiling concentrations) or the plants were grown in soils at very low pH.

The studies where phytotoxicity did occur were considered atypical because of abnormally high metal concentrations in the biosolids or very low soil pH. These high-metal biosolids can no longer be land applied due to pretreatment standards and/or because they are excluded from being land applied by the ceiling concentration limits in the Part 503 rule. In addition, the agricultural use of soils with low pHs (below 5.5) is unlikely because normal agronomic practice calls for maintaining soils above pH 6.0 to prevent the solubilization of naturally occurring metals in soil, such as aluminum and manganese; these metals can have a significant toxic effect on plants (whether or not biosolids are used). Hence, data from these atypical field studies were not used in developing the final phytotoxicity pollutant limits.

Risks to Soil Microbes?

Most studies have shown no adverse effects on soil microbial activity associated with metals in biosolids or soil (including nitrification and mineralization of nitrogen, as well as normal development and functioning of nitrogen-fixing bacteria for legumes, other than white clover). In one study, however, on land known as the Woburn experimental plots in England, a strain of *Rhizobium* lost its ability to fix nitrogen on one strain of white clover. This loss in ability was noted after a 19-year period of biosolids application with moderately high concentrations of metals (e.g., 100 mg Cd/kg biosolids and 3,000 mg Zn/kg biosolids) to sandy soil on which vegetable crops were being grown. (Nitrogen-fixing microbes are important in agriculture and the environment. They have the unique capability, while in symbiosis in nodules on the plant root, of converting nitrogen gas from the air into organic nitrogen, rather than requiring the plant to absorb fertilizer nitrogen from the soil. The organisms live on the root in irregular, rounded, lump-shaped growths with mutual benefit to both the microbes and plant.)

At the Woburn experimental plots, biosolids were applied from 1942 to 1961. The unique circumstances of the field plots and the findings are as follows:

- No legumes have been seeded into the plots since the initial year of biosolids application, and no new soil microorganisms had been deliberately introduced to the plots for over 20 years after the last application of biosolids.
- Researchers have studied the different species of crops that have grown on these plots long after cultivation of vegetable crops and additions of biosolids ceased, and they have found:
  - One strain of naturally occurring *Rhizobium* on one strain of white clover and one strain of blue-green algae were not capable of fixing nitrogen.
  - Regarding the strain of *Rhizobium* affected, no phytotoxicity occurred to the white clover if nitrogen fertilizer was added.
  - If the plots were inoculated with *Rhizobium leguminosarum* biovar *trifoli* (an effective strain of *Rhizobium* that can form nodules with a group of plant species that includes white and red clover and *Phaseolus* beans, among others), normal nodule formation and fixation of nitrogen occurred (McGrath et al., 1988).
  - After inoculation, effective strains of *Rhizobium* persisted in the soils, at least as long as clover was regularly grown on the soil (Angle et al., 1993).
- Strains of white clover *Rhizobium* on the Woburn plots are considerably more sensitive to zinc and cadmium than United States strains studied under similar conditions (Angle et al., cited in Chaney and Ryan, 1993).

Several studies have found effective strains of white clover *Rhizobium* in farm fields rich in metals. One such study involved soils near a zinc smelter in Pennsylvania, where zinc and cadmium levels in the soil were much higher than in the Woburn study (Angle and Chaney, 1988; Angle et al., in Chaney and Ryan, 1993). Another similar study was reported by Obbard and Jones (1993).

Other research on mine spoils with high levels of metals, analogous to free metal salts in soil, has shown that nitrogen fixation was inhibited in free-living bacteria (Rother et al., 1982), but not by white clover *Rhizobium* until metals levels were so high that phytotoxicity to white clover plants was observed. For all the above reasons, EPA concluded that it was not appropriate to use data from the Woburn study to limit metal applications for the Part 503 rule.

A new study (Ibekwe et al., 1995) provides strong evidence that biosolids were not the cause of *Rhizobium* becoming ineffective on the Woburn plots. Instead, researchers determined that low soil pH caused selection of ineffective strains of *Rhizobium* in both experimental controls (soils without biosolids added) and biosolids-amended soils.

Additional Ecological Monitoring Research

As noted earlier in this section, ecological data are limited. Moreover, at the time the Part 503 risk assessments were conducted, EPA did not have an Agency-wide approved procedure for conducting comprehensive ecological risk assessment. As a result, the biosolids risk assessments did not examine effects on species populations or communities; however, EPA did use the best available data on toxicity to wildlife and plants from pollutants in biosolids in its ecological risk assessment. In so doing, EPA evaluated risks to the most sensitive or most exposed species for which such toxicological data existed. EPA believes that its approach of using only toxicity and uptake data for the *same* sensitive species was both appropriate and protective of the environment. EPA did not believe that it was appropriate to apply pollutant toxicity data obtained for one highly sensitive species to another unrelated species in situations where exposure and uptake or ingestion was known to be very high but the pollutant toxicity data were unknown.

As is always the case with limited data sets, additional experimental data would be desirable. To improve its ability to consider ecological risk from land application of biosolids in the future, EPA has committed itself to conducting and supporting work by others on the ecological impacts of biosolids use. EPA also is working on the further development of a methodology that can gain widespread approval for use in conducting full ecological risk assessments. Biosolids-related ecological research on which EPA will be focusing includes:

- Validation of ground-water models
- Validation of surface-water runoff models
- Further investigation of the nature and ability of biosolids matrices to bind metal pollutants
- Further review of the procedures for determining phytotoxicity
- Further evaluation of ecosystem impacts resulting from the land application of biosolids

Step N-4 Allow Use of PSRP and PFRP for Regulating Pathogens

The regulation of pathogens (e.g., disease-causing organisms such as bacteria and enteric viruses) in the final Part 503 rule is not based on a risk assessment because methodologies had not been developed sufficiently to make such calculations. Instead, the Part 503 pathogen operational standard, which is non-risk based, includes pathogen controls and monitoring requirements for all biosolids, and crop-harvesting, animal grazing, and site-access restrictions for certain biosolids. This operational standard was based on extensive experimental data and years of experience and, in the judgment of EPA, is protective of public health and the environment.

Proposed Rule: For the proposed rule, EPA recommended extensive monitoring of pathogens using one of several different monitoring alternatives. The proposed rule did not permit the use of the older, established processes prescribed in EPA's

Part 257 rule to significantly reduce pathogens (PSRP) or to further reduce pathogens (PFRP).

Final Rule: The final rule permits a combination of monitoring requirements and PSRP and PFRP approaches for controlling pathogen densities in biosolids. The Part 503 rule is different from the Part 257 rule in that it contains separate requirements for pathogen reduction and vector attraction reduction. A more complete description of the requirements for controlling pathogens and vector attraction may be found in ***A Plain English Guide to the EPA Part 503 Biosolids Rule*** (U.S. EPA, 1994) and ***Control of Pathogens and Vector Attraction in Sewage Sludge (Including Domestic Septage) Under 40 CFR Part 503*** (U.S. EPA, 1992d).

Step N-5 Regulation of Non-Agricultural Land Application of Biosolids

Proposed Rule: To protect public health and the environment from pollutants in biosolids at non-agricultural land application sites (e.g., forests, reclaimed lands, public contact sites) or at surface disposal sites, EPA proposed a policy-based approach in which pollutant limits were set so that they did not exceed the 98th-percentile concentration of pollutants found in the "40 Cities Study" (see Chapter 2). This approach was recommended because low risk to humans and domestic livestock was expected, given that exposure to pollutants in biosolids at such sites was negligible and pollutant concentrations were found to be low in most biosolids. This approach also was proposed because a risk assessment methodology for such sites did not exist.

Commentors reacted critically to the proposed 98th-percentile approach. They acknowledged that on a simplistic level the 98th-percentile limit would only result in elimination of 2 percent of biosolids from non-agricultural land application or surface disposal. The commentors pointed out, however, that it often was a different 2 percent (of the 26 pollutants proposed for regulation in biosolids) that would be eliminated from use or disposal by this non-risk-based approach, and as many as 52 percent of biosolids could theoretically be eliminated from land application (see Box 8).

Final Rule: The 98th-percentile approach for regulating non-agricultural application and surface disposal was dropped from the final rule because of the difficulties described above. In addition, refined modeling techniques had been developed that the Agency used to conduct formal risk assessments for non-agricultural land application and surface disposal. Hence, in the final Part 503 rule, pollutant limits for non-agricultural land and surface disposal were risk based.

Prior to establishing the final Part 503 risk-based limits for land application of biosolids, the risk-based limits for non-agricultural and agricultural land application were compared and found not appreciably different. Hence, EPA decided to simplify the final rule by using only one set of limits for both types of land application. EPA selected the most stringent of the non-agricultural or agricultural land application limits for each pathway, on which the Part 503 pollutant limits were based regardless of whether the land is being used for agricultural or non-agricultural purposes.

Step N-6 Ceiling Concentration Limits and Caps on Pollutant Concentration Limits

Ceiling Concentration Limits Set After ORD Review

ORD raised an important issue during its final review of the Part 503 rule prior to promulgation regarding the representativeness of the selected plant uptake data. ORD's concern arose because data from experiments involving the use of

Box 8
Potential Impact of a 98th-Percentile Approach on a Biosolids Data Set

- A hypothetical data set contains 100 biosolids and 26 regulated pollutants.
- If there was only one regulated pollutant in the data set of 100 biosolids, then the two biosolids with the highest concentrations of that pollutant would be prohibited from being applied to non-agricultural land or surface disposed, based on the 98th-percentile approach. (It should be pointed out that this prohibition would be imposed regardless of whether those levels were high enough to pose a risk to public health or the environment.)
- Theoretically, if there were 10 regulated pollutants, 20 different biosolids could be prohibited from being applied to non-agricultural land or surface disposed.
- With 26 regulated pollutants, 52 different biosolids could be prohibited from being applied to non-agricultural land or surface disposed using this approach.
- An evaluation of a Michigan data set containing analyses of over 200 biosolids samples revealed that nearly 40 percent of the biosolids from POTWs in that data set would have been prohibited from being applied to non-agricultural land or surface disposed if non-risk-based 98th-percentile concentration limits were the final pollutant limits in the Part 503 rule.

Thus, the 98th-percentile approach was dropped. Part 503 pollutant limits for non-agricultural land application and surface disposal were based on risk assessments.

biosolids with high pollutant concentrations were not included in the data set. EPA did not include these data because they were viewed as nonrepresentative (i.e., uptake of pollutants from high-pollutant concentration biosolids is more like uptake from metal salt and pot studies, discussed earlier in this chapter). To overcome the potential problems associated with phytotoxicity data from soils amended with biosolids containing high pollutant levels or from metal pot/salt studies, a policy decision was made to establish 99th-percentile ***ceiling concentration limits***. These ceiling limits preclude land application of biosolids if any of the regulated pollutant concentrations in the biosolids are greater than the 99th percentile of the pollutant concentrations in the NSSS or the calculated risk-based pollutant concentrations, whichever is the least stringent (also see Chapter 5).

Caps: A Risk Management Decision

EPA also chose to include ***caps*** (as pollutant concentration limits for land application, discussed earlier in this chapter and in Chapter 5) at levels that were previously calculated as permissible by the risk assessment. The pollutant concentrations calculated by the risk assessment were compared with the 99th-percentile pollutant concentrations in the NSSS. If the 99th-percentile concentration was more stringent than the pollutant concentration identified by the risk assessment, as was the case for chromium and selenium, then the 99th-percentile number was used to cap (reduce) the calculated risk-based concentration and became the concentration limit for that pollutant. If the risk assessment limit was more stringent than the NSSS level, the risk assessment number was used as the pollutant concentration limit. For chromium and selenium, these determinations will likely be moot because of court determinations described in Steps P and Q of this chapter.

Additional Discussion

The ceiling concentration limits and the caps on pollutant concentration limits in biosolids in the Part 503 rule provide an additional margin of safety. The ceilings and caps also help ensure that the quality of current biosolids is maintained. The

Corn grown without biosolids (left), compared with corn grown in biosolids-amended soil (right).

decision to use the 99th-percentile ceiling limits and caps was a policy decision, although (as described above) the use of these limits ensures that the biosolids being used have pollutant concentrations consistent with the biosolids field data used for the risk assessment. EPA chose the 99th-percentile rather than the 98th-percentile limits for caps and ceiling limits for the final rule to reduce the impact on wastewater treatment facilities. If ceiling limits and caps had been set at the 98th percentile of the NSSS data, a significantly greater percentage of biosolids generated in the United States would have been precluded from land application (see Box 8). Because neither percentile is risk-based, the less restrictive 99th-percentile limit was chosen. Other means of encouraging the further reduction of metal content in biosolids include the reduced Part 503 regulatory requirements for biosolids meeting pollutant concentration limits and Class A pathogen requirements; guidance provided to biosolids generators; and the continued emphasis on pretreatment and source reduction. As stated above, the determinations pertaining to caps will likely be moot because of court determinations described in Steps P and Q below.

EPA believes that the 99th-percentile approach is appropriate for ceiling concentration limits, given that it prohibits the most contaminated biosolids (which act more like metal salts) from being land applied. This approach supports the selection of data from biosolids field experiments used for the risk assessment, which did not include biosolids with the highest metal content and also did not include metal pot/salt studies.

Step N-7 Protection of Ground Water From Excess Nitrogen

Ground water is protected from biosolids with nitrogen levels in excess of estimated crop needs by the Part 503 rule's requirement that biosolids be land applied at the agronomic rate. Ground water also is protected by Part 503's requirement that nitrate-nitrogen be monitored at biosolids surface disposal sites.

Some commentors on the biosolids rule proposed assigning a fraction of the nitrate-nitrogen Maximum Contaminant Level (MCL) for ground water (which is 10 ppm) to biosolids that are used or disposed. EPA found no basis for such an assignment. Therefore, as EPA does for all pollutant sources of nitrate-nitrogen, the Agency assigned the entire 10-ppm MCL for nitrate-nitrogen content in ground water to biosolids. The Agency agreed to review this decision based on further analysis at a later time.

Step N-8 Management and Regulation of Nutrients

The Part 503 requirement for the application of biosolids at the agronomic rate appropriate for the yield and crop being grown is consistent with sound management of the nutrient nitrogen. Although EPA considered using the Part 503 rule as part of an overall nutrient management model (i.e., for regulating the application of a number of nutrients from various sources), the Agency made a policy decision not to address this complex issue in the Part 503 rule. Many other sources of nutrients would need to be involved in a nutrient management program (e.g., chemical fertilizers, animal manures, other wastes), which EPA does not have the authority to regulate under the Clean Water Act. Moreover, EPA believes that other agencies and knowledgeable parties should be involved in developing such a program. In addition, EPA felt that biosolids should not be singled out from other nutrient sources, particularly because biosolids tend to pose less of a public health and environmental risk due to lower nutrient levels in biosolids than many other sources and because currently no EPA nutrient requirements address these other sources of nutrients.

Step P USDA Comments, EPA Revisions

Issues regarding the final, promulgated Part 503 rule were raised by a number of outside commentors. Some of the issues and recommendations by the U.S. Department of Agriculture (USDA) are presented below to illustrate the interaction between risk assessment and risk management in establishing the Part 503 pollutant limits.

Cadmium: USDA recommended that the ceiling concentration limit for cadmium in biosolids land applied to soils be limited to 21 mg-Cd/kg-soil, dry-weight basis, rather than the current Part 503 limit of 39 mg Cd/kg.

USDA noted that certain European Union (EU) and other potential international markets for U.S. grains and sunflower kernels have established very low cadmium concentration limits for imported grains, even though no risk has been identified from ingestion of grains with such low cadmium levels in careful scientific research. Hence, grains produced in the United States with cadmium contents in excess of the imposed standards of other countries could not be exported to those countries. USDA agrees that grain produced on soils amended with biosolids containing 39 mg Cd/kg does not pose a risk (unless the cadmium to zinc ratio is much higher than normal levels [<0.0145]). Nonetheless, because of these international market restrictions, USDA has recommended lowering the cadmium limit. USDA suggests that a 21 mg Cd/kg limit would be relatively easy to attain given that 91 percent of U.S. wastewater treatment facilities that generate biosolids could meet this limit (based on data from the NSSS).

USDA pointed out that exporting grains containing cadmium is already a problem because some regions of the United States currently cannot meet the EU limits due to naturally occurring levels of cadmium in soils. In addition, certain crop species accumulate higher cadmium levels in their grain than do other crops. USDA is concerned that use of biosolids containing levels of cadmium as high as 39 mg/kg (particularly on acidic soils, which may result in plants taking up more cadmium) could further exacerbate current exportation problems by causing the production of even more grains with cadmium levels above the EU limits.

Changing the limit from 39 mg Cd/kg could be problematic because, as discussed in the next section (see "Provisions of the Rule Remanded by the Court"), the court challenged EPA's use of non-risk-based means for setting certain limits. USDA and EPA are planning to issue guidance on this issue.

Molybdenum: USDA also recommended that EPA reduce the ceiling concentration limit for molybdenum (Mo) in biosolids to 54 mg Mo/kg, the 98th percentile in the NSSS. This recommendation was made because some of the field studies from which plant uptake slopes for molybdenum for sensitive crop species were calculated did not involve alkaline soil pH. USDA was concerned that because molybdenum uptake is much greater at pH 8 than at pH 7, an HEI ruminant animal might not be protected from biosolids with higher concentrations of molybdenum applied to alkaline soils.

EPA deleted all requirements from the Part 503 rule for molybdenum except the ceiling concentration limits as a result of the February 25, 1995, amendment, pending careful additional study and consideration of new data (see Chapter 2). No final decision on establishing new pollutant limits for the deleted molybdenum limits had been reached by EPA at the time of this document's preparation. EPA does not expect to change the existing ceiling concentration limit for molybdenum.

98th Instead of 99th Percentile as a Cap on Pollutant Concentration Limits: USDA believes that lowering the cap on pollutant concentration limits for additional protection (from the current 99th percentile to the 98th percentile, as was previously proposed by EPA) would be a prudent policy decision.

The recent remand by the court that would preclude EPA's use of policy-based 99th-percentile NSSS concentration limits as caps to pollutant concentration limits would suggest that use of 98th-percentile NSSS concentration limits as caps would not be possible (see Step Q below on court remands).

Annual Pollutant Loading Rate Limits: USDA recommended that annual pollutant loading rate (APLR) limits should be deleted from the final Part 503 rule. USDA pointed out the limited usefulness of the APLR approach for regulating the use of biosolids in bags or containers, which was originally devised prior to the development of the "pollutant concentration limit" approach (discussed earlier in this chapter and in Chapter 5). USDA recommends deleting the APLR approach because its use would allow distribution to the public of biosolids containing higher levels of pollutants than the pollutant concentration limit approach.

EPA believes that the likelihood of the APLR approach being used has greatly diminished now that the pollutant concentration limit approach has been adopted in the final rule. The Agency has made no decision about whether to drop the APLR approach from the rule at the time of this document's preparation.

Chromium: USDA has recommended that chromium limits be deleted from the Part 503 rule because there is no evidence of damage to plants or animals from the levels of chromium currently found in biosolids. The court remanded the chromium limits to EPA for modification or additional justification.

EPA plans to delete all chromium limits for land-applied biosolids from the Part 503 rule. An important reason for imposition of the chromium limits by EPA was a policy-based desire to reduce levels of chromium in wastewater effluents and biosolids via pretreatment.

Soil pH: USDA recommended that EPA reconsider its decision not to impose soil pH requirements in the Part 503 rule for biosolids that contain an insufficient lime equivalent to neutralize the acidity generated during oxidation of biosolids in biosolids-amended soils.

EPA has decided not to make this recommended change. (See also the discussion regarding pH earlier in this chapter.)

Selenium: USDA recommended limiting the addition to soil of selenium in biosolids to 28 kg/ha to avoid excessive plant uptake and possible poisoning of certain sensitive livestock or wildlife.

No decision on this issue had been reached by EPA at the time of this document's preparation.

Arsenic: USDA recommended increasing the pollutant concentration limit for arsenic in the Part 503 rule because the conservative policy decision to use a relative effectiveness (RE) value of 1 (i.e., implying that arsenic is highly bioavailable, see Chapter 4) caused the current Part 503 pollutant concentration limit to be much lower than if calculated using experimentally derived RE values (i.e., the bioavailability of biosolids-applied arsenic is much lower than assumed).

EPA has no current plans to change the pollutant concentration limit for arsenic in the Part 503 rule.

Step Q Lawsuits, Provisions of the Rule Remanded by the Court

The provisions of the Part 503 rule remanded to EPA for modification or additional justification by the court are still applicable while EPA studies the remanded issues and decides whether to (1) agree with the court recommendations, (2) justify the provisions, or (3) recommend no or partial change. The remanded provisions are summarized below.

Chromium: The court stated that EPA should drop chromium from the Part 503 rule because the biosolids risk assessment did not identify any chromium level associated with risk to public health or the environment. EPA agrees and plans to delete all chromium limits for land-applied biosolids from the Part 503 rule.

Selenium: In response to the pleadings of a plaintiff that the EPA selenium limits posed a special hardship to certain communities because of naturally occurring high levels of selenium in the area, the court reviewed the various selenium limits in the rule. The court stated that the capped 99th-percentile pollutant concentration limit for selenium was based on a policy decision and should be eliminated. In light of other comments by USDA that the current ceiling limit is too high and may cause a problem for animal life (see preceding section), EPA has a difficult decision to make. If the only basis for lowering the limit is a policy decision, EPA may recommend changing the capped selenium pollutant concentration limit from 36 to 100 mg/kg biosolids.

The court also remanded to EPA the potential for a special provision to allow increased selenium pollutant limits on public contact sites with a low potential for exposure.

Heat-Dried Biosolids: The court remanded to EPA the issue of whether to establish a special provision that would set higher pollutant concentration limits for heat-dried biosolids. The reason for the remand was a plaintiff's pleading that heat-dried biosolids would always be used at low rates and therefore should be allowed higher pollutant concentration limits. Most likely, EPA will not make this change.

Dedicated Beneficial Use of Biosolids: The court asked that EPA consider moving the category of "dedicated beneficial use of biosolids" from the surface disposal to the land application section of the Part 503 rule. A plaintiff argued in his pleading to the court that having dedicated beneficial use of biosolids in the surface disposal section of the Part 503 rule is very detrimental to efforts for gaining public acceptance for using biosolids to improve highly acidic disturbed lands that are also particularly low in organic matter and plant nutrients.

