ENVIRONMENTAL PROTECTION AGENCY

[FRL –7228–9]

STANDARDS FOR THE USE OR DISPOSAL OF SEWAGE SLUDGE

AGENCY: Environmental Protection Agency.

ACTION: Notice of data availability.

SUMMARY: The Environmental Protection Agency (EPA) proposed to amend the Standards for the Use or Disposal of Sewage Sludge to limit dioxin and dioxin-like compounds (''dioxins'') in sewage sludge that is applied to the land on December 23, 1999. Since that time, EPA collected new data on the levels of dioxins in sewage sludge. EPA also has extensively revised the risk assessment which estimates the risks from dioxin and dioxin-like compounds associated with land application of sewage sludge. This document summarizes the new sewage sludge data and risk assessment. In addition, EPA is inviting comment on the effect of applying approaches in EPA's current Draft Dioxin Reassessment concerning non-cancer health effects of exposure to dioxins as they relate to land application of sewage sludge. EPA also conducted a screening analysis of the effects of dioxins in land-applied sewage sludge on ecological species, which is addressed in this notice. EPA is requesting comments on the new data and risk analysis, as well as dioxin exposure information, and any impact that this may have on the proposed rule with respect to land application of sewage sludge.

EPA is under a court-ordered deadline to take final action on the proposed land application rule. The deadline was recently extended to October 17, 2003 with respect to land application; EPA met the previous court-ordered deadline of December 15, 2001 for taking final action on the Round Two proposal concerning surface disposal and incineration in a sewage sludge incinerator. EPA gave final notice of its determination that numeric standards or management practices are not warranted for dioxin and dioxin-like compounds in sewage sludge that is disposed of in a surface disposal site or incinerated in a sewage sludge incinerator (66 FR 66228, Dec. 21, 2001).

DATES: Your comments on this document must be submitted to EPA in writing and must be received or postmarked on or before midnight September 10, 2002.

ADDRESSES: Written comments and enclosures should be mailed or hand-delivered to: W–99–18 NODA Comment Clerk, Water Docket (MC–4101), USEPA, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Hand deliveries should be delivered to: EPA's Water Docket (MC 4101) at 401 M St., SW., Room EB57, Washington, DC 20460. Comments may also be submitted electronically to *OW-Docket@epamail.epa.gov.* Electronic submission of comments is recommended to avoid possible delays in mail delivery. Comments must be received or post-marked by midnight September 10, 2002. For additional information see Additional Docket Information section below.

FOR FURTHER INFORMATION CONTACT: Arleen Plunkett, U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. (202) 566–1119. *plunkett.arleen@epa.gov*

SUPPLEMENTARY INFORMATION:

I. Additional Docket Information

The record for this Notice has been established under docket number W–99–18 and includes supporting documentation as well as the printed paper versions of electronic materials. The record is available for inspection from 9 a.m. to 4 p.m. Eastern Standard or Daylight time, Monday through Friday, excluding legal holidays, at the Water Docket, Room EB57, USEPA Headquarters, 401 M Street, SW., Washington, DC 20460. For access to the docket materials, please call 202–260–3027 to schedule an appointment.

For information on the existing rule in 40 CFR Part 503, you may obtain a copy of A Plain English Guide to the EPA Part 503 Biosolids Rule on the Internet at *http://www.epa.gov/owm/bio.htm* or request the document (EPA publication number EPA/832/R–93/003) from: Municipal Technology Branch, Office of Wastewater Management (4204M), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001.

II. Abbreviations Used

AMSA—Association of Metropolitan Sewerage Agencies
CFR—Code of Federal Regulations
DL—detection limit
ED01—dose corresponding to a one percent increase in an adverse effect relative to the control response
EPA—Environmental Protection Agency
HQ—hazard quotient
kg/m^3—kilograms per cubic meter
LADD—lifetime average daily dose
Ln—natural logarithm
LOEL—lowest-observed-effect level
Max.—maximum
MGD—million gallons per day
mg/kg/day—milligrams per kilogram per day
MOE—margin of exposure
ng/kg—nanograms per kilogram
NOEL—no-observed-effect level
NSSS—National Sewage Sludge Survey
PCBs—polychlorinated biphenyls
PCDFs—polychlorinated dibenzofurans
PCDDs—polychlorinated dibenzo-p-dioxins
pg/kg/day—picograms per kilogram per day
pg TEQ/day—picograms toxic equivalents per day
pg TEQ/kg-d—picograms toxic equivalents per kilogram body weight per day
POTWs—Publicly Owned Treatment Works
ppt—parts per trillion
Q1*—cancer slope factor
RfD—reference dose
SAB—Science Advisory Board
SERA—screening ecological risk analysis
Std. Dev.—standard deviation
TCDD—tetrachlorodibenzo-p-dioxin
TEF—toxicity equivalent factor
TEQ—toxic equivalent
WHO—World Health Organization