The court agrees that EPA does not need to move the "dedicated beneficial use of biosolids" category from the surface disposal to the land application section of the rule. Moving this category to the land application section of the rule, however, would help encourage beneficial use of biosolids and reclamation of disturbed lands, another important EPA goal. No decision on this issue had been reached by EPA at the time of this document's preparation.

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Chapter 4

How the Risk Assessments Identified Pollutant Limits for Biosolids

The goal of the Part 503 biosolids risk assessments was to establish risk-based pollutant limits that protect human health and the environment from reasonably anticipated adverse effects of pollutants in biosolids. EPA used four types of information in its biosolids risk assessments:

- ***Available Scientific Data*** (e.g., toxicity factors commonly used by EPA, such as RfDs or q_1*s, were used to identify adverse effects associated with specific concentrations of pollutants; field study data were used to determine plant uptake of pollutants from biosolids-amended soils).
- ***Assumptions*** when specific information was not available (e.g., 70-year lifetime exposure was assumed for most pathways; assumptions were made regarding quantities of food grown on land amended with biosolids; and linear uptake of pollutants by plants was assumed).
- ***Policy decisions*** when specific scientific data regarding risks were unavailable (e.g., a cancer risk level of 1×10^{-4} was used).
- New or existing ***methodologies*** (e.g., development of a new method for estimating food consumption; for the ground-water pathway, the VADOFT and AT123D computer models were used to estimate pollutant transport through the environment).

How Pollutant Limits Were Derived in the Revised Risk Assessments

This chapter explains how EPA used the revised biosolids risk assessments to develop pollutant limits for evaluated exposure pathways, from which the final Part 503 pollutant limits were selected. The process of developing pollutant limits involved:

- Determining and defining factors to be used in calculating pollutant limits
- Selecting key data, assumptions, and methods to be used, and making related policy decisions as needed

- Performing risk assessment calculations

In describing each of these steps, this chapter provides example risk assessment calculations for several exposure pathways; explanations of how a Part 503 pollutant limit was selected for land application, surface disposal, and incineration of biosolids; and a detailed discussion of the risk assessment conducted for cadmium in land-applied biosolids, exposure pathway 2.

Parameters, Assumptions, Policy Decisions, and Methods Used

The biosolids risk assessments used a series of ***algorithms***, or equations, that mathematically represented each exposure pathway to calculate pollutant limits. A biosolids ***pollutant limit*** is the pollutant loading rate or concentration of a particular pollutant in biosolids that would not be expected to harm public health or the environment via the pathway being evaluated when biosolids are land applied or placed on a surface disposal site. Pollutant limits for the incineration of biosolids protect only public health because ecological pathways were not evaluated.

Each set of algorithms contained a sufficient number of ***parameters*** (appropriate input factors) for calculating the pollutant limits. Some of the parameters used in the algorithms were readily available, such as standard toxicity factors used by EPA (i.e., RfDs or q_1*s). Other parameters had to be calculated using an appropriate methodology, or were selected based on assumptions and/or policy decisions. An example of an assumption is the percentage of food grown on biosolids-amended soils—known as the FC parameter.

Table 6 (in Chapter 2) summarizes the exposure pathways used in the risk assessment for land application and provides a quick reference regarding when certain parameters were used (e.g., for pathways evaluating human, animal, or plant exposures.) For more information on the development of the exposure pathways, see Chapter 2.

Land Application Risk Assessment

All of the parameters used in the different algorithms for conducting the biosolids land application risk assessment are defined in Appendix A. The methodologies (i.e., approach or basis), assumptions, and policy decisions used to establish numeric values for the parameters in the land application risk assessment are described in Appendix B; this table also indicates whether a parameter is conservative or average, and why. How these parameters were used is discussed below.

Risk Assessment Calculations

For all exposure pathways for land application, an allowable dose of each pollutant was identified (e.g., based on an RfD or q_1* for humans; or an appropriate representation of allowable dose for animals, such as a "threshold pollutant intake," or TPI). Initially, this allowable dose included pollutant exposure from all sources (biosolids, food, air, and water). Exposure from sources other than biosolids were then subtracted from the total allowable dose. The resulting value indicated the allowable dose of a pollutant from biosolids only (e.g., an RIA, see Appendices A and B). This health parameter 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.

The selected or calculated values for the parameters (e.g., see Box 9, Chart A, and Box 10, Chart B) were used in algorithms specific to each exposure pathway to calculate pollutant limits. For many of the exposure pathways, calculating pollutant limits involved two or more algorithms. For example, the first algorithm might involve calculating a health-based parameter (e.g., an RIA), followed by one or more interim calculations that relate the health parameter to a pollutant concentration, and a final algorithm that calculates a pollutant limit (an RP or RSC).

Examples of several biosolids risk assessment calculations for land application are shown in Boxes 9 through 14. These examples illustrate how different parameters and algorithms were used to calculate limits for organic and inorganic pollutants that would protect humans, animals, and plants from reasonably anticipated adverse effects via the different exposure pathways. As shown in Box 9, two algorithms were needed to calculate the pollutant limit for arsenic for exposure involving an adult eating crops via Pathway 1. As shown in Box 14, seven different algorithms were needed to calculate the PCB pollutant limit for an adult drinking surface water and ingesting fish from water that had been subjected to runoff from biosolids-amended soils.

Approach Used for the Surface Disposal Risk Assessment

Thus far, examples of how the biosolids risk assessments were conducted have focused on land application. Somewhat different approaches were used to determine pollutant limits for surface disposal and incineration of biosolids, as discussed below.

The risk assessment for surface disposal of biosolids evaluated risks associated with:

- ***Monofills*** (which contain biosolids with a solids content generally of 20 percent or greater) and ***surface impoundments*** (which contain liquid and sediment layers), both lined and unlined, to represent the variety of surface disposal sites.
- Human exposure to pollutants in biosolids through ***ground water*** (from drinking water from different classes of ground water, i.e., Class I, II, and III, according to EPA's ground-water classification system). For the ground-water pathway, lined units generally reduced pollutant transport risks to ground water but increased volatilization risks.
- Human exposure to pollutants in biosolids through ***inhalation of air*** containing pollutants present in biosolids (the vapor, or air, pathway).

Risk-based criteria were developed for Class I and Class II/III ground water. A framework established by EPA for federal and state policymaking efforts concerning ground-water protection (*Ground-Water Protection Strategy*, 54 FR 5812, February 6, 1989) provides the following category definitions:

- *Class I.* An existing source of drinking water of unusually high value that is vulnerable to contamination and is either irreplaceable as a source of drinking water for substantial numbers of people or is ecologically vital (i.e., as habitat for rare or endangered species).
- *Class II.* All non-Class I ground water currently used for, or potentially available for, drinking water.
- *Class III.* Ground water that is not being used as a source of drinking water due to high concentrations of total dissolved solids or pollutants or because the yields are too low to meet the needs of an average household.

Upon completion of the biosolids risk assessment, EPA made a policy decision to regard all ground water as drinkable in accordance with EPA's Class II designation.

Box 9
Example Risk Assessment Calculation: Arsenic for an Adult Person Ingesting Crops Grown in Biosolids-Amended Soils (Pathway 1)

This example illustrates the method used to calculate pollutant limits for inorganic, noncarcinogenic pollutants.

Goal: Calculate the amount of pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without reasonably anticipated adverse effects to humans. This level is defined as the *reference application rate of a pollutant (RP)*. If the pollutant in question is inorganic (like arsenic), then it does not degrade in the environment but accumulates as additional biosolids are added to soils.

Note: The exposure pathway discussed in this example is Pathway 1, in which biosolids are applied to soils, plants are grown in the biosolids-amended soils, and humans eat the plants grown there. Appendices A and B provide additional information on how the parameters presented below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3$$

$$\begin{matrix}\textit{Adjusted reference} \\ \textit{intake of pollutant} \\ \textit{in humans (RIA)}\end{matrix} = \left(\frac{\begin{matrix}\textit{Oral} \\ \textit{reference} \\ \textit{dose (RfD)}\end{matrix} \times \begin{matrix}\textit{Body} \\ \textit{weight} \\ \textit{(BW)}\end{matrix}}{\begin{matrix}\textit{Relative effectiveness of} \\ \textit{ingestion exposure (RE)}\end{matrix}} - \begin{matrix}\textit{Total background} \\ \textit{intake rate from} \\ \textit{all sources (TBI)}\end{matrix} \right) \times 10^3$$

RIA = Amount of additional pollutant ingested by humans without expectation of adverse effects (i.e., the allowable dose).
RfD = Amount of intake of a noncarcinogenic, usually inorganic, pollutant without appreciable risk. RfDs usually are developed in specialized, small animal studies to determine the level of a pollutant above which toxic responses begin to occur. These studies involve extrapolation and the application of safety factors to estimate the safe level of pollutant intake by humans.
BW = Human body weight.
RE = Relative effectiveness of exposure, which accounts for differences in bioavailability if a pollutant is ingested in food or water or is inhaled. Because of limited data, this value was set at 1.0.
TBI = Total pollutant intake from all background sources in water, food, and air.

Step 2:

$$RP_C = \frac{RIA}{Sum(UC \cdot DC \cdot FC)}$$

$$\begin{matrix}\textit{Reference cumulative} \\ \textit{application rate of} \\ \textit{pollutant } (RP_C)\end{matrix} = \frac{\textit{Adjusted reference intake of pollutant in humans (RIA)}}{\sum \begin{matrix}\textit{Uptake response} \\ \textit{of pollutant} \\ \textit{in plants (UC)}\end{matrix} \times \begin{matrix}\textit{Daily dietary} \\ \textit{consumption of} \\ \textit{food group (DC)}\end{matrix} \times \begin{matrix}\textit{Fraction of food} \\ \textit{grown in} \\ \textit{biosolids-amended} \\ \textit{soils (FC)}\end{matrix}}$$

RP_C = The cumulative amount of a pollutant that can be land applied without adverse effects from biosolids exposure via the pathway evaluated.
RIA = Amount of pollutant ingested by humans without expectation of adverse effects (i.e., allowable dose).
UC = Plant uptake slope for pollutant from soils/biosolids.
DC = Dietary consumption of different food groups grown in soils amended with biosolids.
FC = Fraction of different food groups assumed to be grown in soils amended with biosolids.

Box 9 (Continued)

Calculation of the Arsenic Pollutant Limit for Pathway 1

Step 1 Parameters:

Parameter	Value	Units
RfD	0.0008	milligrams per kilogram per day (mg/kg · day)
BW	70	kilograms (kg)
RE	1.0	no units
TBI	0.012	milligrams pollutant per day (mg/day)
10^3	103	conversion factor, micrograms per milligram (µg/mg)

Step 1 Calculation:

$$RIA = \frac{RfD \cdot BW}{RE} - TBI \cdot 10^3 = \frac{0.0008 \cdot 70}{1.0} - 0.012 \cdot 10^3 = 44\ \mu g\ arsenic/g\text{–}day$$

Step 2 Parameters:

Parameter	Value	Units
RIA	44	micrograms pollutant per day (µg/day)
UC		micrograms pollutant per gram of dry plant tissue (µg/g DW)/kg–pollutant/hectare
DC		dry grams of food group in the diet per day (g DW/day)
FC		no units

$\sum UC \cdot DC \cdot FC = 0.00654$ *from Chart A*

Chart A

Values for Parameters Used in Calculating the Pollutant Limit for Arsenic, Pathway 1

Food Group	UC	DC	FC	UC · DC · FC	Other Variables	
Potatoes	0.002	15.5954	0.025	0.00073	RfD	0.0008
Leafy vegetables	0.018	1.9672	0.025	0.00091	BW	70
Legumes	0.001	8.7462	0.025	0.00024	RE	1
Root vegetables	0.004	1.5950	0.025	0.00015	TBI	0.121
Garden fruits	0.001	4.1517	0.025	0.00015	RIA	44
Peanuts	0.001	2.2538	0.025	0.00006	RP_c	6,700
Grains and cereals	0.002	96.6802	0.025	0.00430		
Sum UC · DC · FC				0.00654		

Step 2 Calculation:

$$RP_c = \frac{RIA}{\sum UC \cdot DC \cdot FC} = \frac{44}{0.00654} = 6{,}700\ kg/ha\ of\ arsenic\ biosolids\ (rounded)$$

Note: The most limiting pathway for arsenic was Pathway 3 (see Box 11).

Box 10
Example Risk Assessment Calculation: PCBs for an Adult Person Ingesting Crops Grown in Biosolids-Amended Soils (Pathway 1)

This example illustrates the method used to calculate pollutant limits for degradable, carcinogenic organic pollutants.

Goal: Calculate the amount of pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without reasonably anticipated adverse effects to humans. This level is defined as the *reference application rate of a pollutant (RP)*. The RP for organic pollutants (e.g., PCBs), which degrade in the environment, is an annual application rate (rather than a cumulative loading rate as was used for inorganic pollutants, as in Box 9).

Note: The exposure pathway discussed in this example is Pathway 1, in which biosolids are applied to soils, plants are grown in the biosolids-amended soils, and humans eat the plants grown there. Appendices A and B provide additional information on how the parameters presented below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RIA = \left(\frac{RL \cdot BW}{q_1{*} \cdot RE} - TBI \right) \cdot 10^3$$

$$\text{Adjusted reference intake of pollutant in humans } (RIA) = \left(\frac{\text{Risk level } (RL) \times \text{Body weight } (BW)}{\text{Human cancer potency } (q_1{*}) \times \text{Relative effectiveness of ingestion exposure } (RE)} - \text{Total background intake rate from all sources } (TBI) \right) \times 10^3$$

RIA = Amount of additional pollutant ingested per day by humans without expectation of adverse effects (i.e., the allowable dose).

RL = Cancer risk level. The probability that one additional cancer case could be expected to occur in that part of the population that is exposed. For the biosolids risk assessment, the RL was 1×10^{-4}. This risk is equivalent to the probability of one additional cancer case in a population of 10,000 exposed individuals. Note: The exposed population may be only a small fraction of the total population.

BW = Human body weight.

$q_1{*}$ = Cancer potency value. The $q_1{*}$ factor is the amount of intake of a chemical (organic or inorganic) that results in a specified estimate of cancer risk. The assumption is made that even one molecule of a cancer-causing compound will have some risk. $Q_1{*}$s usually are developed in specialized, small-animal studies. These studies involve extrapolation and the application of safety factors to estimate an acceptable level of pollutant intake by humans. $Q_1{*}$s are conservative estimates (i.e., contain relatively large safety factors).

RE = Relative effectiveness of exposure, which accounts for differences in bioavailability if the pollutant is ingested in food or water or is inhaled. Because of limited data, this value was set at 1.0.

TBI = Total intake of the pollutant from all background sources in water, food, and air—assumed negligible because organic PCB compounds are considered degradable.

Box 10 (Continued)

Step 2:

$$RLC = \frac{RIA}{\sum UC \cdot DC \cdot FC}$$

$$\begin{array}{c}\text{Reference}\\ \text{concentration}\\ \text{of pollutant}\\ \text{in soil } (RLC)\end{array} = \frac{\text{Adjusted reference intake of pollutant in humans } (RIA)}{\begin{array}{c}\text{Uptake response}\\ \text{of pollutant}\\ \text{in plants } (UC)\end{array} \times \begin{array}{c}\text{Daily dietary}\\ \text{consumption}\\ \text{of food group}\\ (DC)\end{array} \times \begin{array}{c}\text{Fraction of food}\\ \text{group grown in}\\ \text{biosolids–amended}\\ \text{soil } (FC)\end{array}}$$

RLC = Pollutant concentration in soil considered to be without expectation of adverse effect for animals or humans.
UC = Plant uptake slope for pollutant from soils/biosolids.
DC = Dietary consumption of different food groups grown on land amended with biosolids.
FC = Fraction of different food groups assumed to be grown on land amended with biosolids.

Step 3:

$$k = \frac{ln2}{T_{0.5}}$$

$$\text{First–order decay rate constant } (k) = \frac{\text{Logarithm factor } (ln2)}{\text{Time factor } (T_{0.5})}$$

k = First-order decay rate constant (yr^{-1})
ln = Natural logarithm
$T_{0.5}$ = Half-life of pollutant in soil (yr)

Step 4:

$$RP = RLC \cdot MS \cdot 10^{-9} \cdot [1 + e^{-k} + e^{-2k} + \ldots + e^{(1-n)k}]^{-1}$$

$$\begin{array}{c}\text{Reference annual}\\ \text{application}\\ \text{rate of}\\ \text{pollutant } (RP)\end{array} = \begin{array}{c}\text{Reference}\\ \text{concentration of}\\ \text{pollutant in}\\ \text{soil } (RLC)\end{array} \times \begin{array}{c}\text{Weight of}\\ \text{upper 15 cm}\\ \text{of soil } (MS)\end{array} \times \begin{array}{c}\text{Decay}\\ \text{factor}\\ (k)\end{array}$$

RP_a = The amount of a pollutant that can be applied to a hectare of land per year without expectation of adverse effects.
MS = Assumed mass of dry soil in the upper 15 centimeters of soil.
10^{-9} = Conversion factor.
e = Base of natural logarithms, 2.718.
k = Loss rate constant.
n = Number of years of application until equilibrium conditions reached.

Box 10 (Continued)

Calculation of the PCB Limit for Pathway 1

Step 1 Parameters:

Parameter	Value	Units
RL	10^{-4}	no units
BW	70	kilograms (kg)
q_1^*	7.7	milligrams per kilogram (mg/kg) · day
RE	1.0	no units
TBI	0.0	milligrams pollutant per day (mg/day)
10^3	10^3	conversion factor, micrograms per milligram (µg/mg)

Step 1 Calculation:

$$RIA = \frac{RL \cdot BW}{q_1{*} \cdot RE} - TBI \cdot 10^3 = \frac{10^{-4} \cdot 70}{7.7 \times 1.0} \cdot 10^{-3} = 0.909\ \mu g/day$$

Step 2 Parameters:

Parameter	Value	Units
RIA	0.909	micrograms pollutant per day (µg/day)
UC		micrograms pollutant per gram dry plant tissue (µg/g DW)/kg-pollutant/hectare
DC		dry grams of food group in the diet per day (g DW/day)
FC		no units

$\sum (UC \cdot DC \cdot FC = 0.00312$ *from Chart B*)

Chart B

Values for Parameters Used in Calculating the Pollutant Limit for PCBs, Pathway 1

Food Group	UC	DC	FC	UC · DC · FC	Other Variables	
Potatoes	0.001	15.5954	0.025	0.00039	RL	$1 \cdot 10^{-4}$
Leafy vegetables	0.001	1.9672	0.025	0.00005	BW	70
Legumes	0.001	8.7462	0.025	0.00022	q_1^*	7.7
Root vegetables	0.001	1.5950	0.025	0.00004	RE	1
Garden fruits	0.001	4.1517	0.025	0.00010	DE	1
Peanuts	0.001	2.2538	0.025	0.00006	MS	$2 \cdot 10^9$
Grains and cereals	0.001	90.6802	0.025	0.00227	k	0.063
Sum UC · DC · FC				0.00312	RIA	0.909
					RLC	290.934
					RP_a	37

Box 10 (Continued)

Step 2 Calculation:

$$RLC = \frac{RIA}{\sum UC \cdot DC \cdot FC} = \frac{0.909}{0.00312} = 291\ \mu g/g\ soil\ DW$$

Step 3 Calculation:

$$k = \frac{ln2}{T_{0.5}} = 0.063\ yr^{-1}$$

Step 4 Parameters:

Parameter	Value	Units
RLC	37	kilogram PCB per hectare per year (kg PCB/ha/yr)
MS	$2 \cdot 10^{9}$	grams soil dry weight per hectare (g soil DW/ha)
k	0.063	(yr^{-1})
e	2.718	no units
n	100	assumed years of application required to reach equilibrium

Step 4 Calculation:

$$RP_a = RLC \cdot MS \cdot 10^{-9} \cdot [1 + e^{-k} + e^{-2k} + \ldots e^{(1-n)k}]^{-1} =$$

$$291 \cdot (2 \cdot 10^{9}) \cdot 10^{-9} \cdot [e^{-0.063} + e^{-2 \times 0.063} \ldots e^{(1-100)} x\ 0.063]^{-1} =$$

$$37\ kg\ PCBs/ha/yr$$

Note: The most limiting pathway for PCBs was Pathway 5; however, PCBs were not included in the final rule (see Chapter 3).

Box 11
Example Risk Assessment Calculation: Arsenic for a Child Ingesting Biosolids (Pathway 3)

This example illustrates the method used to calculate pollutant limits for children for inorganic chemicals, based on RfDs (see Box 3); the method is similar for organic pollutants, except that q_1*s and cancer risk levels were used instead of RfDs. The same method was used for inorganic and organic pollutants because this pathway conservatively assumes the direct ingestion of biosolids by a child without the biosolids pollutants having had an opportunity to degrade or to otherwise be reduced by being mixed into soils.

Goal: Calculate the concentration of the pollutant in biosolids that can be ingested by a child consuming biosolids without expectation of adverse effects. This level is known as the reference concentration of a pollutant in biosolids (RSC).

Note: The exposure pathway discussed in this example is Pathway 3, which involves a child eating biosolids that have not been mixed with soil. Appendices A and B provide additional information about how the parameters presented below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3$$

This step is similar to Step 1 in Box 9, which shows an example calculation for an adult ingesting crops grown on land to which biosolids have been applied. The major difference in this example is that the body weight for a child is used (versus the adult body weight in the example in Box 9).

Step 2:

$$RSC = \frac{RIA}{I_s \cdot DE}$$

$$\textit{Reference concentration of pollutant in biosolids (RSC)} = \frac{RIA}{\textit{Biosolids ingestion rate } (I_s) \times \textit{Exposure duration adjustment (DE)}}$$

RSC = The concentration of a pollutant in biosolids that can be ingested without expectation of adverse effects.
RIA = The amount of pollutant ingested by humans without expectation of adverse effects (i.e., allowable dose).
I_s = The rate of biosolids ingestion by children.
DE = Exposure duration adjustment. This parameter attempts to include considerations of less-than-lifetime exposures by children, because the RfDs used in Step 1 are based on lifetime (i.e., adult) exposure. Because no EPA-approved method was available for such adjustments prior to promulgating the Part 503 rule, the DE was set at 1.