III. How Does This Document Relate to the Proposed Rule?

A. What EPA Proposed

In December 1999, EPA proposed to amend management standards for sewage sludge by adding a numeric concentration limit for dioxins in sewage sludge that is applied to the land (64 Fed. Reg. 72045, Dec. 23, 1999) (''Round Two proposal'').[1] The proposed numeric limit would prohibit land application of sewage sludge that contains greater than 300 parts per trillion (ppt) toxic equivalents (TEQ) of dioxins. EPA based this proposed numeric limit on the results of a risk assessment for dioxins in sewage sludge that is applied to the land.

EPA proposed a standard for dioxins in sewage sludge that is applied to the land in order to protect public health and the environment from unreasonable risks of exposure to dioxins. The purpose of this standard would be to prohibit land application of sewage sludge containing concentrations of dioxins above the limit, and thereby protect the health of highly exposed individuals as well as the health of the general population.

EPA also proposed to exclude from the proposed numeric limit and monitoring requirements treatment works with a flow rate equal to or less than one million gallons per day (MGD) and certain sewage sludge-only entities that receive sewage sludge for further processing prior to land application. This exclusion was based on the relatively small amount of sewage sludge that is prepared by these facilities and entities and, therefore, the low probability that land application of these materials could significantly increase risk from dioxins to human health or the environment.

Finally, EPA proposed technical amendments to the frequency of monitoring requirements for pollutants other than dioxin. These amendments were intended to clarify but, with one exception, not alter the monitoring schedule in the existing sewage sludge rule. The one exception would require preparers of material derived from sewage sludge to determine the appropriate monitoring schedule based on quantity of material derived rather than quantity of sewage sludge received for processing.

B. Developments Since Proposal

The Agency's risk assessment for land application of sewage sludge used for the proposal estimated that sewage sludge with concentrations of dioxins above the proposed limit may present an unreasonable cancer risk to specific highly exposed individuals. Subsequently, for reasons discussed below, the Agency extensively revised the land application risk assessment. EPA also gathered new data on dioxins in sewage sludge that was used in the revised risk assessment. This information, however, does not change the overall technical approach for the proposal.

The new data and the methodology of the revised risk assessment are summarized in this notice. In addition, the results of the revised risk assessment are described in today's notice. Also discussed in today's notice are the possible implications of the new data and revised risk assessment on the proposed limit, the monitoring requirements, the small entity exclusion, and the projected cost of the proposed regulation.

Another development since the proposal in December 1999 concerns EPA's Dioxin Reassessment, which began in 1991. In September 2000, EPA provided Draft Dioxin Reassessment documents to the Science Advisory Board (SAB) for their review, and in May 2001, the SAB issued its report. The current Draft Dioxin Reassessment (USEPA, 2000a), ''Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds,'' consists of three parts. Part I. Estimating Exposure to Dioxin-Like Compounds focuses on sources, levels of dioxin-like compounds in environmental media, and human exposures. Part II. Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds includes information on critical human health end points, mechanisms of toxicity, pharmacokinetics, dose-response, and toxic equivalent factors (TEFs). Part III. Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds describes key findings pertinent to understanding the potential hazards and risks of dioxins, including a discussion of important assumptions and uncertainties.

The Draft Dioxin Reassessment documents do not represent Agency policy or factual conclusions, and EPA has not yet issued final findings or conclusions as a result of the Dioxin Reassessment process. However, much of the information incorporated into the Draft Dioxin Reassessment documents reflects the state of knowledge with respect to dioxin, and scientific updates resulting from or reflected in these

[1] Section 405(d)(2)(A) of the Clean Water Act (CWA), 33 U.S.C. § 1345(d)(2)(A) required EPA to establish numeric limits and management practices for toxic pollutants in sewage sludge identified on the basis of available information. In 1993, EPA promulgated the ''Round One'' rule for such toxic pollutants in sewage sludge that is applied to the land, disposed of in surface disposal units, and incinerated in sewage sludge incinerators. 58 Fed. Reg. 9248 (Feb. 19, 1993). Under section 405(d)(2)(B), EPA was directed to propose and promulgate regulations for other toxic pollutants not regulated in Round One, i.e., ''Round Two.'' The Round Two proposal identified dioxins, and included proposed standards for land-applied sewage sludge, but did not propose further regulation of sewage sludge disposed of by surface disposal or incineration.

documents are relevant to the assessment of risk from dioxins in sewage sludge that is applied to the land. For example, the revised sewage sludge land application risk assessment incorporates the latest science and state of knowledge concerning characteristics of dioxin and exposure pathways which are described in the Draft Dioxin Reassessment.