Calculation of the Arsenic Limit for Pathway 3

Step 1 Variables:

Parameter	Value	Units
RfD	0.0008	milligrams pollutant per kilogram BW per day (mg/kg/day)
BW	16	kilograms (kg) for a 1-to-6-year-old child
RE	1.0	no units
TBI	0.0045	milligrams pollutant per day (mg/day)
10^3	10^3	conversion factor, micrograms per milligram (µg/mg)

Box 11 (Continued)

Step 1 Calculation:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3 = \left(\frac{0.0008 \cdot 16}{1.0} - 0.0045\right) \cdot 10^3 = 8.3\ \mu g\ arsenic/g\text{-}day$$

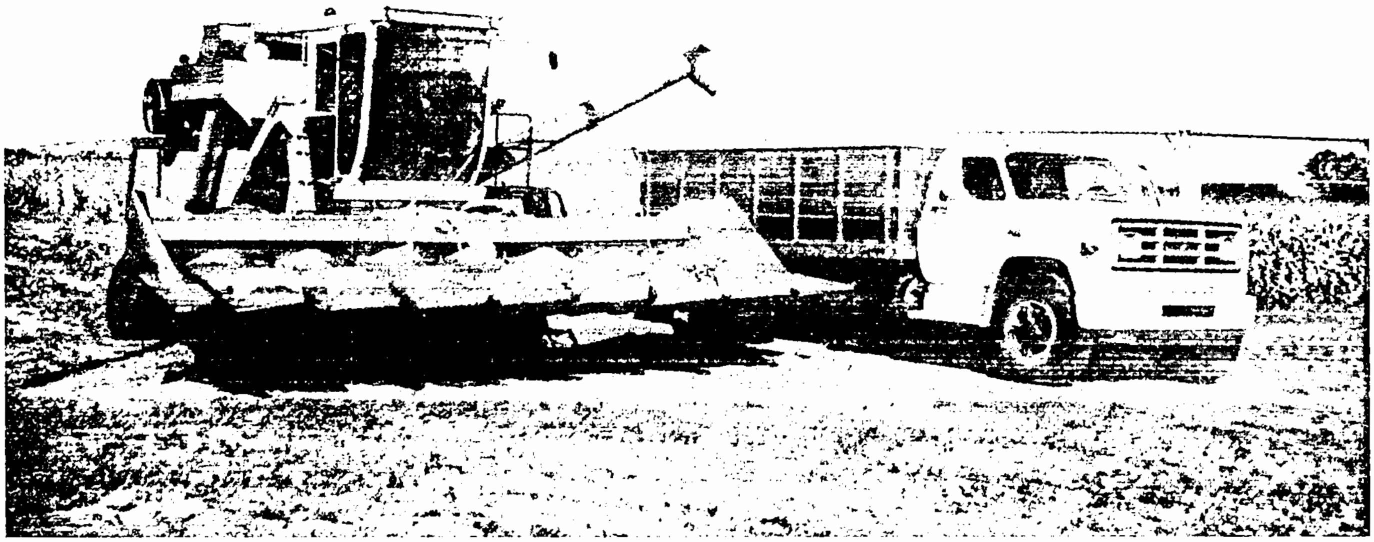
Step 2 Parameters:

Parameter	Value	Units
RIA	8.3	micrograms pollutant per day (µg/day)
I_s	0.2	grams of soil DW per day (g/day)
DE	1	no units

Step 2 Calculation:

$$RSC = \frac{RIA}{I_s \cdot DE} = \frac{8.3}{0.2 \cdot 1} = 41\ \mu g\ \ of\ \ arsenic/g\ of\ biosolids\ DW\ (rounded)$$

Note: Pathway 3 was the most limiting pathway for arsenic.



Grain is one of many crops grown in soils amended with biosolids.

Box 12
Example Risk Assessment Calculation: Arsenic for an Animal Ingesting Plants Grown on Biosolids-Amended Soils (Pathway 6)

This example illustrates one method used to calculate pollutant limits for animals for inorganic chemicals. The most sensitive/most exposed animal species varied according to the particular pollutant.

Goal: Calculate the amount of each pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without adverse effects to animals. This level is defined as the *reference application rate of a pollutant (RP)*.

Note: The exposure pathway discussed in this example is Pathway 6, which involves the application of biosolids to soil, the uptake of biosolids pollutants in soil by plants, and the consumption of these plants by animals. In this case, pollutant transfer began with forage plants taking up the pollutant from biosolids-amended soils; this forage then constituted 100 percent of the animal's diet. Appendices A and B provide additional information about how the parameters described below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RF = TPI - BC$$

$$\begin{matrix}\textit{Reference concentration of} \\ \textit{pollutant in forage (RF)}\end{matrix} = \begin{matrix}\textit{Threshold pollutant} \\ \textit{intake level (TPI)}\end{matrix} - \begin{matrix}\textit{Background concentration of} \\ \textit{pollutant in forage (BC)}\end{matrix}$$

RF = The allowable concentration of a pollutant in the animal diet from forage grown in biosolids-amended soils.
TPI = The maximum pollutant intake level in the animal diet without observed toxic effect on the most sensitive or most exposed species (based on National Research Council data).
BC = The background concentration of pollutant in forage tissue.

Step 2:

$$RP = \frac{RF}{UC}$$

RP = The amount of a pollutant that can be applied to a hectare of land without expectation of adverse effects.
RF = The allowable concentration of a pollutant in the animal diet from forage grown on biosolids-amended soils.
UC = Plant uptake of pollutants from soil/biosolids (see Chapter 3 for a detailed discussion of plant uptake of pollutants).

Calculation of the Arsenic Limit for Pathway 6

Step 1 Parameters:

Parameter	Value	Units
TPI	50	micrograms of pollutant per gram of forage (grown in biosolids-amended soils) in diet DW (μg/g DW)
BC	0.304	Micrograms of pollutant per gram of forage tissue DW(μg/g DW)

Step 1 Calculation:

$$RF = TPI - BC = 50 - 0.304 = 49.7 \ (\mu g \ pollutant/g \ diet \ DW)$$

Box 12 (Continued)

Step 2 Parameters:

Parameter	Value	Units
RF	49.7	micrograms of pollutant per gram of diet DW (µg/g DW)
UC	0.030	(micrograms of pollutant per gram of plant tissue DW) (kilograms of pollutant per hectare)$^{-1}$ (µg/g DW) (kg/ha)$^{-1}$

Step 2 Calculation:

$$RP_C = \frac{RF}{UC} = \frac{49.7}{0.030} = 1{,}600\ kg\ arsenic/ha\ (rounded)$$

Note: The most limiting pathway for arsenic was Pathway 3 (see Box 11).

Carefully replicated field research yielded valid data for the Part 503 risk assessment for land application.

Box 13
Example Risk Assessment Calculation: Zinc for Plants Grown in Soils Amended With Biosolids (Pathway 8)

This example illustrates the method used to calculate pollutant limits for plants for inorganic chemicals; no organic pollutants were evaluated for this pathway because organics occur in biosolids at very low concentrations and are rarely taken up by plants in quantities beyond background levels.

Goal: Calculate the amount of each pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without adverse effects to plants. This level is defined as the *reference application rate of a pollutant (RP)*.

Note: The exposure pathway discussed in this example is Pathway 8, which involves the application of biosolids to soil and the uptake of pollutants in biosolids by plants. Pathway 8 involved determining RPs (defined above) by two different approaches and then choosing the more restrictive result from the two approaches as the pollutant limit. Chapter 3 and Appendices A and B provide more information about how the parameters described below were used to determine pollutant limits for biosolids.

Approach 1 - The Probability Approach:

1. A phytotoxicity threshold (PT_{50}) value—the concentration of a pollutant in plant tissue associated with a 50 percent retardation in growth of young tissue, which in turn was used to establish the concentration in plants associated with phytotoxicity—was identified for each pollutant from short-term experiment data on corn. The relationship between soil metal loading and resulting metal concentration in plant tissue was established based on studies in which only one metal element, often in the form of a metal salt, had been added to the growth medium (so that plant damage could be attributed to a specific metal).
2. A calculation was made to determine the probability that the metal concentrations in plants grown on soils amended with biosolids would exceed the PT_{50} at various metal loading ranges, using data only from field studies.
3. An acceptable level of tolerable risk of exceeding the PT_{50} was set at 0.01. That is, it was deemed acceptable to exceed the PT_{50} 1 out of every 100 times.
4. The highest biosolids loading rate having a less than 0.01 probability of causing the PT_{50} to be exceeded was the allowable loading rate—the RP.

For Zinc:

1. PT_{50} for zinc = 1,975 μg zinc/g plant tissue DW.
2. The probability that corn grown on biosolids-amended soils would exceed the PT_{50} was computed for 12 zinc loading ranges (e.g., from 0, 0-50, through 2,500-3,500 kg/ha).
3. As specified earlier, the acceptable level of tolerable risk for exceeding the PT_{50} was set at 0.01.
4. None of the loading rates evaluated exceeded the probability of 0.01 (see Chart C). Therefore, the highest loading rate evaluated was chosen as the allowable loading rate (the RP) for biosolids that would not cause a significant phytotoxic effect in corn: *RP = 3,500 kg zinc/ha*.

Box 13 (Continued)

Approach 2 - The Lowest-Observed-Adverse-Effects-Level (LOAEL) Approach:

Description of the Algorithm

$$RP = \frac{TPC - BC}{UC}$$

$$\text{Reference cumulative application rate of pollutant } (RP) = \frac{\text{Threshold phytotoxic concentration of pollutant in plant tissue } (TPC) - \text{Background concentration of pollutant in plant tissue } (BC)}{\text{Uptake response of pollutant in plant tissue } (UC)}$$

RP = The amount of a pollutant that can be applied to a hectare of land without expectation of adverse effects.
TPC = The concentration of a pollutant in a sensitive plant tissue species (e.g., lettuce, as opposed to a less sensitive species, such as corn, used in Approach 1) associated with the LOAEL, as an indication of phytotoxicity.
BC = Background concentration of pollutant in plant tissue.
UC = Plant uptake of pollutants from soil/biosolids (see Chapter 3 for a detailed discussion of plant uptake of pollutants).

For Zinc:

Parameters

Parameter	Value	Units
TPC	400	micrograms of pollutant per gram of plant tissue (lettuce) DW (µg/g DW)
BC	47.0	micrograms of pollutant per gram of plant tissue (lettuce) DW (µg/g DW)
UC	0.125	micrograms of pollutant per gram of plant tissue (lettuce) (kilograms of pollutant per hectare)$^{-1}$ (µg/g DW)(kg/ha)$^{-1}$

Calculation:

$$RP = \frac{TPC - BC}{UC} = \frac{400 - 47.0}{0.125} = 2{,}800 \textit{ kg zinc/ha (rounded)}$$

Results From Approaches 1 and 2

RP, Approach 1 = 3,500 kg zinc/ha *RP, Approach 2 = 2,800 kg zinc/ha*

The more restrictive result of the two approaches was chosen as the pollutant limit: *RP = 2,800 kg zinc/ha.*

The limit set for Pathway 8 was the pollutant limit used in the Part 503 rule for zinc.

Box 13 (Continued)

Chart C

Probability of Zinc in Corn Grown on Biosolids-Amended Soils Exceeding the Phytotoxicity Tolerance Threshold

Zinc Loading Range (kg/ha)	Number of Observations	Probability of Exceeding Tolerance Threshold PT_{50} 1,975 µg/g
0	51	<0.0001
0-50	16	<0.0001
50-100	28	<0.0001
100-150	16	<0.0001
150-200	14	<0.0001
200-300	22	<0.0001
300-400	19	<0.0001
400-500	14	<0.0001
500-750	19	<0.0001
750-1,000	17	<0.0001
1,000-1,500	17	<0.0001
1,500-2,500	12	0.0020
2,500-3,500	10	<0.0001

Box 14
Example Risk Assessment Calculation: PCBs for an Adult Person Ingesting Surface Water and Fish Impacted by Pollutants in Runoff From Biosolids-Amended Soils (Pathway 12)

This example illustrates the method used to calculate pollutant limits for people (adults) for carcinogenic, organic pollutants evaluated in the biosolids land application risk assessment for surface water.

Goal: Calculate the amount of pollutant in biosolids that can be applied to a given area of land (e.g., kilograms per hectare per year) without adverse effects to humans. This level is defined as the *reference application rate of a pollutant (RP).*

Note: The exposure pathway discussed in this example is Pathway 12, which involves the application of biosolids to soil, the erosion of soil containing pollutants in biosolids, the transfer of the pollutants contained in the eroded soil to surface water, and the ingestion of the surface water and fish living in the surface water by humans. The calculations for surface water below have been summarized (i.e., not all calculations are presented) to simplify this example. For the more detailed calculations conducted for this pathway, see the *Technical Support Document for Land Application of Sewage Sludge* (U.S. EPA, 1992a). Appendices A and B provide more information about how the variables described below were used to determine pollutant limits for biosolids.

Description of Algorithm

Step 1: Mass Balance

The relative rates of pollutant loss for the site through erosion, volatilization, and leaching were calculated. These rates were then combined to give a total loss rate of pollutant from soil at the site (K). For Pathway 12, the ratio of the erosion loss rate to the total loss rate was then calculated to provide the fraction of pollutant loss caused by erosion (f_{ero}). For the additional calculations involved in the mass balance, see the *Technical Support Document for Land Application of Sewage Sludge* (U.S. EPA, 1992a).

$$f_{ero} = \frac{K_{ero}\,(yr^{-1})}{K_{tot}\,(yr^{-1})}$$

f_{ero} = fraction of total loss caused by erosion
K_{ero} = loss rate coefficient for erosion (yr-1)
K_{tot} = total loss rate for the pollutant in biosolids-amended soil (yr-1)

Step 2: Reference (Allowable) Intake of Pollutant (RI)

For carcinogenic pollutants (including some inorganics, i.e., arsenic):

$$RI = \frac{RL}{q_1^*}$$

For noncarcinogenic pollutants:

$$RI = RfD - \text{background intake sources other than biosolids}$$

Box 14 (Continued)

Step 3: Reference (Allowable) Water Concentration of Pollutant in Surface Water (RC_{sw}):

$$RC_{sw} = \frac{RI \cdot BW}{BCF \cdot FM \cdot P_t \cdot I_f \cdot + I_w}$$

RI = reference (allowable) intake
BW = body weight
BCF = pollutant-specific bioconcentration factor
FM = pollutant-specific food chain multiplier
P_f = ratio of pollutant concentration in the edible portion of fish to concentration in whole fish
I_f = daily consumption of fish
I_w = daily consumption of water

Step 4: Reference Concentration of Pollutant in Eroded Soil Entering the Stream (RC_{sed}):

$$RC_{sed} = RC_{sw} \, [KD_{sw} + \left(\frac{P_l}{P_s}\right)\left(\frac{1}{\rho_w}\right)]$$

RC_{sed} = reference concentration of pollutant in eroded soil entering the stream
RC_{sw} = reference water concentration for surface water
KD_{sw} = partition coefficient between solids and liquids within the stream
P_l = percent liquid in the water column
P_s = percent solids in the water column
ρ_w = density of water

Step 5: Dilution Factor (DF):

$$DF = \frac{A_{sma} \; S_{sma}}{A_{sma} \;\; S_{sma} + (A_{ws} - A_{sma}) \; S_{ws}}$$

DF = dilution factor
A_{sma} = area affected by land application of biosolids (SMA=biosolids management area)
S_{sma} = sediment delivery ratio for the SMA
A_{ws} = area of the watershed (ha)
S_{ws} = sediment delivery ratio for the watershed

Note: The dilution factor (DF) describes how eroded soil from the SMA is diluted by soil from the untreated remainder of the watershed. It represents the fraction of the stream's sediment originating in the SMA. Step 5 assumes that rates of soil erosion from the SMA and the remainder of the watershed are the same; calculations for S_{sma} and S_{ws} were previously calculated but are not shown here (see *Technical Support Document* cited above for further information).

Box 14 (Continued)

Step 6: Reference Pollutant Concentration for Soil Eroding From the SMA (RC_{sma}):

$$RC_{sma} = \frac{RC_{sed}}{DF}$$

RC_{sma} = reference pollutant concentration in soil eroding from the SMA
RC_{sed} = reference concentration of pollutant in eroded soil entering the stream
DF = dilution factor

Step 7: Reference Annual Application Rate of Pollutant (RP_a):

$$RP_a = \frac{RC_{sma} \cdot ME_{sma} \cdot 10^{-6}}{fero}$$

RP_a = reference annual application rate of pollutant
RC_{sed} = reference pollutant concentration in soil eroding from the SMA
ME_{sma} = estimated rate of soil loss for the SMA
10^{-6} = conversion factor
f_{ero} = fraction of total loss caused by erosion

Calculation of the PCB Limit for Pathway 12

Parameter	Value	Units	Parameter	Value	Units
K_{ero}	0.004	yr^{-1}	$\frac{P_1}{P_s}$	62,500	unitless
K_{tot}	0.12	yr^{-1}	ρ_w	1	kg/1
RL	10^{-4}	lifetime	A_{sma}	1,074	ha
q_1*	7.7	kg-day/mg	S_{sma}	0.46	unitless
RI	1.3×10^{-5}	mg/kg-day	A_{ws}	440,300	ha
BW	70	kg	S_{wa}	0.17	unitless
BCF	3.1×10^{-4}	l/kg	RC_{sed}	9.4×10^{-3}	mg/kg
FM	10	unitless	DF	0.0066	unitless
P_f	0.5	unitless	RC_{sma}	1.43	mg/kg
I_f	0.04	kg/day	ME_{sma}	8,400	kg/ha-yr
I_w	2	l/day	conversion factor	10^{-6}	kg/mg
RC_{sw}	1.5×10^{-7}	mg/l	f_{ero}	0.033	unitless
KD_{sw}	1,510	l/kg			

Box 14 (Continued)

Step 1 Calculation:

$$f_{ero} = \frac{K_{ero}\,(yr^{-1})}{K_{tot}\,(yr^{-1})} = \frac{0.004}{0.12} = 0.033$$

Step 2 Calculation:

$$RI = \frac{RL}{q_1*} = \frac{10^{-4}}{7.7} = 1.3 \times 10^{-5}\ mg/kg \cdot day$$

Step 3 Calculation:

$$RC_{sw} = \frac{RI \cdot BW}{BCF \cdot FM \cdot P_f \cdot I_f \cdot I_w} = \frac{(1.3\ x\ 10^{-5})\ (70)}{(3.1\ x\ 10^{-4})\ (10)\ (0.5)\ (0.04) + (2)} = 1.5 \times 10^{-7}\ mg/kg$$

Step 4 Calculation:

$$RC_{sed} = RC_{sw}\ [KD_{sw} + \left(\frac{P_1}{P_s}\right)\left(\frac{1}{\rho_w}\right)] = (1.5\ x\ 10^{-7})\ [(1{,}510) + (62{,}500)\ (1)] = 9.4\ x\ 10^{-3}\ mg/kg$$

Step 5 Calculation:

$$DF = \frac{A_{sma}\ S_{sma}}{A_{sma}\ S_{sma} + (A_{ws} - A_{sma})\ S_{ws}} = \frac{(1{,}074)\ (0.46)}{(1{,}074)\ (0.46) + [(440{,}300) - (1{,}074)]\ (0.17)} = 0.0066\ (unitless)$$

Step 6 Calculation:

$$RC_{sma} = \frac{RC_{sed}}{DF} = \frac{9.4 \times 10^{-3}}{0.0066} = 1.43\ mg/kg$$

Step 7 Calculation:

$$RP_a = \frac{RC_{sma} \cdot ME_{sma} \cdot 10^{-6}}{f_{ero}} = \frac{(1.43)\ (8.400)\ 10^{-6}}{(0.033)} = 0.348\ kg/ha \cdot yr$$

Note: The limiting pathway for PCBs is Pathway 3; however, organic pollutants, including PCBs, were not included in the final rule for land application (see Chapter 3).

Surface Disposal: Ground-Water Pathway

The risk assessment for the ground-water pathway for surface disposal of biosolids began with a mass balance that calculated pollutant loss to ground-water leaching, volatilization, effluent or water discharge (for surface impoundments), and degradation. An ***adjusted reference water concentration*** (RC_{gw}) for each pollutant, which was a health-based number based on MCLs or q_1*s, was calculated. Computer models (the VADOFT model for the unsaturated soil zone, and the AT123D model for the saturated zone) were then used to calculate pollutant transport to the ground water and lateral dispersion of the pollutant in the ground water beneath a surface disposal site.

Site-specific parameters for biosolids and ground water were used in the computer models (e.g., area and active lifetime of facility; thickness and porosity of the cover, if any; distance to well; solids concentrations of biosolids; soil type and porosity; depth to ground water; thickness of aquifer; net recharge or seepage; leaching rate; hydraulic conductivity). Chemical-specific factors also were used in the ground-water models (e.g., decay rates, diffusion and soil-water partition coefficients). The surface impoundment risk assessment also included inflow and outflow factors and exchange between the liquid and sediment layers.

Pollutant concentrations in nearby, downgradient well water were used to calculate seepage beneath the surface disposal facility, called the ***reference concentration of pollutant in water leaching from the monofill or seeping from the bottom of the surface impoundment*** (RC_{lec} or RC_{sep}), in milligrams per liter (mg/L). For monofills, the mass of solids in 1 m^3 of biosolids (MS) and the mass of biosolids in 1 hectare of a monofill (SC) were then calculated. (The SC was calculated by multiplying the depth of a monofill cell by the fraction of its total volume containing biosolids and the mass of solids per cubic meter of biosolids.) The RC, MS, SC, and well data were used to derive a ***reference concentration of pollutant*** in biosolids (RCS), expressed in milligrams per kilogram (mg/kg), which was identified as the risk-based pollutant limit.

Many of the assumptions made for the surface disposal ground-water pathway were conservative and probably contributed to overestimation of exposure and hence risk. Some of these assumptions included:

- A 150-meter distance to a downgradient receptor well for Class II/III aquifers, because no one drinks well water on site (based on EPA specifications for facilities that it regulates or on state requirements based on EPA regulations).
- The site life (i.e., the length of time a monofill receives biosolids, or the time it takes to fill a surface impoundment with biosolids) for monofills was assumed to be 20 years, and the site life for surface impoundments was assumed to be 7 years. After these periods, maximum pollutant loss (e.g., through leaching and volatilization) and pollutant concentrations in a receptor well were modeled for a 300-year period assuming a constant release of pollutants.
- For Class II/III aquifers, a 1-meter depth to ground water was assumed, which is less than the depth at most operating facilities. This conservative assumption is designed to protect aquifers at relatively shallow depths.
- Maximum pollutant concentrations at the 150-meter, downgradient well were calculated within the first 300 years after the life of the surface disposal site lapsed. In contrast, for the vapor pathway discussed below, a maximum 70-year average ambient air pollutant concentration was used.

Surface Disposal: Vapor (Air) Pathway

For the risk assessment for the vapor pathway for surface disposal of biosolids, the estimated volatile emissions of organic pollutants was first calculated. Inhalation volume and dispersion factors also were important parameters used. Expected concentrations of organic pollutants in ambient air at the property boundary of the surface disposal site were then calculated (using a simplified ISCLT model).

The health-based parameter for the vapor pathway was the ***reference air concentration for the pollutant*** (RC_{air}), expressed in micrograms per cubic meter ($\mu g/m^3$), which was based on q_1*s. A ***reference concentration of pollutant*** in biosolids (RCS) was then calculated, which was identified as the risk-based pollutant limit for the vapor pathway for surface disposal.

Approach Used for the Incineration Risk Assessment

One pathway was evaluated in the biosolids risk assessment for incineration—the inhalation pathway. A pathway to evaluate exposures to ingested pollutants from biosolids incineration was not evaluated because of limited procedural and data availability. In the inhalation pathway risk assessment, health-based ***risk-specific concentrations*** (RSCs) were calculated in an algorithm for arsenic, cadmium, chromium, and nickel. RSCs represented the allowable increase in average, daily ground-level ambient air concentrations above background levels for the pollutant from biosolids incineration. The RSC, based on q_1*s and inhalation rates, was then used in a second algorithm along with site-specific factors on:

- Pollutant dispersion in the ambient air
- Incinerator control efficiency
- Biosolids feed rate to the incinerator

The second algorithm identified risk-based pollutant limits for biosolids incineration, calculated as ***the allowable average daily concentration of the pollutant in biosolids*** (C), expressed in mg/kg of total solids (DW).

In addition to the RSCs and site-specific factors used to develop pollutant limits for biosolids incineration, an inhalation pathway pollutant limit also was developed for lead in biosolids that are incinerated based on 10 percent of the National Ambient Air Quality Standard (NAAQS) for lead. This percentage of the NAAQS for lead was substituted for the RSC and factored into the second algorithm along with site-specific factors, as discussed above, to identify a risk-based pollutant limit for lead in biosolids. Pollutant limits for beryllium and mercury in biosolids that are incinerated also were included in the final Part 503 rule, based on National Emissions Standards for Hazardous Air Pollutants (NESHAPS) for these two pollutants.

Pollutant limits for organic pollutants also were evaluated in the risk assessment for biosolids incineration. Organic pollutants associated with biosolids incineration, however, were regulated in the Part 503 rule through an "operational standard" (discussed below and in Chapter 5) that requires monitoring for and restrictions on emissions of total hydrocarbons (THCs) in the stack gas. An operational standard was used because not all of the organic pollutants in the incineration emissions (e.g., products of incomplete combustion) are known.

EPA estimated the risk for the technology-based THC operational standard using a weighted toxicity value for all organic pollutants for which there was a q_1*. This risk-based analysis first used parameters such as the 100-ppm THC standard and site-specific dispersion factors and gas flow rates to derive site-specific RSCs (discussed above). These RSCs, along with other parameters, including a weighted q_1^*, an inhalation rate, and body weight, were then used to determine the degree of risk posed by the THC emission standard under site-specific conditions. (The "weighted" q_1^* represented the cancer potency value for all organic compounds emitted from a biosolids incinerator that have the potential to create an adverse health effect, using data on 21 compounds in tests at eight biosolids incinerators, as well as data for numerous organics that were potentially present but not detected in the tests. The q_1^* for each chemical was weighted in that it was multiplied by a "weighted fractional concentration" based on the compound's detected or assumed concentration.) The results of this risk assessment indicated that the risk associated with emissions at a 100-ppm THC level, based on data from 23 POTWs, did not exceed a 1 x 10^{-4} risk level, which was the level established in Part 503 to protect public health. Based on these results, in the EPA Administrator's judgment, the THC operational standard is protective of public health.

An amendment to the Part 503 rule allows carbon monoxide (CO) monitoring to be used in lieu of THC monitoring (see Chapter 2) because of good correlation between CO and THC levels. This amendment does not change the operational standard. If the CO is below 100 ppm when the emissions are monitored continuously, THCs in the emissions are assumed to be below 100 ppm.

Use of Risk Assessment Results and "The Most Limiting Pathway" Approach To Establish Part 503 Pollutant Limits

Calculating Exposure Pathway Pollutant Limits

Pollutant limits were calculated for each of the exposure pathways evaluated for the land application, surface disposal, and incineration risk assessments using the parameters and algorithms discussed above. The numeric results of these calculations are shown in Tables 10, 12, and 14.

Land Application Pollutant Limits

For land application, the calculation of pollutant limits warrants further explanation. Pollutant limits were first calculated separately for agricultural and non-agricultural lands (i.e., forest, public contact, and reclamation sites). The lower of the agricultural or non-agricultural pollutant limits was selected for each exposure pathway (see Table 10).

The pollutant limits for land application exposure pathways were expressed in different units for inorganic and organic pollutants to account for the fact that many organics degrade in the environment, in contrast to inorganics, which increase over time rather than degrade. This difference can be seen in Table 10 by the use of a cumulative application rate of pollutant (RP_c) for inorganics, expressed in kilograms of pollutant per hectare (kg-pollutant/ha), and an annual application rate of pollutant (RP_a) for most organics, expressed in kilograms of pollutant per hectare per year (kg-pollutant/ha-yr). In Pathways 1, 2, 4, and 11, RP_cs are listed for the organics aldrin/dieldrin and chlordane (and DDT for Pathway 11) because of their long halflife, while RP_as are listed for most other, degradable organics.

In some cases (Pathways 3, 5, and 7), a pollutant concentration in biosolids (an RSC) was used rather than a pollutant loading rate (a RP) to represent a pollutant limit when the pathway involved direct ingestion of biosolids. For further information

Table 10
Biosolids Risk Assessment Results for Land Application

Inorganic Pollutants:

Exposure Pathway	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Pollutant	RP_c	RP_c	RSC	RP_c	RSC	RP_c	RSC	RP_c	RP_c	RP_c	RP_c	RP_c	RP_c	RP_c
Arsenic	6700	930	41			1600	3100					66000		1200
Cadmium	610	120	39	1600	68000	140	650			53		63000		unlimited
Chromium			79000				190000	3000				unlimited		12000
Copper			10000			3700	2000	1500	2900			unlimited		unlimited
Lead			300			11000	1200			5000		unlimited		unlimited
Mercury	180	370	17	1500	24000							1100		unlimited
Molybdenum			400			18	530							
Nickel	63000	10000	820			1800	5400	420				unlimited		13000
Selenium	14000	1200	100	15000	13000	790	130							
Zinc	16000	3600	16000	150000	2200000	12000	36000	2800						

Organic Pollutants:

Exposure Pathway	1		2		3	4		5	6	7	8	9	10	11	12	13	14
Pollutant	RP_a	RP_c	RP_a	RP_c	RSC	RP_a	RP_c	RSC					RP_a	RP_c	RP_a	RP_a	RP_a
Aldrin/ Dieldrin		280		64	7.0		17	2.7						30000			
Benzo(a) pyrene	230		54		15										1.3	3500	unlimited
Chlordane		3400		790	86		13000	2300							5.3	3.9	unlimited
DDT	560		130		320	46		150						100000	1.2	45	unlimited
Heptachlor	990		220		24	65		7.4									
Hexachloro-benzene	320		75		70	25		29									
Hexachloro-butadiene	43000		10000		1400			600									
Lindane	2300		540		8.4	600		140							2100	110	unlimited
n-Nitrosodi-methylamine	87		20		2.1										29000	22	0.056
PCBs	37		8.5		14	2.4		4.6					0.50	200	0.34	1.4	unlimited
Toxaphene	2800		650		100	43		10							5.0	120	unlimited
Trichloro-ethylene	220000		51000		10000										unlimited	420	unlimited

Note: All results rounded down to two significant figures.

RP_c = reference cumulative application rate of pollutant (kg-pollutant/ha), used for inorganics and organics that do not degrade.

RSC = reference concentration of pollutant in biosolids (µg-pollutant/g-biosolids DW).

RP_a = reference annual application rate of pollutant (kg-pollutant/ha-yr), used for degradable organics.

Unlimited = calculated risk-based pollutant loadings for these media and practices were an unlimited value and therefore not of concern for public health or the environment.

Blank = pollutants for these pathways were excluded from the risk assessment based on either earlier hazard screening (e.g., hazard index, see Chapter 2), very low levels (e.g., organics in plant pathways; inorganics in volatilization pathways), or lack of an RFD for lead in Pathways 1 and 2.

Table 11

Pollutant Limits for Biosolids Identified in the Land Application Risk Assessment

Inorganic Pollutants

Pollutant	Highly Exposed Individual of Limiting Pathway	Most Limiting Pathway	Pollutant Limit (as RP_c) (kg- pollutant/ha)	Pollutant Limit (as RSC) (µg-pollutant/g-biosolids DW)[a]
Arsenic	Child Eating Biosolids	3	41	41
Cadmium	Child Eating Biosolids	3	39	39
Chromium[b]	Plant Phytotoxicity	8	3,000	3,000
Copper	Plant Phytotoxicity	8	1,500	1,500
Lead	Child Eating Biosolids	3	300	300
Mercury	Child Eating Biosolids	3	17	17
Molybdenum[c]	Animal Eating Feed	6	18	18
Nickel	Plant Phytotoxicity	8	420	420
Selenium	Child Eating Biosolids	3	100	100
Zinc	Plant Phytotoxicity	8	2,800	2,800

Organic Pollutants[d]

Pollutant	Highly Exposed Individual of Limiting Pathway	Most Limiting Pathway	Pollutant Limit (as RP_a) (ug-pollutant/g-biosolids DW, except as indicated)	Pollutant Limit (as RSC) (µg-pollutant/g-biosolids, DW)
Aldrin/Dieldrin	Adult Eating Animal Products (animals ate biosolids)	5	2.7	2.7
Benzo(a)pyrene	Child Eating Biosolids	3	15	15
Chlordane	Child Eating Biosolids	3	86	86
DDT/DDD/DDE	Adult Eating Fish/Drinking Surface Water	12	1.2(kg-poll/ha-yr)	120
Heptachlor	Adult Eating Animal Products (animals ate biosolids)	5	7.4	7.4
Hexachlorobenzene	Adult Eating Animal Products (animals ate biosolids)	5	29	29
Hexachlorobutadiene	Adult Eating Animal Products (animals ate biosolids)	5	600	600
Lindane	Child Eating Biosolids	3	84	84
n-Nitroso-dimethyl-amine	Child Eating Biosolids	3	2.1	2.1
PCBs	Adult Eating Animal Products (animals ate biosolids)	5	4.6	4.6
Toxaphene	Adult Eating Animal Products (animals ate biosolids)	5	10	10
Trichloroethylene	Child Eating Biosolids	3	10,000	10,000

[a]RSC = reference concentration of a pollutant in biosolids (µg-pollutant/g-biosolids, DW). By expressing pollutant limits as RSCs, limits for inorganic and organic pollutants can be compared (see Appendix D for conversion factors used to attain same units).

[b]Chromium may be deleted from the rule because of a court suit (see Section Q, Chapter 3).

[c]Only the ceiling concentration limit for molybdenum is currently included in the Part 503 rule pending revaluation of additional data (see Section P, Chapters 2 and 3).

[d]Limits for organic pollutants were not included in the final Part 503 rule (see Chapters 3 and 5).

Table 12
Summary of Biosolids Risk Assessment Results For Surface Disposal

Pollutant	Unlined		Lined	
	Monofill	Surface Impoundment	Monofill	Surface Impoundment
Vapor Inhalation Pathway (Pathway 1)				
Arsenic	NA[a,b]	NA	NA	NA
Benzene	6,100	3,300	6,000	3,400
Benzo(a)pyrene	unlimited	unlimited	unlimited	unlimited
Bis(2-ethylhexyl)phthalate	unlimited	unlimited	unlimited	unlimited
Cadmium	NA	NA	NA	NA
Chlordane	unlimited	unlimited	unlimited	unlimited
Chromium	NA	NA	NA	NA
Copper	NA	NA	NA	NA
DDT/DDD/DDE	unlimited	unlimited	unlimited	unlimited
Lead	NA	NA	NA	NA
Lindane	unlimited	28,000	unlimited	28,000
Mercury	NA	NA	NA	NA
Nickel	NA	NA	NA	NA
n-Nitrosodimethylamine	3,000	15	2,300	16
PCBs	unlimited	110	unlimited	100
Toxaphene	unlimited	26,000	unlimited	26,000
Trichloroethylene	unlimited	10,000	unlimited	10,000
Ground-Water Pathway (Pathway 2)				
Arsenic	140[b]	73	unlimited[c]	unlimited
Benzene	1,200	140	unlimited	unlimited
Benzo(a)pyrene	unlimited	unlimited	unlimited	unlimited
Bis(2-ethylhexyl)phthalate	unlimited	unlimited	unlimited	unlimited
Cadmium	unlimited	unlimited	unlimited	unlimited
Chlordane	unlimited	unlimited	unlimited	unlimited
Chromium	unlimited	600	unlimited	unlimited
Copper	unlimited	46,000	unlimited	unlimited
DDT/DDD/DDE	unlimited	unlimited	unlimited	unlimited
Lead	unlimited	unlimited	unlimited	unlimited
Lindane	unlimited	unlimited	unlimited	unlimited
Mercury	unlimited	unlimited	unlimited	unlimited
Nickel	unlimited	690	unlimited	unlimited
n-Nitrosodimethylamine	0.47	0.88	790	3,400
PCBs	unlimited	unlimited	unlimited	unlimited
Toxaphene	unlimited	unlimited	unlimited	unlimited
Trichloroethylene	unlimited	9,500	unlimited	unlimited

[a]NA indicates that it was not applicable to conduct a risk assessment on these pollutants for the vapor inhalation pathway because they do not tend to volatilize.

[b]Limits are expressed in milligrams per kilogram.

[c]Unlimited indicates that the calculated risk-based pollutant concentrations for those media and disposal practices were of an unlimited value and are therefore not of concern for public health or the environment.

Table 13

Pollutant Limits for Biosolids Identified in the Surface Disposal Risk Assessment

Inorganic Pollutants

Pollutant	Pollutant Limit (mg/kg)[a]	Limiting Pathway[b]
Arsenic	73	2
Cadmium	unlimited[c]	—
Chromium	600	2
Copper	46,000	2
Lead	unlimited	—
Mercury	unlimited	—
Nickel	690	2

[a]Results are from the risk assessments conducted for Class II/III ground water. Class I results are not included because EPA decided to regulate all ground water as Class II for the purposes of the Part 503 biosolids rule.

[b]Exposure pathways for surface disposal are described in Table 7 (in Chapter 2). Numbers in this column reflect results of the risk assessment for unlined surface impoundments (versus lined surface impoundments or unlined or lined monofills) because for all inorganics evaluated, this pathway resulted in the lowest limits.

[c]Unlimited indicates that the calculated risk-based pollutant values for the pollutants indicated in the media evaluated (ground water for inorganics) were of an unlimited value (i.e., no risk level identified). Risk assessments for inorganics were not conducted for the inhalation pathway because these pollutants do not tend to volatilize.

Organic Pollutants

Pollutant	Pollutant Limit (mg/kg)[a]	Limiting Pathway[b]
Benzene	140	2 (unlined surface impoundment)
Benzo(a)pyrene	unlimited[b]	—
Bis(2-ethylhexyl)phthalate	unlimited[b]	—
Chlordane	unlimited[b]	—
DDT/DDD/DDE	unlimited[b]	—
Lindane	28,000	1 (unlined or lined surface impoundment)
n-Nitrosodimethylamine	0.47	2 (unlined monofill)
PCBs	110	1 (unlined surface impoundment)
Toxaphene	26,000	1 (unlined or lined surface impoundment)
Trichloroethylene	9,500	2 (unlined surface impoundment)

[a]Pathways for surface disposal are described in Table 7 (in Chapter 2).

[b]Unlimited indicates that the calculated risk-based values for the pollutants indicated in the media evaluated (ground water and vapor for organics) had no limits (i.e., no risk level identified).

Table 14

Risk-Based Results for Biosolids Identified in the Incineration Risk Assessment

Pollutant[a]	Risk-Specific Concentration ($\mu g/m^3$)[b] (vapor inhalation pathway)
Arsenic	0.023
Cadmium	0.057
Chromium	
Fluidized-bed with scrubber	0.65
Fluidized-bed with wet scrubber and wet electrostatic precipitator	0.23
Other types with wet scrubber	0.064
Other types with wet scrubber and wet electrostatic precipitator	0.016
Nickel	2.0

[a]Only inorganic results are listed because organics are regulated in the Part 503 rule through an "operational standard" rather than pollutant limits identified in a risk assessment (see text).

[b]Risk-specific concentrations were used along with site-specific information to calculate pollutant limits (see text). Only the inhalation pathway (see Table 7) was evaluated for incineration; thus this pathway is the "limiting pathway" (see text) from which the pollutant limits were calculated.

on the different types of pollutant limits, see Appendices A and B and Boxes 9 to 14.

For some land application exposure pathways, no pollutant limit is given in Table 10. In most cases, this is because these pollutants were excluded from further evaluation during the hazard index/hazard ranking process (i.e., they were not considered toxic via that particular exposure pathway, as explained in Chapter 2). In addition, lead was not evaluated for Pathways 1 and 2 because no RfD was available. Organic pollutants were not analyzed for Pathway 8 because organics occur in biosolids at very low levels and are rarely taken up by plants at levels above background levels. Zinc and aldrin/dieldrin were not evaluated for Pathway 10 because new data indicated that they were not a concern to predators of soil organisms. For Pathway 13, no inorganic pollutants were analyzed because metals do not volatilize at ambient temperatures; therefore, levels would be negligible for this volatilization pathway.

For some pathways, the pollutant limits in Table 10 are listed as "unlimited." This means that no application (i.e., loading) rate of pollutants in biosolids (RP) was identified that would result in adverse effects via that particular pathway.

Using Exposure Pathway Pollutant Limits To Calculate Part 503 Pollutant Limits

For each pollutant evaluated, EPA considered the exposure pathway with the lowest pollutant limit as the "limiting pathway" for that pollutant for land application and surface disposal. Tables 11 and 13 list the risk assessment results for inorganic and organic pollutants for land application and surface disposal of biosolids and the associated limiting pathways. For example, for nickel in the land application risk assessment, Pathway 8 resulted in the lowest pollutant limit (RP = 420 kg of nickel/ha of land), as shown in Tables 10 and 11. This lowest pollutant limit was used directly in the Part 503 rule as the "cumulative pollutant loading rate" for nickel for land application. For other types of Part 503 pollutant limits for land application, the values identified in the risk assessment were further modified, as described in Chapter 5.

To allow comparisons between exposure pathways for land application, the pollutant limits for all inorganics in Table 10 were converted to the same unit, RP_C, as shown in Table 11 (conversions are provided in Appendix D). Note that in Table 11, the pollutant limits have been further converted to the unit RSC, so that inorganics and organics can be compared. Pollutant limits for organics are shown but were deleted from the final Part 503 rule for land application, as discussed in Chapters 3 and 5.

Detailed Risk Assessment Example: Cadmium, Pathway 2, Land Application

This section provides a detailed example of the analysis conducted for cadmium for Pathway 2 of the risk assessment for land application. This example provides a closer look at how the risk assessments were conducted, highlights how key scientific data and EPA assumptions and policy decisions were used, and illustrates why the risk assessment results are conservative.

The Highly Exposed Individual, Pathway 2

The highly exposed individual (HEI) for Pathway 2 in the land application risk assessment for the final Part 503 rule was the subsistence home gardener who over a lifetime grows a major portion of his or her diet in biosolids-amended soil. Data indicate that 5.5 percent of the U.S. population have gardens large enough to produce a major portion of their annual food consumption. Given that less than 2 percent of the U.S. population live in the same county for a lifetime, the HEI population of home gardeners for Pathway 2 is probably between 0.1 percent (5.5 x 0.02) and 2 percent of the population, with estimates pointing to less than 1 percent (Ryan and Chaney, 1993). The actual population of HEIs is probably lower because these estimates are based on short-term data and only a small number of home gardeners will garden their entire lifetime. Furthermore, to reach the estimated exposure for a 70-year lifetime, the subsistence gardener would have to continuously consume crops always produced in garden soil that contains the maximum amount of any given biosolids pollutant being evaluated (the RP) during that 70-year period. As illustrated by Ryan and Chaney (1995), this is an unlikely event.

Algorithms Used in Pathway 2

The algorithms used for Pathway 2 in the land application risk assessment were the same as those used for Pathway 1 (see Boxes 9 and 10). Because the HEI differs, however (see Table 6 in Chapter 2), the values of some of the key parameters used in Pathway 2 vary from the values used in Pathway 1, particularly for the FC and to some extent for the DC parameters. The values for each of the parameters used for cadmium in Pathway 2 are presented below, followed by a discussion of how each of the parameter values were selected; whether they are conservative or average values; and how the combination of all of the parameters contributed to making the pollutant limit (RP) conservative.

Calculation of the Adjusted Reference Intake: RIA

The first algorithm used for cadmium in Pathway 2 was:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3 = \left(\frac{0.001 \cdot 70}{1} - 0.01614\right) \cdot 1{,}000 = 53.86\ \mu g\ Cd/day$$

Parameters Used To Calculate the RIA

Adjusted Reference Intake, RIA. The RIA represents the allowable dose of a pollutant in biosolids (e.g., in this pathway, the amount of cadmium ingested in food by the subsistence home gardener). As discussed previously in this chapter (see also Appendix B), the RIA was an important health-based parameter used in many algorithms throughout the land application risk assessment to calculate pollutant limits. The RIA value is inherently conservative because it is designed to protect sensitive members of the population based on the conservative RfD for inorganic pollutants or the q_1* for organic pollutants (see Chapter 2, Box 3 for a discussion of why RfDs and q_1*s are conservative). The RIA was called "adjusted" because a standard (average) adult male body weight (70 kg) was factored in, and the total background intake of pollutants from sources other than biosolids (e.g., food, water, air) was subtracted from the overall allowable dose to determine the allowable dose from biosolids. Differences in routes of exposure (e.g., ingestion versus inhalation) and bioavailability also were considered in developing the RIA (using the RE parameter, see below). All the parameters used to develop the RIA are discussed below.

Oral Reference Dose (RfD) for Cadmium. Like other inorganic pollutants in the land application risk assessment, cadmium in Pathway 2 was considered a noncarcinogen because only noncarcinogenic effects were associated with the pollutant through this pathway (food ingestion of homegrown crops). Thus, the EPA-established threshold for noncarcinogens (the RfD) for cadmium was used: 0.001 mg pollutant/kg body weight•day (or 0.070 mg Cd/70 kg body weight•day). The RfD is based on conservative data and is designed to protect even the most sensitive members of a population, based on data on the most sensitive adverse health effect. For cadmium, this value was based on the most sensitive adverse effect known to occur through oral exposure of cadmium, called renal proximal tubular proteinuria, in which low-molecular-weight proteins appear in the urine, probably indicating decreased protein reabsorption by the tubules in the kidney. Although a number of studies (Kjellstrom and Nordberg, 1978; Nogawa et al., 1978, 1987; Sharma et al., 1983) have shown that much higher levels of cadmium (e.g., ranging from 0.2 to 1.0 mg/day) could be ingested daily for a lifetime without adverse effects, the biosolids risk assessment conservatively used the RfD value of 0.07 mg Cd/70 kg body weight•day.

Human Body Weight (BW). The choice of body weight for use in the risk assessment depended on the definition of the individual at risk, which in turn depended on exposure and susceptibility to adverse effects. Because the RfD is defined as the dose of pollutant per unit of body weight that can be tolerated over a lifetime, a standard adult ("lifetime") average body weight of 70 kg was used in Pathway 2. (For the child ingestion exposure pathway, Pathway 3, an average body weight of 16 kilograms was used.) An average value for the BW parameter was considered adequate because it was combined with other, more conservative parameters (e.g., the RfD).

Relative Effectiveness of Exposure (RE). The RE parameter was used to reflect differences in toxicological effects due to differences in bioavailability and exposure routes. For example, the bioavailability of cadmium is greatly lessened when zinc is also present in the diet. Higher zinc levels in the diet of Japanese subsistence rice eaters (discussed in Box 7, Chapter 3) probably would have reduced or eliminated the intestinal absorption of cadmium and the severe *itai itai* disease experienced by this population. In addition, the binding ability of the biosolids matrix reduces the availability of biosolids metal pollutants (see also Section J-3 in Chapter 3). A policy decision was made to set the RE conservatively at 1 for the land application risk assessment. Setting RE at 1 assumes 100 percent bioavailability intake. Hence, setting the RE equal to 1 underestimates the allowable dose of biosolids pollutants.

Total Background Intake Rate of Pollutant From All Other Sources of Exposure (TBI). The background intake values for water were based on EPA reports on occurrence of and exposure to pollutants in relation to drinking water regulations, and the TBI data for dietary exposure were based on U.S. Food and Drug Administration (FDA) market basket analyses for food and liquids (except drinking water) from 1988 to 1992. Average values were used for the TBI parameter because it was combined with other, more conservative parameters. A lifetime TBI average was not based on a maximum daily intake because daily intake from background sources is variable throughout a lifetime. Hence, a TBI value represents an average estimate of pollutant intake. A TBI value for cadmium of 0.0161 mg Cd/day was used.

Calculation of the Pollutant Limit (RP)

The second algorithm used in the Pathway 2 risk assessment combined the RIA value from the first algorithm discussed above with additional parameters to calculate a pollutant limit, shown below for cadmium:

$$RP_C = \frac{RIA}{\sum(UC_i \cdot DC_i \cdot FC_i)} = \frac{53.86}{0.4408} = 122\ kg\ Cd/ha^*$$

* Listed as 120 kg Cd/ha in Table 15 due to rounding to two significant figures.

Parameters Used To Calculate the Reference Application Rate of Pollutant (RP)

Uptake Response Slope of Pollutant in Plant Tissue (UC). The UC parameter reflected the amount of a pollutant taken up by plants from soil/biosolids. This value was very important in the biosolids risk assessment for land application because it was used (in this pathway and others) to help assess human toxicity from consumption of plants containing pollutants in biosolids. The methodology used for calculating UC (for Pathways 1 and 2) was shown in Chapter 3 in the section "Calculating Plant Uptake Slopes." For Pathway 2, uptake slopes for the following seven food groups were evaluated because these were deemed likely to be grown by the home gardener (the HEI for this pathway): potatoes, leafy vegetables, fresh legumes, root vegetables, garden fruits, sweet corn, and grains and cereals. Table 15 lists the UC values for these different food groups for cadmium in Pathway 2.

A combination of conservative (very low probability of occurrence) and less conservative (low to average probability of occurrence) assumptions were used to calculate UC values in the biosolids land application risk assessment. This UC value is an overestimation of actual plant uptake because several of the key assumptions and data sets used were conservative, including: the assumption that plant response slope is linear; the use of high-metal-content biosolids data; and the use of short-term data from field studies (1 or 2 years after application), in which equilibrium had not been attained (these and other conservative assumptions used are explained below). Because of this conservatism, the geometric mean, rather than the more conservative arithmetic mean, was used to statistically represent the log normal distribution of UC data because the geometric mean provides a better estimate of central tendency for data with this type of distribution (i.e., by using the geometric mean, UC reflects median data). If the more conservative arithmetic mean had been used, a higher UC value would have resulted that reflected higher

Table 15

Parameter Values for Cadmium, Pathway 2, Land Application

Food Group	UC	DC	FC	UC · DC · FC	Other Variables	
Potatoes	0.004	15.5954	0.37	0.0230	RfD	0.001
Leafy vegetables	0.182	1.9672	0.59	0.2112	BW	70
Fresh legumes	0.002	3.2235	0.59	0.0036	RE	1
Root vegetables	0.032	1.5950	0.59	0.0305	TBI	0.01614
Garden fruits	0.045	4.1517	0.59	0.1104	RIA	53.86
Sweet corn	0.059	1.5969	0.59	0.0552	RP_c	120
Grains and cereals	0.018	89.0833	0.0043	0.0070		
Sum UC·DC·FC				0.4408		

percentiles of the data (e.g., possibly 70th to 80th percentiles). (A median value, which is the same as the 50th percentile, is the point at which one-half of the observations of the amounts of cadmium taken up by plants are less than this value and one-half are greater than this value. The 80th percentile is the point at which 80 percent of the observed cadmium uptake values are less than this number and 20 percent are greater.)

Minimum Plant Uptake Value Used. To address data uncertainties, a minimum value of 0.001 mg/kg for plant uptake of a pollutant was assumed, even when data indicated no increase in pollutant concentration in plants or when uptake was negative. This assumption of minimum plant uptake is conservative and results in an overestimation of UC, because lower UC values would have resulted if the actual values were used. The precise degree of overestimation is unknown. For cadmium, 14 percent of the 196 data points used had plant uptake slopes of 0.001; thus, overestimation might be from 0 to 14 percent. (By comparison, 73 percent of the 52 data points for lead had UC values of 0.001, representing a much higher overestimation of risk for lead) (Ryan and Chaney, 1993).

Use of Linear Response Slope. Another conservative assumption in calculating the value for the UC parameter involved the use of a linear response slope to represent plant uptake of metals, as discussed in Chapter 3. Briefly, numerous field studies indicate that plant uptake of metals is curvilinear (i.e., increases up to a point and then levels off, or plateaus, even if more pollutant is added to the soil), given the ability of biosolids to bind pollutants in biosolids/soil mixtures. Nevertheless, the biosolids risk assessment conservatively assumed a linear response (i.e., uptake continues to increase indefinitely). The linear response slope was used because most of the individual studies used on plant uptake did not have sufficient rates of application to test for lack of linearity (Ryan and Chaney, 1993). Using a linear response slope results in an overestimate of plant uptake of metals. For cadmium in Pathway 2, overestimation was probably at least RP/20, assuming a maximum biosolids application rate of 1,000 mt/ha.

Inclusion of Acidic pH Data. The UC data included results from field studies that represented both low pH (acidic) and neutral soil conditions, even though low pH is unlikely to occur for very long (certainly not for the 70-year lifetime exposure of the HEI) because gardeners probably would quickly correct the soil pH (e.g., add lime) to improve plant health (see Chapter 3, "Ecological Risks," for a more detailed discussion on biosolids and low pH soils). In addition, increases in the solubility of two metals, aluminum and manganese, will cause injury in most plant species in low pH soil conditions, even if no additional metals are added (e.g., from biosolids). Thus, including data for low pH conditions overestimates UC values. Nevertheless, because acidic soil conditions can periodically occur, and because data show that low pH can result in phytotoxicity, plant response under acid soil conditions was included in the data set. Forty percent of the data used to calculate UC values was based on studies with a pH of less than 6.0. Using these low pH data, a garden would be strongly acidic for approximately 30 of the 70 years of HEI exposure for Pathway 2, an unlikely occurrence (Ryan and Chaney, 1993).

In addition, in the case of cadmium, if low pH conditions are not corrected (allowing for high cadmium uptake by plants), the presence of zinc (in a ratio less than or equal to 0.015 cadmium to zinc), which also is taken up by plants under low pH but otherwise normal soil conditions, will lower cadmium risks for two reasons. First, zinc is known to reduce the phytoavailability of cadmium for plant uptake. Second, the reduction in plant yield resulting from zinc toxicity would reduce potential consumption of crops containing high levels of cadmium (Fox, 1983, 1988; McKenna et al., 1992a, 1992b; Chaney and Ryan, 1994; Chaney, 1990; Logan and Chaney, 1983; Strehlow and Barltrop, 1988).

Use of Short-Term Data To Predict Long-Term Pollutant Uptake. Bioavailability of metals for plant uptake is highest in the first year after land application of biosolids (Chang et al., 1987). Nonetheless, long-term UC values (i.e., for 70 years of exposure) were conservative, based primarily on short-term data (i.e., from biosolids/soil systems established for less than 5 years) in the risk assessment. Use of these early-year data causes overestimation of long-term UC values.

Impact of Combining Conservative and Less Conservative Factors To Calculate UC. Combining the conservative factors discussed above for UC (e.g., the 0.001 bounding estimate, linearity, short-term data, and acid pH systems) with one or two less conservative factors (e.g., the geometric mean) to estimate the UC resulted in a calculated value for UC that was greater than the actual UC and, hence, overestimates risk in exposure pathways that use this parameter.

Dietary Consumption of Food Group (DC). As discussed above, the types of foods considered likely to be grown by the home gardener and therefore evaluated for this pathway were potatoes, leafy vegetables, fresh legumes, root vegetables, garden fruits, sweet corn, and grains and cereals. Determining DC values for Pathway 2 involved a methodology similar to that used for Pathway 1 (i.e., use of EPA's reanalysis of the FDA Revised Total Food Diet list to develop an Estimated Lifetime Average Daily Food Intake; see Chapter 3, "Food Consumption"), with additional revisions to account for home garden production. For example, while the Pathway 1 food group listed as "legumes" included both dried and fresh legumes, for Pathway 2 only fresh legumes were included in this category because home gardeners are unlikely to grow the dried legumes they consume. Similarly, peanuts were excluded from the Pathway 2 risk assessment (although included in Pathway 1) because home gardeners are unlikely to grow peanuts. Also, sweet corn was added as a separate category for Pathway 2 because many gardeners grow sweet corn (corn was included in Pathway 1 under the category "grains and cereals," but was subtracted from this category for Pathway 2 because home gardeners do not usually grow field corn for processing in the home). The DC values for cadmium for Pathway 2 are listed in Table 15.

The value used for the DC parameter can be considered average; however, this average DC value was based on conservative estimates (i.e., short-term dietary data was used to estimate long-term food consumption) (Ryan and Chaney, 1993). Extrapolating short-term data to long-term exposure estimates is known to result in overestimation of actual exposure (U.S. EPA, 1991). These short-term data were nevertheless used because they represented the best data available.

The subsistence home gardener HEI is likely to be at lower risk than the sensitive population that the RfD and the biosolids Pathway 2 analysis is designed to protect. This is because although the home gardener will potentially be adversely exposed to cadmium in vegetables he or she produces and consumes from his or her biosolids-amended garden soils, these same vegetables also contain significant levels of zinc, calcium, and iron, which are known to reduce cadmium absorption and hence adverse exposure. (See also Box 7 in Chapter 3.)

Fraction of Food Group Produced on Biosolids-Amended Soil (FC). The value for the FC parameter in Pathway 2 differed significantly from Pathway 1, even though the algorithms used were the same (see Boxes 9 and 10). This is because the percent of food grown for human consumption on biosolids-amended land will most likely be greater for the home gardener (the HEI for Pathway 2) than for an individual who consumes only store-bought foods, some of which are produced on biosolids-amended soils (the HEI for Pathway 1). USDA data from surveys on homegrown foods were revised to arrive at appropriate food production values for the FC parameter for Pathway 2. Assuming that 100 percent of gardeners produce some of their own food (a reasonable worst-case assumption made for the biosolids risk assessment), the revised USDA values used in the biosolids risk assessment for FC in Pathway 2 were:

Food Group	Percent Homegrown (rounded)
Potatoes[a]	37
Vegetables[b]	59
Flour, cereal	0.43

[a]Includes sweet potatoes.
[b]Includes leafy vegetables, fresh legumes, root vegetables, garden fuits (e.g., tomotos, eggplant), sweet corn.

The above values for FC are conservative because they represent the percent of homegrown garden foods for the small segment of home gardeners at the high end of the food consumption distribution. For example, it would be difficult for most home gardeners to grow 59 percent of the leafy vegetables they consume annually, given that (1) the harvesting season for leafy vegetables in most parts of the country is only several weeks long, while leafy vegetables are consumed fresh all year round, and (2) only 5.5 percent of the population have gardens large enough to produce a significant portion of their annual food consumption (Ryan and Chaney, 1993).

Thus, the conservative assumption of 59 percent homegrown production of leafy vegetables probably significantly overestimates exposure. If a more reasonable assumption of 10 percent (rather than 59 percent) annual leafy vegetable production by a home gardener were used, while retaining the 59 percent production for other foods in this food group, the pollutant limit (RP) could be increased by approximately a factor of 2 (Ryan and Chaney, 1993).

Conservative Parameters Result in a Conservative Pollutant Limit

When all of the parameter values discussed above, which are based primarily on conservative assumptions, are used together to calculate a pollutant limit (RP), it is apparent that the resultant pollutant limit is also highly conservative. In addition, it is highly unlikely that all the conservative conditions assumed would exist at the same time. For example, it is unlikely that a person would grow a large portion of the vegetables he or she consumes for an entire lifetime on biosolids-amended soil

(FC parameter) while gardening on strongly acidic soils for many years (UC parameter) and adhering to a poor quality diet that favors cadmium absorption (DC parameter) (Chaney and Ryan, 1993).

Summary. The pollutant limits identified by the biosolids risk assessments are conservative and very protective, as illustrated by the analysis done for cadmium, Pathway 2, for land application. Many of the parameters used to calculate the pollutant limits were based on conservative data sets, assumptions, and/or policy decisions including:

- ***HEI Assumption.*** The HEI for Pathway 2 grows a major portion of his or her diet on biosolids-amended soil for a lifetime. In reality, data indicate that this HEI population is small (between 0.1 to 2 percent of the U.S. population) (Ryan and Chaney, 1993). In addition, few people will have home gardens their entire lifetimes, and only a small portion of those persons will use biosolids that can produce the high soil concentrations of biosolids pollutants that would result in exposures at the pollutant limit. Equally conservative assumptions were made for many of the other pathways in the biosolids risk assessments.
- ***RfD and q_1* Data.*** RfDs and q_1*s, used in many of the exposure pathways, are based on conservative data and are designed to protect even the most sensitive members of a population, based on data on the most sensitive adverse health effect.
- ***RE Policy Decision.*** Although the ingestion route of exposure may pose less risk than other exposure routes, the relative effectiveness of exposure (RE) parameter was conservatively set at 1 because of limited data. A more accurate RE for pollutants in biosolids via food ingestion might be a value less than 1. Based on known data, the RE was considerably overestimated.
- ***UC Data and Assumptions.*** Numerous factors used to calculate plant uptake of pollutants (metals) were conservative, including:
  - Use of a minimum value (0.001 mg/kg) for plant uptake of metals (UC), even when the data showed no increase, or a decrease, in plant uptake of metals.
  - Use of a linear response slope (which assumes that plant uptake continues to increase) because of a lack of data on biosolids application rates, even though numerous data show that in reality plant uptake is curvilinear (increases initially, then levels off, or plateaus).
  - Use of data from short-term experiments in which the UC was atypically high (U.S. EPA, 1992a).
- ***FC Data.*** Use of high estimates of homegrown food consumed by the HEI for Pathway 2, particularly the 59-percent value used for leafy vegetables.
- ***Short-Term Data To Predict Long-Term Pollutant Uptake and Food Consumption.*** Short-term data were used to predict long-term uptake by plants and long-term food consumption by the HEI population for Pathway 2.
- ***Most Biosolids Cannot Exceed the Pollutant Limit for Cadmium.*** Data indicate that less than 10 percent of current biosolids, and probably less than 3 percent, could ever reach the pollutant limit for cadmium, expressed as a soil concentration limit. (This limit is known as the RLC, which is the allowed cumulative soil concentration of a pollutant in µg/g DW; conversion of the RP pollutant application rate limit to an RLC soil concentration limit is shown in Chapter 6 and Appendix D.) In addition, it would take a minimum of 300 years (and possibly up to 600 years) of continuous application at agronomic rates (e.g., 10 mt/ha/yr) before the soil concentration of cadmium would become equal to the biosolids concentration and before it would reach the RLC. It

would also take 300 years under agronomic application rates for the upper 1 percent of biosolids (those containing the highest pollutant concentrations) to produce dietary increases in excess of the RfD. It is unlikely that continuous yearly application would occur for this time frame; therefore, soil concentrations are not likely to reach the RLC, and exposure of lifetime subsistence gardeners is unlikely to reach the RfD in any year, and even less likely for 70 years (Chaney and Ryan, 1993, 1994; Ryan and Chaney, 1995).

Summary

This chapter explains how pollutant limits were derived in the risk assessments conducted for the final Part 503 rule. Included in the discussion are descriptions of the many parameters involved and several example calculations to show how different types of parameters, models, data, and algorithms were used to calculate pollutant limits for different pathways. The conservative nature of many of the parameters also is discussed. The conservativeness remaining after combining conservative and less conservative data, assumptions, and parameters to calculate a pollutant limit is described. Finally, a detailed example is included to show the high level of protection involved in calculating a pollutant limit (cadmium in Pathway 2 for land application). While the exact degree of conservativeness varies somewhat for each of the pathways and pollutant limits developed as a result of the Part 503 risk assessments, EPA believes that all the pollutant limits conservatively protect public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids. The conservative pollutant limits identified in the revised biosolids risk assessments were used to establish the pollutant limits for the final Part 503 rule, as discussed in Chapter 5.

Chapter 5

How the Biosolids Risk Assessment Results Were Used in the Part 503 Rule

The results of the biosolids risk assessments were used to establish Part 503 pollutant limits. Other elements of the Part 503 rule were established to provide a more comprehensive and protective regulation (see Figure 1 in Chapter 1), for example:

- To be consistent with data used in the various risk assessments (e.g., an assumption used in the risk assessment calculation was a 10-meter buffer zone between land-applied biosolids and surface waters. Hence, a Part 503 management practice was placed in the rule that requires a 10-meter buffer zone from surface waters for land application).
- To ensure that the information needed to meet pollutant limits would be available (e.g., some Part 503 monitoring and recordkeeping requirements pertain to operating conditions and emissions from biosolids incinerators; others ensure that biosolids meet cumulative pollutant loading rate limits for land application).
- To provide protection for areas not addressed by the risk assessments (e.g., the Part 503 operational standard for pathogen reduction and vector attraction reduction, and many of the Part 503 management practices).

This chapter first summarizes the biosolids risk assessments, as discussed throughout this document. It then briefly presents key aspects of the Part 503 rule as they relate to the risk assessments, focusing on how the biosolids risk assessment results were used to establish the Part 503 pollutant limits. Some of the Part 503 requirements that were not based on the risk assessments also are discussed. For more information on the Part 503 rule, see EPA's ***A Plain English Guide to the EPA Part 503 Biosolids Rule*** (U.S. EPA, 1994).

Synopsis of the Biosolids Risk Assessments

History of the Risk Assessment Process

As discussed in Chapter 2, the process of establishing pollutant limits was extensive. In 1984, EPA produced a preliminary list of 200 pollutants potentially found in biosolids for which a risk assessment might be appropriate. Experts reviewed this list and narrowed it down to approximately 50 pollutants to be considered for regulation, based on toxicity and exposure data. After initial evaluations of these 50 pollutants (i.e., a hazard index screening, see Chapter 2, Tables 2 and 3), EPA determined that 31 of these pollutants should undergo a detailed biosolids risk assessment. From 1986 to 1988, the initial, detailed risk assessments for these 31 pollutants were conducted for the proposed Part 503 rule. After receiving numerous peer review and public comments on the proposed rule published in 1989, a second round of risk assessments was conducted with the assistance of biosolids experts from outside the Agency from 1990 to 1992 for the final Part 503 rule. These revised risk assessments incorporated numerous changes based on the review comments (as discussed in Chapters 2 and 3). The results of the revised risk assessments were the basis for setting pollutant limits in the final Part 503 rule.

Defining Exposure Pathways and Highly Exposed Individuals

The basic approach for assessing risks from biosolids involved:

- Identifying appropriate pollutants to be evaluated (as discussed above and in Chapter 2).
- Defining the highly exposed individuals (HEIs) for relevant exposure pathways (e.g., a child ingesting biosolids or an adult eating crops grown on biosolids-amended soils) for pollutants of concern.
- Identifying or developing appropriate parameters (e.g., variables for toxicity, dietary consumption, and food production) that could be used in algorithms (equations) to calculate pollutant limits (as discussed in Chapter 4).
- Assessing risks to HEIs in relevant pathways of exposure. (HEIs and the biosolids exposure pathways used are listed in Chapter 2, Tables 6, 7, and 8).

This approach was used for all types of risks—to people, animals, or plants—associated with inorganic and organic pollutants. Defining realistic HEIs (i.e., highly exposed individuals that really could exist in a population) was one of several key challenges of the risk assessments. The approach used early on in the biosolids risk assessment process (i.e., for the proposed rule) was the use of a most exposed individual (MEI). Reviewers of this approach commented that the definition of the MEI involved so many conservative assumptions that it was highly improbable that such an individual could exist. In risk assessment terminology, the MEI represented bounding estimates. Further evaluation of the MEI showed that his or her exposure would be higher than the 100th percentile (i.e., higher than 100 percent of the most exposed population). Thus, for the revised risk assessment for the final Part 503 rule, EPA used the concept of an HEI rather than an MEI to define individuals that because of their circumstances were at the high end of the exposure distribution, but still had a finite possibility of existing (i.e., did not exceed the 100th percentile for exposure). The HEI was defined by a combination of conservative (high-end) and average (mid-range) assumptions, as recommended in EPA's 1992 risk assessment guidance (Habicht, 1992, see Chapter 3). Nevertheless, the HEIs remain conservative representations of the exposed population (as shown in the example risk assessment for cadmium in Chapter 4).

Choosing Parameters To Identify Pollutant Limits

Risks to People and Animals

Different parameters were used to calculate pollutant limits for different types of risks (or, different values were assigned to the same parameter). For example:

- For human health risks, the fundamental health-based parameters used were the risk reference dose (RfD) for noncarcinogens and the cancer potency value (q_1*) for carcinogenic pollutants (see Chapter 2). These parameters define intakes of pollutants that, based on an array of considerations, are considered acceptable. Both RfDs and q_1*s include significant safety factors, which contribute to the conservatism of the Part 503 pollutant limits for protection of humans in relevant exposure pathways.
- For risks to domestic animals and wildlife, the primary protective health parameter used was the threshold pollutant intake (TPI) of the most sensitive or most exposed species. This parameter was the calculated maximum pollutant intake in the diet associated with no toxic effects. Risks to animals also included factors for bioavailability and bioaccumulation to account for the uptake of pollutants in soil by earthworms and earthworm predators as well as a bioconcentration factor in fish for the surface-water pathway.
- For risks to soil organisms, a pollutant concentration in soil considered to have no adverse effects (called the RLC) was developed and used as the protective health parameter.

Risks to Plants

For risks to plants, a series of comprehensive approaches was used. In conjunction with other experts, EPA conducted an in-depth review of the scientific literature on plant uptake of metals (including over 270 journal articles) and field study data on plant metal concentrations. For such risks:

- EPA first analyzed different levels of vegetative growth reduction (e.g., from 8 to 50 percent reduction in growth) associated with various leaf concentrations of metals and corresponding soil metal loadings. Maximum loading rates were identified that would not exceed an acceptable phytotoxicity threshold.
- Next, EPA analyzed data to identify plant tissue levels of metals associated with first detectable yield reductions in sensitive plant species as an alternate way to develop phytotoxicity thresholds and pollutant limits. Plant response slopes for the uptake of metals were then calculated from the thresholds for sensitive species to identify metals application rates that would not exceed the thresholds.
- As described in Chapter 3 (Section N-3) and Chapter 4 (Box 13), EPA then selected the more restrictive of the two phytotoxicity limits (as determined by the approaches noted above) as the pollutant limit for phytotoxicity in the risk assessment.
- In reality, no loading rates for potentially phytotoxic metals were identified in any of the field studies analyzed that would exceed the established phytotoxicity threshold concentrations. Thus, extra protection was provided by the conservatively established pollutant limits for phytotoxicity.

Choosing a Pollutant Limit

As described in Chapter 4, a number of different exposure pathways were evaluated for each pollutant. The pathway with the lowest pollutant limit was identified as the "limiting pathway," and this lowest value was used as the pollutant limit in the risk assessment for each pollutant. The most limiting pathways and the risk assessment pollutant limits are listed in Tables 11, 13, and 14 (Chapter 4) for land application, surface disposal, and incineration.

Evaluating Inorganic and Organic Pollutants

Both inorganic and organic pollutants were evaluated in the biosolids risk assessments. For these two types of pollutants, different parameters and algorithms were used in the risk assessment calculations to reflect the fact that many organic pollutants degrade in the environment. Organic pollutants for land application and surface disposal were not regulated in the Part 503 rule, however, for the reasons discussed in Chapter 3. For incineration, organic pollutants were regulated through a THC (or CO) operational standard (discussed later in this chapter).

Using Conservative Assumptions

For many of the parameters and methodologies used, a number of associated assumptions and policy decisions were made. For example, assumptions were made regarding plant uptake of pollutants (the UC parameter) and the fraction of food produced on biosolids-amended land (the FC parameter), as discussed in Chapter 4. In many cases, the assumptions and policy decisions made were conservative to account for uncertainties that remained in the carefully assembled data sets. Three examples are:

- The assumption that a certain minimal level of plant uptake of pollutants occurs, even when available data showed no increased plant uptake.
- The assumption that home gardeners produce and consume 59 percent of their annual yearly leafy vegetable consumption, while a more reasonable assumption might be the production and consumption of 10 percent of their leafy vegetables.
- The selection of the most exposed or most sensitive species as the HEI for protection of ecological species.

A number of key assumptions were changed (i.e., made less conservative) after EPA received comments indicating that the proposed Part 503 pollutant limits were based on unrealistically conservative assumptions. Thus the revised risk assessments were calculated combining assumptions having conservative high-end (low) probabilities of occurrence with assumptions having mid-range (average) probabilities of occurrence. Using this approach, the 95th to 98th percentiles of the subset of the population comprised of individuals who might be adversely effected by pollutants in biosolids were protected by the final Part 503 rule (such as the subsistence home gardener described in Chapter 4, who might be consuming food produced in soils where the cumulative pollutant loadings were already at their maximum permitted level). The revised risk assessments resulted in a final Part 503 rule that was both highly protective and more realistic and less stringent than the initial proposed rule.

The Biosolids Risk Assessments and the Part 503 Rule

The pollutant limits identified in the biosolids risk assessments were used either directly or with modification to establish the pollutant limits in the Part 503 rule, as discussed below.

Pollutant Limits for Land Application

Four Types

The four types of pollutant limits established for land application in the final Part 503 rule are shown in Table 16 and described below:

- **Cumulative pollutant loading rates (CPLRs):** One type, called the CPLR, was taken directly from the biosolids risk assessment results (Table 2 in Part 503). CPLRs apply to biosolids with pollutant concentrations in excess of Part 503's Table 3 values (see also Table 16 in this guidance document) that are applied to land in bulk. Part 503 requires that accurate records be kept of the amounts of pollutants applied to a site from biosolids subject to CPLRs. Attainment of the CPLR for a pollutant means that no more CPLR biosolids can be applied to that site. Even at the CPLR, however, the pollutant loading is protective of public health and the environment. Other biosolids that meet the pollutant concentration limits, described below, can still be land applied safely, even on a site where the CPLR has already been reached.

Table 16
Risk Assessment Results and Part 503 Pollutant Limits for Land Application

Pollutant		Table 2, Part 503 Rule	Table 4, Part 503 Rule	Table 1, Part 503 Rule	Table 3, Part 503 Rule
	Risk Assessment Results (RP_C, kg-pollutant/ ha, DW)	CPLR Limit[a] (kg-pollutant/ ha, DW)	APLR Limit[b] (kg-pollutant/ ha/yr, DW)	Ceiling Concentration Limit[c] (mg-pollutant/ kg- biosolids, DW)	Pollutant Concentration Limit (mg-pollutant/ kg- biosolids, DW) (monthly average)
Arsenic	41	41	2.0	75	41
Cadmium	39	39	2.0	85	39
Chromium[d]					
Copper	1,500	1,500	75	4,300	1,500
Lead	300	300	15	840	300
Mercury	17	17	0.85	57	17
Molybdenum[e]	18			75	
Nickel	420	420	21	420	420
Selenium	100	100	5.0	100	100[f]
Zinc	2,800	2,800	140	7,500	2,800

[a]CPLR limits were taken directly from the risk assessment results and pertain only to biosolids applied in bulk.

[b]APLR limits were derived from the CPLR limits (see text) and pertain only to biosolids sold or given away in bags or other containers.

[c]Ceiling concentration limits are either the 99th-percentile concentrations in the National Sewage Sludge Survey or the risk assessment pollutant limits, whichever were least stringent (see text and Box 15).

[d]Chromium limits are not shown because they most likely will be deleted from the rule (see also Chapter 3).

[e]Some molybdenum limits are not shown because they are under reconsideration and are presently not part of the rule (except for the ceiling concentration limit, which remains in effect).

[f]A change in the pollutant concentration limit for selenium is expected based on a recent court decision (see also Chapter 3).

- **Annual pollutant loading rates (APLRs):** A second type of Part 503 biosolids pollutant limit is the APLR. The APLRs, which apply only to biosolids that are sold or given away in a bag or other container, identify the maximum amounts of pollutants in biosolids that can be applied to a site in any one year. APLR biosolids, like CPLR biosolids, contain pollutant levels in excess of the Part 503 Table 3 pollutant concentration limits. The APLRs were derived by dividing the CPLRs by 20, reflecting an assumed 20 applications annually at the same rate to a given site. APLRs were established because imposing CPLRs was not practical, given the difficulty in establishing a chain of control from preparer to applier of bagged or containerized biosolids. Part 503 requires that APLR biosolids must be accompanied with labeling information to ensure that they are used properly and that the APLR is not exceeded.

  EPA concluded that 20 years is a reasonable conservative assumption for APLRs because biosolids sold or given away in a bag or other container will probably be applied to a lawn, home garden, or public contact site and therefore probably will not be applied longer than 20 years at the same site, particularly not 20 consecutive years.

- **Ceiling concentration limits:** A third type of pollutant limit for land application, called the ceiling concentration limit, identifies biosolids with the maximum allowable concentrations of pollutants that can be land applied. These limits were established in Part 503 as minimum-quality limits to prohibit the lowest quality (highest metal content) biosolids from being land applied. Biosolids with high metals concentrations are a concern because metals at high levels might behave more like metal salts, which are taken up by plants much more readily than metals at the low levels typically found in biosolids (see Chapter 3). Including ceiling limits also may bolster public confidence in the land application of biosolids. The ceiling concentration limits are either the 99th-percentile concentration for each pollutant, as defined by the National Sewage Sludge Survey (NSSS), or the pollutant limits identified in the risk assessment, whichever is the least stringent (see Box 15, this chapter, and Section N-6 of Chapter 3).
- **Pollutant concentration limits:** The last and most stringent type of Part 503 limit is called the pollutant concentration limit. These risk-based limits were derived by assuming a 1,000-mt/ha application of biosolids in which the cumulative pollutant loading rates would be met but not exceeded. The pollutant concentration limits define no-adverse-effect biosolids that can be land applied safely without the applier keeping track of cumulative pollutant loadings, as is required for biosolids meeting CPLRs discussed above (see also the description of pollutant concentration limits in Chapter 3). The pollutant concentration limits were derived from the pollutant limits identified in the risk assessments. (Prior to a recent court decision [see Section Q, Chapter 3], the 99th-percentile NSSS concentrations were imposed as pollutant concentration limits when they were lower than the risk assessment limits.)

  If biosolids can be shown to meet the pollutant concentration limits listed in Table 3 of Part 503, as well as certain Part 503 pathogen and vector control requirements (discussed later in this chapter), these biosolids (sometimes called exceptional quality [EQ] biosolids) can be land applied as freely as other fertilizers and soil conditioners without also having to show they meet the Part 503 management practices and general requirements. Recordkeeping, monitoring, and reporting requirements would still be in effect, but the burden of these stipulations would be considerably diminished without the need to track pollutant loadings. Numerous field studies supported this approach; research results showed no adverse effects from applying biosolids with the low levels of pollutants defined by the pollutant concentration limits.

As discussed above, the derivation of ceiling concentration limits was based on prohibiting the use of lower quality (high metal) biosolids, including pollutants that would behave more like metal salts. At the same time, the use of pollutant concentration limits encourages the use of high-quality biosolids. The decision to use ceiling concentration and pollutant concentration limits, whether arising from risk-based calculations or other data, was an EPA policy decision. This decision helped implement EPA's comprehensive risk management policy that incorporates the goals of promoting the use of high-quality biosolids and maintaining the existing quality of land-applied biosolids. The policy decision to use these types of limits also added further conservatism to the Part 503 rule. Box 15 provides an example of how Part 503 ceiling concentration limits and pollutant concentration limits were derived.

To summarize, all land-applied biosolids must meet the Part 503 ceiling concentration limits. Biosolids also must meet either (1) the Part 503 pollutant concentration limits, or (2) the Part 503 CPLRs or APLRs, as discussed above. Thus, EPA used both risk-based limits and policy decisions to develop the land application pollutant limits in the Part 503 rule.

Box 15
How Part 503 Ceiling and Pollutant Concentration Limits Were Derived

Example for copper:

- The **pollutant limit** (RP_C) identified in the biosolids land application risk assessment for copper was 1,500 kg of copper per hectare (see Chapters 3 and 4).
- To convert the pollutant limit to a **pollutant concentration limit**, EPA used the assumptions that biosolids would be applied to a site for 100 years at a rate of 10 metric tons per year (a total of 1,000 metric tons per hectare of biosolids application), which represents 1,500 mg of copper per kg of biosolids:

$$\textit{Pollutant concentration limit} = \frac{1{,}500 \textit{ kg of copper per hectare (risk assessment limit)}}{100 \textit{ (site life, yrs)} \cdot 10 \textit{ (annual application rate, mt–biosolids DW/ha} \cdot \textit{yr)} \cdot 0.001}$$

$$= 1{,}500 \textit{ mg of copper per kg of biosolids}$$

(Note: 0.001 is a conversion factor)

Including pollutant concentration limits encourages the use of superior quality biosolids, because if the pollutant concentration limits and certain Part 503 pathogen and vector requirements are met, the biosolids can be used as freely as any other type of fertilizer or soil conditioner.

- To derive the **ceiling concentration limit**, the 99th-percentile pollutant concentration in the National Sewage Sludge Survey (NSSS) was identified. For copper, this was 4,300 mg of copper per kg of biosolids. The results of the risk assessment and the NSSS survey were then compared and the least stringent (i.e., higher) of the risk assessment or NSSS number (4,300 mg/kg) was selected as the ceiling concentration limit; this limit prevents biosolids with high concentrations of pollutants from being land applied.

	Risk Assessment Pollutant Limit	NSSS 99th %	Part 503 Ceiling Concentration Limit	Part 503 Pollutant Concentration Limit
Copper	1,500	4,300	4,300	1,500[a]

[a]All numbers are mg of pollutant/kg of biosolids, DW. The Part 503 pollutant concentration limits are monthly averages.

Pollutant Limits for Surface Disposal

EPA used either the 99th-percentile pollutant concentrations from the NSSS or the pollutant limits identified in the risk assessment, whichever were more stringent, as the pollutant limits for unlined surface disposal units in the Part 503 rule. The Agency determined that risks from surface disposal sites with liners and leachate collection systems were negligible; thus, the Part 503 approach for surface disposal includes pollutant limits only for biosolids disposed at surface disposal sites without liners and leachate collection systems.

Surface disposal sites often comprise a number of cells, or units, that accept biosolids and may or may not be active. Part 503 pollutant limits for active units without liners and leachate collection systems differ depending on the distance between the unit boundary and the surface disposal site boundary. The risk assessment proved to be sensitive to the assumption of distance to the property line for unit boundaries 150 feet or less from the surface disposal site property line, and thus the Part 503 limits reflect these distance differences. The Agency made a decision to manage risks by tailoring limits for active biosolids units within surface disposal sites based on property line distance, rather than requiring all surface-disposed biosolids to meet unnecessarily restrictive limits based on worst-case property line distances. The Agency also determined that risks from the surface disposal of biosolids through the surface-water pathway could be managed much more efficiently through management practices (discussed later in this chapter) that prevent biosolids from entering surface water rather than through substantially more stringent pollutant limits.

Some inorganic pollutants (copper, lead, and mercury) were not regulated in Part 503 for surface disposal because they met one of three criteria that EPA used to delete pollutants from biosolids regulation (i.e., they were not expected to exceed the pollutant limits identified in the risk assessment, based on NSSS data; see "Deletion of Pollutants" in Chapter 3).

Pollutant Limits for Incineration

Four of the seven inorganic pollutant limits in Part 503 for biosolids incineration were derived using information from the biosolids risk assessment (i.e., risk-specific concentrations for arsenic, cadmium, chromium, and nickel), as described in Chapter 4. Because of the limited number of incinerators affected, the Agency chose to use site-specific pollutant limit calculations. This approach allows risks to be managed in accordance with incinerator performance (see Box 16).

Beryllium and mercury pollutant limits were incorporated by reference to the National Emission Standards for Hazardous Air Pollutants (NESHAPS) for these pollutants, which are health-based standards. The pollutant limit for lead was based on a percentage of the National Ambient Air Quality Standard (NAAQS), rather than a risk-specific concentration for lead. EPA chose this approach for beryllium, mercury, and lead to be consistent with existing air quality regulations. EPA concluded that meeting the NESHAPS, or the pollutant limit calculated for lead using the NAAQS factor and site-specific data, protects public health from reasonably anticipated adverse effects of these pollutants in biosolids.

Other Elements of the Part 503 Rule

In addition to pollutant limits, other elements of the Part 503 rule include general requirements; operational standards; management practices; and frequency of monitoring, recordkeeping, and reporting requirements (see also Figure 1 in Chapter 1). Several of these additional elements are discussed below to highlight their relationship to the risk-based pollutant limits.

Box 16
Equations Used To Calculate Part 503 Pollutant Limits for Incineration

For arsenic, cadmium, chromium, and nickel:[a]

$$\text{Part 503 pollutant limit} = \frac{RSC \cdot 86{,}400}{DF \cdot (1-CE) \cdot SF}$$

For lead:[a]

$$\text{Part 503 pollutant limit} = \frac{0.1 \cdot NAAQS \cdot 86{,}400}{DF \cdot (1-CE) \cdot SF}$$

Where:

RSC = Risk specific concentration (micrograms per cubic meter)

NAAQS = National Ambient Air Quality Standard for lead (micrograms per cubic meter)

Site-Specific Factors:

DF = Dispersion factor, site-specific (micrograms per cubic meter per gram per second)

CE = Biosolids incinerator control efficiency for arsenic, cadmium, chromium, lead, or nickel; site-specific (hundredths)

SF = Biosolids feed rate, site-specific (metric tons per day), dry-weight basis

Hypothetical example calculation for arsenic:

Parameter	Value	Units
RSC	0.023	$\mu g/m^3$
Conversion factor	86,400	sec/day
Site-Specific Factors		
DF	3.4	$\mu g/m^3/g/sec$
CE	0.975	hundredths
SF	12.86	mt/day, DW

$$\textit{Part 503 pollutant limit} = \frac{RSC \times 86{,}400}{DF \times (1-CE) \times SF} = \frac{0.023 \times 86{,}400}{3.4 \times (1-0.975) \times 12.86} = 1{,}818 \ \textit{mg/kg of arsenic}$$

[a]See the Part 503 rule for specific requirements for these calculations (e.g., stack height, performance tests)

Operational Standards

In most cases, EPA determined that risk-based pollutant limits could be calculated to achieve the goal of protecting public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids, given the state of the science of risk assessment. In three cases, however, risk assessment methodologies were not sufficiently developed to provide a reasonable estimate of risk. Thus, EPA determined that the most appropriate way for the Agency to manage risks in these instances was to use operational standards rather than risk-based pollutant limits. The Clean Water Act specifically provides for alternatives to numeric limits for biosolids use or disposal in certain circumstances:

> If...it is not feasible to prescribe or enforce a numeric limitation for a pollutant...the Administrator may instead promulgate a design, equipment, management practice or *operational standard* [emphasis added]...which in the Administrator's judgment is adequate to protect public health and the environment from any reasonably anticipated adverse effect of such pollutant. [Clean Water Act, Section 405(d)(3)]

The Part 503 rule contains three operational standards. One standard regulates pathogen reduction in biosolids; the second addresses vector attraction reduction in biosolids; and the third covers total hydrocarbon (THC) limits in incinerator emissions. Each of these operational standards is discussed below.

The Operational Standards for Pathogen and Vector Attraction Reduction

EPA determined that a risk assessment approach for pathogen and vector attraction reduction in biosolids was not yet sufficiently developed to establish risk-based limits. Thus, EPA chose to manage risks from pathogens (and risks from vectors spreading those pathogens) through operational standards. The Agency concluded that the best way to meet the objective of protecting public health and the environment was to have biosolids meet certain technology-based requirements for minimizing or eliminating pathogen densities and reducing vector attraction. These requirements can be met either directly by taking measurements or by using certain approved processes known to reduce pathogens and vector attraction to levels judged reasonably safe by EPA.

With respect to pathogens, two levels of control can be met: Class A, which allows the use of biosolids with fewer restrictions because pathogen densities are below detectable levels; and Class B, which, because pathogen densities are reduced but are still detectable, is associated with a number of site and harvesting restrictions that allow sufficient time for environmental degradation of pathogens prior to contact. Domestic septage is required to meet certain pH requirements and site restrictions similar to those for Class B biosolids. More information on the Part 503 pathogen and vector attraction reduction requirements can be found in EPA's ***A Plain English Guide to the EPA Part 503 Biosolids Rule*** (U.S. EPA, 1994) and ***Control of Pathogens and Vector Attraction in Sewage Sludge*** (U.S. EPA, 1992d).

The Operational Standard for THC

Based on comments received on the proposed Part 503 rule, the Agency decided to replace its proposed risk-based THC concentration approach with an operational, technology-based standard. EPA set the operational standard for THC in emitted incinerator off-gases at 100 ppm based on testing at three incinerators. After evaluating the aggregate impact analysis, which indicated minimal health effects from current biosolids incinerator practices, along with site data on THC emissions, EPA concluded that this operational standard would protect public health from any reasonable anticipated adverse effects. As discussed in Chapters 2 and 4, EPA later included carbon monoxide (CO) monitoring (100-ppm limit) as an alternate, acceptable method of ensuring that the THC emissions operational standard would be met.

Management Practices

In general, management practices in the Part 503 rule were stipulated for the three use or disposal practices (land application, surface disposal, or incineration) for one of three reasons:

- To protect public health and the environment when specific pathways or end-points were not analyzed in the risk assessment (e.g., threatened or endangered species requirements for land application and surface disposal of biosolids).
- To embody assumptions that were incorporated into the risk assessment and thus need to be met in practice to ensure that risk levels are not exceeded (e.g., a 10-meter buffer zone around bodies of surface water for land-applied biosolids).
- To require that information be provided where risk levels might be exceeded if biosolids were not handled properly (e.g., labeling requirement for bagged or containerized biosolids for land application).

Thus, management practices were included in Part 503 to (1) constrain risks when actual risks were not evaluated, (2) support risk modeling assumptions, or (3) ensure proper handling of biosolids. Where risks were determined to be negligible (as discussed below), the Agency considered the appropriate strategy was to refrain from subjecting the biosolids to management practice requirements. The management practice requirements for the three use or disposal practices are listed in Table 17 and are discussed below.

Management Practices for Land Application

As shown in Table 17, management practices are used in conjunction with pollutant limits and other elements of the Part 503 rule to govern the land application of biosolids. Management practices are used to protect threatened or endangered species; restrict land application on flooded, frozen, or snow-covered land; impose a 10-meter buffer between land-applied biosolids and U.S. waters; require agronomic rates pertaining to nitrogen; and require labeling for bagged or containerized biosolids, unless certain conditions, discussed below, are met.

Biosolids that meet the Part 503 pollutant concentration limits and certain Part 503 pathogen and vector attraction reduction requirements are not subject to the general requirements and management practices (listed in Table 17) for land application because the Agency has determined that the risks associated with the land application of these biosolids are negligible. Also, bagged biosolids applied to a lawn or home garden are not subject to management practice requirements other than labeling because the Agency determined that it is unlikely that large amounts of bagged biosolids would be applied to a lawn or home garden multiple times. The risks associated with this scenario are thus considered negligible.

Management Practices for Surface Disposal

EPA established the Part 503 management practices listed in Table 17 for surface disposal of biosolids when risks to human health and the environment were not addressed by the risk assessment, and to ensure protection of surface water, air quality, ground water, and human health from pollutants that may be present in biosolids at surface disposal sites.

Table 17
Part 503 Management Practices

Management Practice	Reason Included in Rule
Land Application[a]	
Protection of threatened or endangered species	Consistency with federal regulation (50 CFR 17.11 and 17.12)
Restriction of land application on flooded, frozen, or snow-covered land	Prevents biosolids from entering surface waters and wetlands
Ten-meter buffer for U.S. waters	Protects waters of the U.S.; helps ensure risk is no greater than that calculated in the biosolids risk assessment, which assumed a 10-m buffer zone from surface waters
Agronomic application rate limit for nitrogen	Protects ground water from nitrate contamination
Labeling requirements for bagged or containerized biosolids	Helps ensure that appliers use proper application rates, which ensure that pollutant limits are met
Surface Disposal	
Protection of threatened or endangered species	Consistency with federal regulation (50 CFR 17.11 and 17.12)
Prohibition against restriction of base flood flow	Protects area's flooding capacity; also protects surface water and public health from the release of pollutants in biosolids if a base flood occurs
Geological stability requirements	Protects the structural integrity of the surface disposal site and prevents the release of leachate (which may contain pollutants in biosolids) from the site
Protection of wetlands	Protects wetlands from possible contamination when biosolids are placed in a surface disposal site
Collection of runoff	Prevents runoff from a surface disposal site (which may contain pollutants in biosolids) from being released into the environment
Collection of leachate	Prevents leachate from a surface disposal site from being released into the environment
Methane gas limit	Ensures explosive conditions do not exist at site
Restriction on crop production	If no crop production, prevents pollutants in biosolids at surface disposal sites from being consumed by humans/animals; if crop production allowed,[b] helps ensure levels of pollutants taken up by crops do not negatively affect the food chain
Restriction on grazing	If no grazing, prevents animals from ingesting pollutants in biosolids at surface disposal sites; if grazing allowed,[b] helps ensure that levels of pollutants taken up by crops do not negatively affect the food chain
Restriction of public access	Minimizes public contact with pollutants that may be present in biosolids at surface disposal sites
Protection of ground water	Protects ground water from nitrate contamination
Incineration	
Measurement of THC or CO in stack gases Measurement of oxygen in stack gases Measurement of moisture content in stack gases Measurement of combustion temperature Measurement of operating parameters for pollution control devices	Protects air quality by ensuring proper incinerator operation
Protection of threatened and endangered species	Consistency with federal regulation (50 CFR 17.11 and 17.12)

[a]In addition to these management practices, site and harvesting restrictions are included in the pathogen and vector attraction reduction requirements to protect human/animal health for crop consumption by ensuring that pathogen concentrations in crops are at or below levels identified in the risk assessment.

[b]Crop production or grazing are allowed at surface disposal sites only if the site owner/operator can demonstrate that human health and the environment are protected from reasonably anticipated adverse effects of pollutants in biosolids.

Management Practices for Incineration

The Part 503 rule requires that management practices relating to the measurement of key parameters must be followed at biosolids incinerators. The required measurements are necessary to show that the incinerator is operating properly and to ensure that pollutant limits are being met. They are also a necessary enforcement tool. The management practices for incineration are listed in Table 17.

Part 503 Monitoring, Recordkeeping, and Reporting Requirements

Monitoring, recordkeeping, and reporting are necessary to ensure that risks are properly managed. Further, these requirements form the basis for enforcing the regulation. Without the ability to enforce the rule, the Agency cannot be sure that the risk levels specified in the rule will be met. The Agency determined, however, that the frequency of monitoring, the types of records and reports maintained, and report submission requirements could vary, given the variable risks posed by different practices, quantities of biosolids produced, and classifications of POTWs.

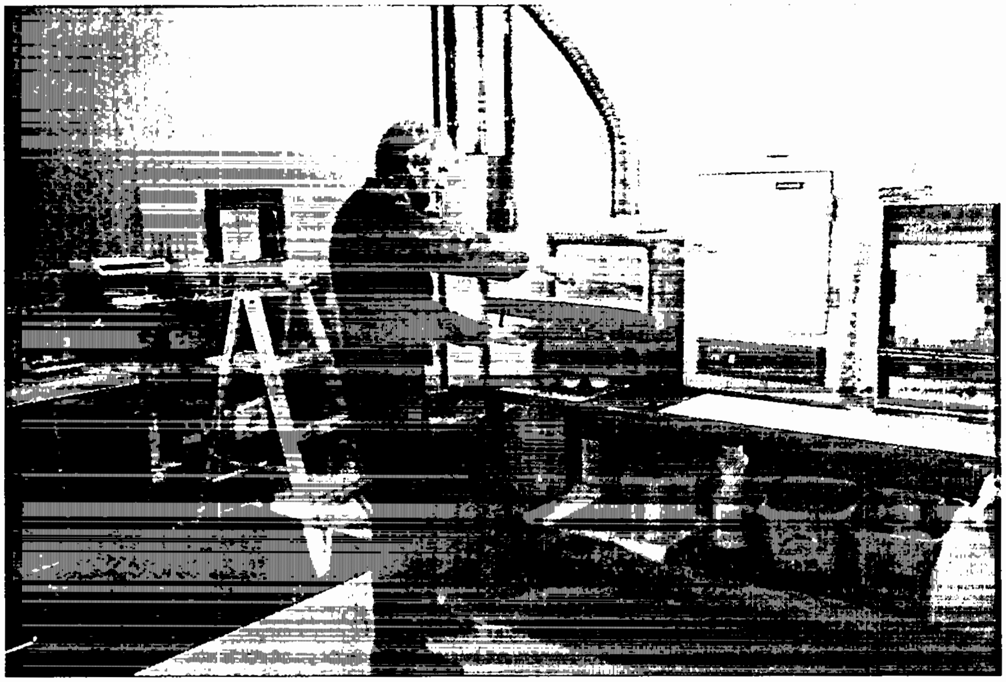
For further information on all of the elements of the Part 503 rule, see EPA's ***A Plain English Guide to the EPA Part 503 Biosolids Rule*** (U.S. EPA, 1994). For the Part 503 rule's approach for regulating domestic septage (i.e., less burdensome requirements than for biosolids at certain types of sites), see EPA's ***Domestic Septage Regulatory Guidance: A Guide to the EPA Part 503 Rule*** (U.S. EPA, 1993).

General Summary

EPA conducted three comprehensive risk assessments for pollutants in biosolids that are land applied, surface disposed, or incinerated. The risk assessments evaluated risks to human health through relevant exposure pathways for each of the three use or disposal practices, as well as ecological risks (to animals and plants) for land application and surface disposal. Using appropriate parameters that represented relevant data and assumptions, the risk assessments quantitatively identified allowable concentrations or application rates of pollutants in biosolids that are used or disposed that protect human health and the environment from reasonably anticipated adverse effects.

The results of the risk assessments were used as a basis for establishing the final Part 503 pollutant limits, aided in some cases by EPA policy decisions. The risk assessments involved a number of conservative assumptions and data management decisions that provided protective yet realistic Part 503 requirements. Additional protective measures also were included in the rule (e.g., operational standards, management practices, and monitoring and recordkeeping requirements) to address areas not included in the risk assessment or to support assumptions made in the risk assessment. Where risks were negligible, less burdensome requirements were allowed, such as exempting "clean" (or "exceptional quality") biosolids from management practices and general requirements for land application and setting alternate requirements for domestic septage.

Using the best available data, the biosolids risk assessments identified limits for pollutants in biosolids that protect public health and the environment. The Part 503 rule, based on the risk assessments, sets forth conservative pollutant limits and other requirements without being overly restrictive, while allowing the beneficial and safe use of biosolids.



Ongoing monitoring ensures that biosolids are being used in accordance with Part 503 requirements that were established based on the biosolids risk assessments. The top photograph shows a technician collecting a representative composite sample of a dried biosolids product. The bottom photograph shows this sample being dry ashed in preparation for chemical analysis.

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 x 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 x 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 x 10^{-4} risk in the Part 503 rule, were any pollutant limits established on the basis of a 1 x 10^{-4} risk?

A: Yes and no. Yes, in that pollutant limit determinations based on a 1 x 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 x 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 x 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 x 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

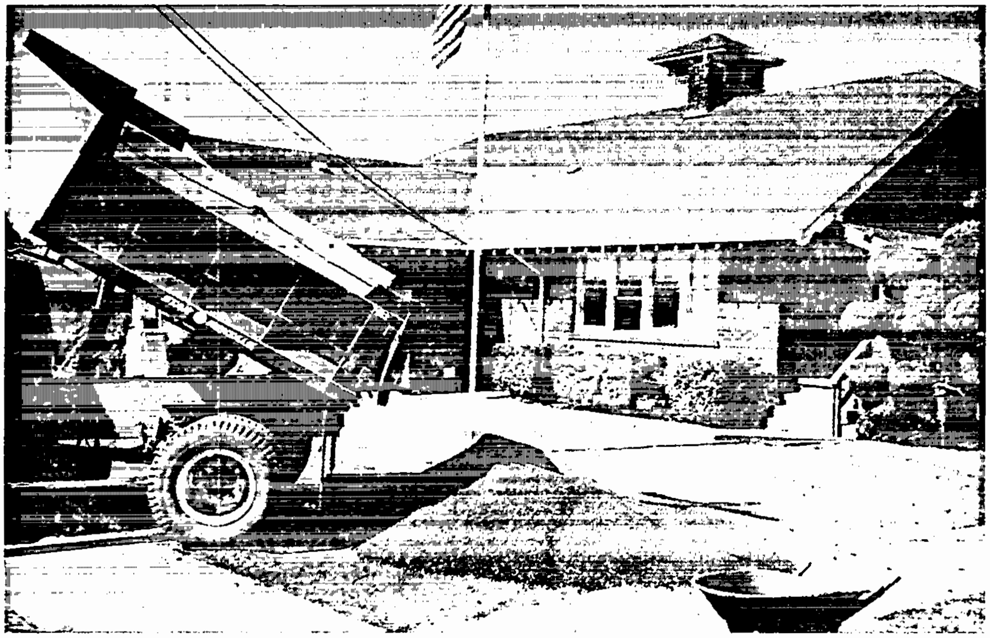
[c]Holmgren et al., 1993

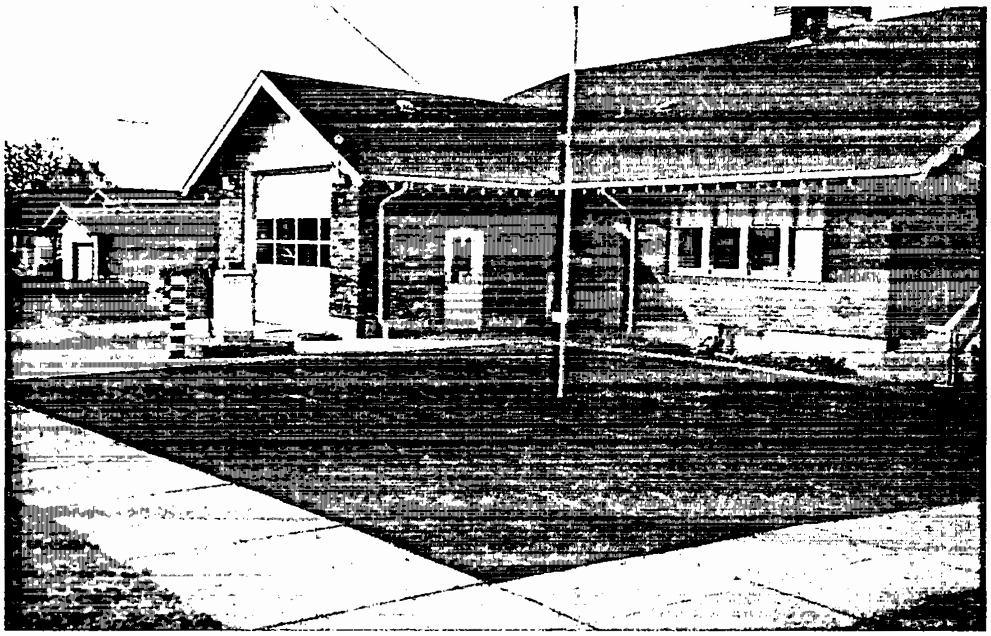
[d]To be deleted from the Part 503 rule based on a court decision (see Section Q, Chapter 3).

[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.

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Chapter 7

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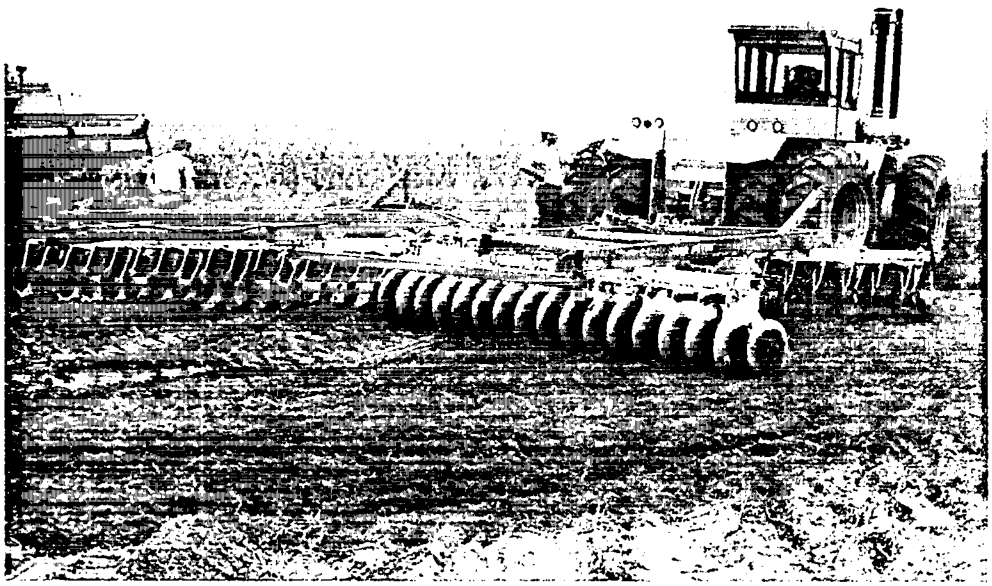

Appendix A

Parameters Used in the Land Application Risk Assessment for Biosolids

Parameter Definition	Abbreviation Used in Calculation of Pollutant Limit	Pathway Where Used (see Table 6)	Source of Further Information
Pollutant Limit Calculated via the Risk Assessment Process:			
(1) The amount of a pollutant that can be applied to a hectare of land without adverse effects	RP	For most pathways (Pathways 1,2,4,6,8, 9,10,11,12,13,14; except 3,5,7)	Appendix B (most parameters); Chapter 4, Boxes 9-14 (RP or RSC parameters)
(2) The concentration of pollutant in biosolids that can be ingested without adverse effects	RSC	(Pathways 3,5,7)	

RP & RSC used for Pathways 1–11:

$$RP \text{ or } RSC = \frac{\text{Allowable Dose of Pollutant}}{\text{Plant Uptake x Dietary Consumption} \times \text{Food Production parameters (whichever is relevant)}}$$

or

RP for Pathways 12 (surface water [sw]), 13 (air) and 14 (groundwater [gw]) based on:

$$RP = \frac{\begin{array}{c}\text{Parameters for pollutant concentration (includes health parameters) in eroding soil [for sw]}\\ \text{or air emissions [for air] or beneath site [for gw]} \times \text{loss rate parameter [for sw and gw]}\end{array}}{\text{Fraction of total loss parameter (erosion [for sw], volatilization [for air], or leaching [for gw])}}$$

The parameters used in the risk assessment calculations are described below:

Parameter Definition	Abbreviation Used in Calculation of Pollutant Limit	Pathway Where Used (see Table 6)	Source of Further Information
Health-Based Parameters Used in Risk Assessment Calculations:			
For People:			
Amount of pollutant ingested by humans without expectation of adverse effects (based on RfD or q_1*, BW, RL, RE, TBI, see below)	RIA	Pathways 1,2,3,4,5	Chapter 4, Boxes 9-11
— *Risk reference dose (RfD)*–daily intake of chemical that during an entire lifetime appears to be without appreciable risk on the basis of all the known facts at the time (Lu, 1983); or *cancer potency value* (*q_1**)-conservative quantitative indication of the likelihood of a pollutant inducing or causing cancer during the lifetime of a continuously exposed individual	RfD or q_1*, or an RDA when there was no RfD for a pollutant	All human pathways (Pathways 1,2,3,4,5, 12,13,14)	Chapter 2, Box 3
— *Cancer risk level*–the probability that one additional cancer case could be expected to occur in an exposed population of a certain size (e.g., the RL could be set at 1 x 10^{-4} = 1 add. cancer case in a population of 10,000 exposed individuals)	RL	In conjunction with q_1*s (Pathways 1,2,3,4,5,12,13,14)	Chapter 3, text
— *Human body weight (kg)*—average adult male body weight of 70 kg (154 lbs) was used to represent a "lifetime" weight, since the RfD/q_1* represents a lifetime dose (70 years)	BW	All human pathways (Pathways 1,2,4,5,11,12,13,14)	
— *Child:* average body weight—16 kg (35 lb) for child (ages 1-6) with respect to agricultural land and 19 kg (42 lb with respect to nonagricultural land (also see Appendix B)	BW	Pathway 3	
— *Relative effectiveness of exposure*—accounts for differences in bioavailability and routes of exposure (e.g., inhalation vs. ingestion); because of limited data, this value was conservatively set at 1	RE	Pathways 1,2,3,4,5	
— Allowable ("reference") concentration of pollutant in human diet ingested as a result of animal tissue consumption (based on RIA, and UA, DA, FA, see below)	RF	Humans eating animal products (Pathways 4,5)	
— Allowable ("reference") intake of pollutant, based on q_1* and RL, or RfD (RL/q_1* or RfD–background intake)	RI	Surface water (Pathway 12)	Chapter 4, Box 14
— Allowable ("reference") water concentration of a pollutant in surface water, air, or ground water	RC_{sw} RC_{air} RC_{gw}	Surface water, air, or ground-water pathways (Pathways 12,13,14)	
— Allowable ("reference") concentration of pollutant in:		Surface water or ground water	Chapter 4, Box 14
soil eroding into the surface water stream	RC_{sed}	(Pathway 12)	
soil eroding from the biosolids application area (SMA)	RC_{sma}	(Pathway 12)	
leachate beneath the land application site	RC_{lec}	(Pathway 14)	

Parameter Definition	Abbreviation Used in Calculation of Pollutant Limit	Pathway Where Used (see Table 6)	Source of Further Information
Health-Based Parameters (continued):			
For Animals:			
Allowable ("reference") concentration of pollutant in animal diet ingested as a result of eating plants, based on:	RF	Animals eating plants (Pathways 6,7)	Chapter 4, Box 12
— Maximum pollutant intake level in animal diet without observed toxic effect on most sensitive or most exposed species (threshold pollutant intake)	TPI	For animal toxicity (Pathways 6,7)	
Environmental Parameters:			
For Soil Organisms and Soil Concentration Values:			
Pollutant concentration in soil considered to have no adverse effects on soil organisms, or minimal effects on animals or humans in pathways where people or animals are the target organism (e.g., for degradable organics, or when diet is soil/soil organisms)	RLC	For Pathways 1,2,4,9,10	
For Plants:			
Toxicity based on:			
— (1) *Phytotoxicity threshold*—Concentration of a pollutant in plant tissue associated with a 50% retardation in growth of young vegetative tissue based on studies of plants grown in pots of metal amended soil or nutrient solution	PT_{50}	For plant toxicity (Pathway 8)	Chapter 3, text (see Pot/Salt vs. Field Studies, Sludge Binding, and Ecological Risk Assessment); Chapter 4, Box 13
or			
— (2) *Threshold pollutant concentration* in plant tissue assoc. with phytotoxicity, based on lowest observed adverse effect level (LOAEL) of the most sensitive/most exposed plant species in field soils	TPC	For plant toxicity (Pathway 8)	Chapter 3; Chapter 4, Box 13
The most limiting number from approaches (1) and (2) above was used to set the pollutant limit for Pathway 8.			
Dietary Consumption Parameters:			
— Daily consumption by humans of different food groups grown on land amended with biosolids	DC	Humans eating plants (Pathways 1,2)	Chapter 3, text; Chapter 4 (cadmium example)
Daily human consumption of different types of animal products	DA	Humans eating animal products (Pathways 4,5)	
— Rate of soil ingestion by children	I_s	Toxicity to child (Pathway 3)	Chapter 3, text Chapter 4, Box 11
— Daily consumption of:		Surface water (Pathway 12)	Chapter 4, Box 14
fish	I_f		
water	I_w		

Parameter Definition	Abbreviation Used in Calculation of Pollutant Limit	Pathway Where Used (see Table 6)	Source of Further Information
Parameters for Fraction of Diet Produced on Biosolids-Amended Land:			
— Fraction of different food groups assumed to be grown on land amended with biosolids	FC	Humans eating plants (Pathways 1,2)	Chapter 4 (cadmium example)
— Fraction of different animal products assumed to be raised on forage grown on biosolids-amended soils	FA	Humans eating animal products (Pathways 4,5)	
— Fraction of animal diet that is biosolids	FS	Animals eating biosolids (incl. animal products eaten by humans) (Pathways 5,7)	
— Fraction of diet comprised of soil organisms	FD	Animals (soil organism predators) eating soil organisms (Pathway 10)	
Parameters for Plant Uptake of Pollutant:			
— *Plant uptake slope* for pollutants from soil/biosolids	UC	Humans and animals eating plants; plants themselves (Pathways 1,2,4,6,8)	Chapter 3, text; Chapter 4 (cadmium example)
— Uptake factor relating pollutant concentration in each animal product to pollutant concentration in forage crop/animal diet consumed by the animal	UA	Humans eating animal products (Pathways 4,5)	
Loss-Factor Parameters:			
— *First-order loss rate constant*–accounts for amount of organic pollutant lost to degradation, leaching, and/or volatilization, based on half-life data	k	For most degradable organic pollutants (Pathways 1,2, 4,5,10)	Chapter 4, Box 10
— *Mass balance of pollutant loss*–calculates relative rates at which a pollutant is removed (lost) from a site through soil erosion, leaching, volatilization, and/or degradation	K	Surface water, air, ground water (Pathways 12,13,14)	Chapter 4, Box 14
— Mass balance of pollutant loss–calculates fraction of total loss caused by volatilization	f_{vol}	Air (Pathway 13)	
— Mass balance of pollutant loss–calculates fraction of total loss caused by leaching	f_{lec}	Ground water (Pathway 14)	
— Estimated rate of soil loss for the biosolids management area (SMA)	ME_{sma}	Surface water (Pathway 12)	Chapter 4, Box 14
— Estimated rate of soil loss for the watershed	ME_{ws}	Surface water (Pathway 12)	Chapter 4, Box 14
— Fraction of total cumulative loading lost in a human lifetime (inorganics)	f_{ls}	Surface water (Pathway 12)	
— Mass of pollutant at end of a human lifetime (inorganics)	M_{LS}	Surface water (Pathway 12)	

Parameter Definition	Abbreviation Used in Calculation of Pollutant Limit	Pathway Where Used (see Table 6)	Source of Further Information
Background Parameters:			
— *Total background intake rate* of pollutants from sources of exposure other than biosolids (e.g., from drinking water, food, air)	TBI	All human food chain pathways (Pathways 1,2,3,4,5)	Chapter 4, Boxes 9-11
— Background concentration of pollutant in soil	BS	For animal (incl. soil organism) toxicity (Pathways 7,9,10)	
— Background concentration of pollutant in plant tissue	BC	For animal and plant toxicity (Pathways 6,8)	Chapter 4, Boxes 12, 13
Bioavailability and Bioaccumulation Parameters:			
— Fractional toxicity of pollutants in biosolids (compared to metal salt-amended diets)	BAV	Animals eating soil organisms (Pathway 10)	Chapter 3, text (see Ecological Risk Assessment)
— Pollutant-specific bioconcentration factor	BCF	Surface water (Pathway 12)	Chapter 4, Box 14
Pollutant-specific food chain multiplier	FM		
Exposure Through Inhalation:			
Allowable concentration of pollutant in dust, based on:	MDC, based on:	(Pathway 11)	
— NIOSH air quality criteria for the pollutant	NIOSH		
— ACGIH total dust standard	TDA		
— Ratio relating the concentration of pollutant in ambient air (at HEI's location) to the rate at which the pollutant is emitted from biosolids-amended soil	SSR	(Pathway 13)	
— Reference annual flux[a] of pollutant emitted from the site	RF_{air}	(Pathway 13)	
Additional Parameters Specific to Surface Water:			
— Density of water	P_w	(Pathway 12)	
Partition factors (used to derive concentration of pollutant in surface water):		(Pathway 12)	
— partition coefficient between solids and liquids within the stream	KD_{sw}		
— percent liquid and solids in the water column	P_L, P_s		
Additional Parameters Specific to Ground Water:			
— Ratio of predicted concentration of pollutant in well to concentration in leachate	f_{wel}	(Pathway 14)	
— Reference annual flux[a] (net recharge in m/yr) of pollutant beneath the site	RF_{gw}	(Pathway 14)	

Parameter Definition	Abbreviation Used in Calculation of Pollutant Limit	Pathway Where Used (see Table 6)	Source of Further Information
Additional Parameters Specific to Ground Water (continued):			
— Length of square wave[b] in which maximum total loss rate of pollutant depletes total mass of pollutant applied on site (inorganics)	TP	(Pathway 14)	

[a]Flux is the amount of air or ground water flowing across a given area per unit of time (RF_{gw}/f_{lec} = application rate [RP]).

[b]Square wave refers to a pulse of constant magnitude representing maximum annual pollutant loss (kg/ha · yr) occurring over the 300-yr simulation model. Used in VADOFT model to predict concentration of pollutant at the water table.

Appendix B

Parameters, Approach, Assumptions, and Degree of Conservatism Used: Land Application Risk Assessment

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Pollutant Limit Is:			
RP *or*	Cumulative or annual application rate of pollutant that can be land applied without expectation of adverse effects: cumulative rate—nondegradable pollutants (inorganics; aldrin/dieldrin, chlordane) annual rate—degradable pollutants (organics)	Certain pollutants assumed not to degrade in environment	C—Many of the parameters used to calculate RP or RSC are conservative, resulting in inherently conservative pollutant limits
RSC	RSC based on poll. conc. in biosolids was calculated (except for lead, Pathway 3) by relating human or animal health/exposure parameters (e.g., RIA, TPI) to exposures from biosolids/ soil: —parameter for the ingestion of poll. in biosolids/soil by children (I_s), or —uptake of poll. in plant tissue (consumed by animals) and of animal tissue consumed by humans (UA), and parameter for fraction of animals' diet that is biosolids		

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Pollutant Limit Is (continued):			
RSC (continued)	Lead pollutant limit determined using EPA's Integrated Uptake Biokinetic Model (IEUBK), for lead (Pathway 3)	Policy decision for lead to set limit lower than number derived from IEUBK to provide additional margin of safety (i.e., from livestock data on lead)	
Health Parameters:			
RIA	Health-based value (e.g., RfD or q_1*) adjusted for body weight, with exposure to pollutant from sources other than biosolids (food, water, air) subtracted		C—Designed to protect most sensitive members of population from biosolids pollutant; based on conservative RfD or q_1*
RfD or q_1*	See Chapter 2, Box 3 If pollutant associated with both cancer and noncancer effects, cancer was used as most sensitive endpoint unless the cancer was associated with a different route of exposure	Continuous 70-yr lifetime Any exposure to carcinogen has a risk (q_1*) Threshold (i.e., minimal risk) levels exist for noncarcinogens (RfDs)	C—Both RfD and q_1* predict greater adverse effects than are likely to occur; both assume lifetime exposure, which is unlikely; q_1* based on most sensitive species and conservative extrapolation from high to low dose; RfDs use safety factors to offset uncertainties
RL	Standard U.S. Government scientific approach used to establish cancer risk level	Lifetime (70 yr) exposure Risk level of 1×10^{-4} chosen (policy decision)	A—Risk level of 1×10^{-4} chosen because related data indicated minimal risk associated with biosolids use or disposal
BW	Standard adult male value used Two alternative values for child weights	Adult: 70-kg (154 lb) male (except Pathway 3); Child: for Pathway 3 — Child (ages 1-6) = 16 kg (35 lb) for agricultural land and (ages 4-6) = 19 kg (42 lb) for nonagricultural land	A (adult)—Average value used A (child)—Peak absorption age is 1.5 years
RE	RE value of 1.0 was based on EPA policy to be conservative; REs of less than 1.0 should be used only where good data exist on RE or pharmacokinetics; limited data existed for this risk assessment	Relative effectiveness of exposure (RE) = 1 (compares exposure routes, e.g., ingestion vs. inhalation)	C—A value of 1 probably overestimates risks through food consumption
RF	Poll. conc. in human or animal diet (RF) was needed to calculate soil-based RSC value; RF relates health parameter (e.g., RIA, TPI) to uptake (UA) and dietary (DA, FA) parameters	100% of livestock diet consists of forage grown on biosolids-amended land (Pathway 6)	A—It is not unusual for livestock to forage on biosolids-amended land

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Health Parameters (continued):			
RC_{sw}, RC_{air}, RC_{gw}	RC_{sw} based on the smaller value of the risk assessment calculation, chronic or acute freshwater criteria for the poll., or LOAEL; RC_{air} based on q_1* and RL; RC_{gw} based on q_1* and RL for organics, and MCLs for inorganics	Distance to well = 0 Buffer zone = 10 meters (bet. biosolids management area and nearest body of surface water) Soil type = sandy soil	C—Based on conservative health criteria and assumptions
RC_{gw}	Background pollutant concentration values subtracted from MCL to derive reference (allowable) water concentration	If background concentration of pollutant was below the detection limit, assigned a value to the background concentration equal to one-half of the detection limit Background conc. of organics = 0	A
RC_{lec}	Models used to simulate flow and transport of pollutants through soil and ground water: — VADOFT (from RUSTIC) model (unsaturated zone) — AT123D model (saturated zone)	The overly conservative approach in the proposed risk assessment was changed for the revised risk assessment to more realistically assess the portion of a pollutant transferred to ground water (e.g., fate and transport models [CHAIN and MINTEQ] used for pollutants in the unsaturated zone were replaced with a more appropriate model [VADOFT]); assumption that 100 percent of a pollutant could be simultaneously transferred to ground water, surface water, and air, was changed to a "mass balance" approach; more realistic, site-specific geologic, hydraulic, and chemical parameters were used as inputs to computer models).	C—Results well within acceptable EPA risk levels
TPI[c]	Based on recommendations of experts about best available data on most sensitive and most exposed species	Shrews and moles assumed to be the most exposed species for cadmium and lead (most sensitive species not identified) (Pathway 10) Chickens believed to be a more representative species (e.g., than mink) for PCBs (Pathway 10)	C—Based on most sensitive or most exposed species

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Environmental Parameters:			
RLC	Because plant uptake of organic pollutants was regressed against soil concentration, a reference (allowable) pollutant concentration in soil was calculated (RLC), which was then converted to an annual application rate (RP) (Pathways 1, 2, 4)	Limit based on available data adequately protects soil organisms from adverse effects	A—Because data available for only a few species
	Based on best available data (NOAEL for earthworms) (Hartenstein et al., 1980), although no species identified as the most sensitive/most exposed (Pathway 9)		
PT_{50} or TPC	Limit based on PT_{50} for corn, or TPC for most sensitive/exposed species, whichever resulted in the more limiting number in calculations	Short-term retardation in growth of young plant may reflect some level of reduced yield at maturity (PT_{50})	C—Most conservative result of PT_{50} or TPC chosen as poll. limit; short-term phytotoxicity often does not result in yield reduction at maturity; TPC more sensitive indicator of phytotoxicity than PT_{50}
	Calculation for TPC based on biosolids field studies	0.01 = probability (99 times out of 100) that the PT_{50} concentration was not exceeded in field studies; PT_{50} was set as the tissue concentration that was not to be exceeded	
	Based on literature search (computer databases and 2,713 original articles) (PT_{50})	Agricultural pollutant limits also protect wild species in nonagricultural settings (based on lit search) (PT_{50}, TPC)	
	Only PT_{50} approach used for chromium because data unavailable for TPC approach	Uptake of pollutants is through plant roots (PT_{50}, TPC)	
Dietary Consumption Parameters:			
DC	EPA Estimated Lifetime Average Daily Food Intake, based on surveys/studies of dietary intake (reanalyzed Pennington 1983): food consumption for different age groups among males and females were averaged and used to calculate a lifetime weighted average intake (Pathways 1,2)		A—Food consumption averaged over a lifetime
	EPA reanalysis of FDA Revised Total Diet List (1982) (Pathway 2)		

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Dietary Consumption Parameters (Continued):			
DA	Estimated Lifetime Average Daily Food Intake (see DC above); only animal tissue food groups used for DA	Human food consumption of products from animals that have ingested biosolids ranges from 3-10% depending on food type (Pathway 5) HEI consumes animal tissue foods daily (ag and nonag pathways) (Pathway 4)	A—Food consumption averaged over a lifetime
I_w, I_f	Daily consumption of fish (Javitz, 1980) and water (standard EPA assumption).	HEI consumes 2 liters/day of drinking water and ingests 0.04 kg/day of fish from surface waters into which soil eroded from a site where biosolids were applied	C—The fish value is highly conservative for the population, and the water value is high-end but not as conservative as the fish value
I_s	EPA OSWER recommended value for amount of soil ingested by a child each day for 5 years from age 1 to 6 (U.S. EPA, 1989b)	0.2 g/day = soil ingestion rate for children Biosolids not diluted with soil Child is not a PICA child	C—Designed to protect children at highest risk, except: A—Does not consider pica child (a pica child is one who has an abnormal craving to eat materials other than food, such as soil and dirt)
Parameters for Fraction of Diet Produced on Biosolids-Amended Land:			
FC	Adaptation of estimates of % of human diet crops grown on biosolids-amended soils (from CAST 1976) x % of biosolids land applied (Pierce and Bailey 1982) (Pathway 1)	2.5% = amount of human diet (vegetables, fruit, grain) (except for home gardener) grown on land receiving biosolids (agricultural) (Pathway 1) 25% = fraction of evaluated foods (berries, mushrooms) produced on biosolids amended soil (nonagricultural) (Pathway 1)	A—Amount of food grown was reduced to exclude crops not consumed by people (i.e., crops consumed by animals) (Pathway 1)
	Based on USDA survey of homegrown foods (1982)	HEI produces 37-59% of own crops grown on biosolids-amended land, varies depending on food group (agricultural; not analyzed for nonag) (Pathway 2)	C—Very few home gardeners actually grow 59% of the leafy vegetables they consume, on land amended with biosolids, continuously for 70 years (Pathway 2)
FA		Fraction of food group assumed to be derived from animals that ingest forage grown on biosolids-amended soil ranges from 3-11% depending on food type (agricultural) and 100% (deer) and 50% (elk) (nonagricultural) (Pathway 4)	A—for livestock farmers C—for U.S. population

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Parameters for Fraction of Diet Produced on Biosolids-Amended Land (Continued):			
FS	Weighted average chronic lifetime model, based on cattle biosolids ingestion studies, adjusted for % of biosolids-amended land	1.5% = fraction of biosolids ingested by grazing animals on land amended with biosolids 30 days prior to grazing (averaged over a season) (Pathways 6,7)	A—Averaged over a lifetime
	Based on 2.5% ingestion of biosolids from pastures in year of biosolids application and 1.0% in non-application year	33% = maximum fraction of a farm's area amended with biosolids in any one year (Pathways 6,7)	C
FD	Based on available studies of earthworm consumption (McDonald, 1983)	33% = fraction of earthworms in predator's diet (Pathway 10)	C—Based on maximum chronic consumption of earthworms by wildlife
Parameters for Plant Uptake of Pollutants:			
UC	$\frac{\textit{Plant tissue concentration}}{\textit{Metal application rate}} = \textit{Slope}$	Plant uptake is linear (increases as more metal added)	C—Plant uptake of metals in biosolids is, in fact, curvilinear (plateaus), i.e., metals become less available to plants over time, even if more metal added (see Chap. 3); also, data from high-metal studies were included
	or, linear regression	0.001 = default value for plant uptake slope for inorganics when slope was negative or <0.001, or when no data available, and for all organics	
	Based primarily on field studies; some field spiked-metal or greenhouse/pot studies, or other non-biosolids metals studies used when field studies unavailable	Geometric mean used (see UA below)	
UA	Animal tissue uptake slopes calculated (regression): $\frac{\textit{Concentration of poll. in animal tissue}}{\textit{Concentration of poll. in feed}}$	Geometric mean used to average plant and animal uptake slopes from different studies	C
Loss Factor Parameter:			
K	Mass balance (see Appendix A)	8.5 mt/ha · yr = annual losses to erosion (USDA, 1987)	A
		Mass balance, organics: assumes equilibrium reached (annual loading of poll. = annual loss of poll.); thus organics could be applied indefinitely in water or air because they do not accumulate	
		Mass balance, inorganics: assumes equilibrium not achieved; conc. of poll. assumed to increase with repeated applications until limit reached; based on max. predicted av. conc. of poll. in surface water over 70 yrs.	

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Background Parameters:			
TBI	Background intake rate of pollutants from sources of exposure other than biosolids was subtracted from RfDs/q_1*s; remainder = amt. of poll. from biosolids that will not exceed threshold		A—Average background values used
BS	Background concentration of pollutant in soil (BS) subtracted from allowable soil concentration to determine allowable pollutant concentrations in soil from biosolids	Median background inorganic pollutant concentrations in agricultural soils used (Holmgren et al., 1993) Background soil levels of organic pollutants = 0 (i.e., for organics the amount of pollutant applied annually is assumed to be degraded at the same rate it is applied—is in equilibrium)	A—Average values used
BC	Geometric mean of background pollutant concentration in plants grown in *non*biosolids-amended soil = BC		A—Average values used
Bioavailability and Bioaccumulation Parameters:			
BAV	Based on available studies, which indicate that pollutants are not 100% available	Bioavailability factors: Cadmium = 21.4% for a highly contaminated heat-dried biosolids (the BAV for Part 503 Table 3 biosolids = near 0%) Lead = 40% (BAV usually far under 5%; cows retain less than 1% of ingested Pb) PCBs = 100% (biosolids PCBs = 50%)	C—Assumptions overestimate pollutant availability in biosolid
BACC	Analogous to use of uptake slope in other parts of the risk assessment; BACC describes conc. of poll. present in earthworms because of bioavailable poll. conc. in soil	Bioaccumulation factors: Cadmium = 6 Lead = 0.45 PCBs = 3.69 (µg-pollutant/g-soil biota DW) (µg-pollutant/g-soil DW)$^{-1}$	A
Parameter for Exposure Through Inhalation:			
MDC, based on:		1 meter = distance from tractor driver to soil surface (Pathway 11)	
NIOSH TDA	NIOSH-recommended standards (Pathway 11) American Conf. Gov. Indus. Hygienists (ACGIH) recommendation	10 mg/m^3 = max. dust level exposure (above this level, ACGIH recommends closed cab) (Pathway 11)	C—Within acceptable government risk levels

Parameter Used in Calculation of Pollutant Limit[a,b]	Approach or Basis	Assumptions/ Policy Decisions	Parameter Is Conservative (C) or Average (A) and Why
Parameter for Exposure Through Inhalation (continued):			
RF_{air} (Pathway 13)	Only organic pollutants evaluated because inorganics do not volatilize at ambient air temperatures	Inhalation rate = 20 m^3/day of air contaminated with pollutants from biosolids Wind direction assumed never to change, keeping HEI downwind of site HEI lives at downwind boundary of biosolids management area	C—Exposure will not always occur downwind of the site and at the site boundary
Parameter for Exposure Through Ground Water:			
TP	See Appendix A	300-yr. ground-water contamination simulation model used Site receives worst-case 1,000 mt/ha application (over 60 cm on surface) (policy decision) Depth to ground water = 1 meter Soil type = loamy sand Porosity = 0.4	C—Depth to ground water may be more than 1 meter; worst-case application rate used; based on pollutant transport over 300 years

[a]Appendix A describes the parameters used; Chapter 3 discusses issues involving some of the key parameters.

[b]Boxes 9 to 14 (in Chapter 4) provide examples of how the parameters were used to calculate pollutant limits for biosolids.

[c]Threshold pollutant intake level (TPI), *or* tolerable conc. of poll. in whole kidney, DW used (Pathway 10); also, cadmium = 4 different approaches, most limiting # used (Pathway 10).

Appendix C

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Appendix D

Conversions Used To Place Pollutant Limits in the Same Units

1) Conversions for Inorganic Pollutants

Pollutant limits originally expressed in RSCs were converted to RP_cs using the following equation:

$$RP_c = RSC \times AWSAR \times 0.001 \times SL$$

where:

RP_c	=	cumulative reference application rate of pollutant in biosolids (kg-pollutant/ha-land)
RSC	=	reference concentration of pollutant in biosolids (mg-pollutant/kg-biosolids DW)
AWSAR	=	annual whole biosolids application rate (mt-biosolids DW/ha/yr)
0.001	=	conversion factor
SL	=	number of years of site life

The annual whole biosolids application rate (AWSAR) is the maximum amount of biosolids that can be applied to a hectare in a year, as defined in the Part 503 rule. An AWSAR of 10 mt-biosolids DW/ha/yr, which is somewhat higher than the typical application rate of 7 mt, and a site life of 100 years, a reasonable maximum site life, were used. Therefore:

$$RP_c = RSC \times 0.001 \times 10 \times 100$$

Because of the factors used, the RP_cs for Pathways 3,5, and 7 are the same numbers as the analogous RSCs, but the units differ. The RP_cs and RSCs for inorganics are shown in Chapter 4, Table 11.

2) Conversions for Organic Pollutants

Pollutant limits originally expressed in RSCs were converted to RP_as using the following equation:

$$RP_a = RSC \times AWSAR \times 0.001$$

where:

RP_a	=	reference annual application rate of pollutant (kg-pollutant/ha/yr)
RSC	=	reference concentration of pollutant in biosolids (mg-pollutant/kg-biosolids DW)
AWSAR	=	annual whole biosolids application rate (mt-biosolids DW/ha/yr)
0.001	=	conversion factor

Therefore, based on the same assumption regarding the AWSAR discussed above (10 mt-biosolids DW/ha/yr):

$$RP_a = RSC \times 10 \times 0.001$$

A "site life" was not used for degradable organic pollutants (as it was for inorganics above) because for organics that degrade, there is no limit on site life. The RP_as and RSCs for organics are shown in Chapter 4, Table 11.

3) Additional Useful Conversions

Additional conversions derived from the above two conversions were useful for comparing pollutant limits, including:

For inorganics:

$$RP_c = \frac{RP_a}{0.01} = 100 \times RP_a$$

For organics:

$$RP_a = \frac{RP_c}{100}$$

4) Equation Used To Express Pollutant Limit as a Soil Concentration

$$RLC = \frac{RP}{MS \times 10^{-9}}$$

where:

RLC	=	allowed soil concentration of pollutant (µg-pollutant/g-soil DW)
RP	=	reference application of pollutant (kg-pollutant/ha-land)
MS	=	2×10^9 g/ha (assumed mass of soil in upper 15 cm)
10^{-9}	=	conversion factor (kg/µg)

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Indicate how you are best described:

☐ Concerned citizen ☐ Local official ☐ Researcher

☐ Consultant ☐ State official ☐ Student

☐ Other ______________________________

Name and Phone Number (optional) ______________________________

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Guide to the Biosolids Risk Assessments for the EPA Part 503 Rule

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