The Draft Dioxin Reassessment also presents conclusions and findings which are still under review and which EPA has not applied to the analysis of dioxins in sewage sludge. These aspects of the Draft Dioxin Reassessment include, for example, a revised cancer slope factor for calculating cancer risk from exposure to dioxins, and discussions of various approaches to evaluating risks of non-cancer health effects from exposure to dioxins. Although not incorporated into the revised risk assessment, today's Notice also discusses potential implications that these aspects of the Draft Dioxin Reassessment could have for this rulemaking, when and if the Dioxin Reassessment is issued by EPA in final form, and if the final version takes the same approaches and reaches the same conclusions as the current draft.

Finally, EPA was under a consent decree deadline of December 15, 2001 to take final action on the proposed rule. *Gearhart* v. *Whitman,* Civil No. 89–6266–HO (D. Ore.). In accordance with the consent decree, EPA took final action on the proposal not to establish numeric limits or management practices for dioxins in sewage sludge that is disposed of in surface disposal units or incinerated in sewage sludge incinerators. 66 Fed. Reg. 66228 (Dec. 21, 2001). The consent decree deadline was extended to October 17, 2003, for EPA to take final action on the land application portion of the proposed Round Two rule.

C. Proposed Definition of Dioxins

The proposed rule included a definition of ''dioxins'' to specify the seven 2,3,7,8,-substituted congeners of polychlorinated dibenzo-p-dioxins (PCDDs), the ten 2,3,7,8-substituted congeners of polychlorinated dibenzofurans (PCDFs), and the twelve coplanar polychlorinated biphenyl (PCB) congeners to which the numeric standard applies. The vast majority of information on the toxicity of dioxins relates to the congener 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). Animals exposed to 2,3,7,8-TCDD exhibit a variety of biological responses and adverse effects. These include both carcinogenic and non-carcinogenic effects. These effects are primarily classified as chronic effects and consequently they are generally associated with long term exposure over years and decades. Relatively speaking, these exposures and effects are observable at very low levels in the laboratory and in the environment when compared with other environmental toxicants (USEPA, 1994a).

Studies to elucidate the mechanism of toxicity for 2,3,7,8-TCDD in mammalian and other species have indicated that the overall shape and chlorine substitution of this congener are keys to its biological potency. The fact that all of the lateral positions (the 2,3,7,8 positions) on the multi-ring system are substituted with chlorine and that the overall molecule assumes a flat or planar configuration apparently are essential factors that make this congener biologically active. Other congeners with a similar structure and chlorine substitution pattern are assumed to exhibit similar biological properties. These include the other six 2,3,7,8-chlorinated substituted dibenzo-p-dioxin congeners, the ten 2,3,7,8-chlorinated substituted dibenzofuran congeners and the 12 coplanar PCB congeners. Coplanar PCB congeners are those congeners with no more than one ortho position and both para positions substituted with chlorine in the biphenyl ring system. Additionally, the coplanar PCB molecule assumes a relatively planar (i.e., flat) configuration.

The proposed TEQ numeric limit would apply to these 29 congeners in ppt TEQ or nanograms TEQ per kilogram of dry sewage sludge. The TEQ concentration is calculated by multiplying the concentration of each congener in the sewage sludge by its corresponding ''toxicity equivalent factor,'' or TEF, and then summing the resulting products from this calculation for all 29 congeners. The TEFs (relative potencies) are based on expert judgment about toxicity and other biological effects for the individual compounds. The TEQs of these compounds are summed because they are believed to act by the same mechanism of toxicity. The December 1999 proposal specified that the International TEF scheme described in USEPA, 1989, would be used for the 17 2,3,7,8-substituted PCDDs and PCDFs, and the World Health Organization's TEF scheme (Van den Berg M, et al., 1998) would be used for the 12 coplanar PCBs, because the sewage sludge data EPA had at that time used these TEF schemes. The World Health Organization (WHO) has subsequently recommended and developed a single TEF scheme which includes all relevant information on dioxins, furans and dioxin-like (coplanar) PCBs. As part of this process, various terminologies or definitions applicable to TEFs were reviewed and standardized.

The 2001 sewage sludge data and the revised risk assessment use the WHO's 1998 TEF scheme (Van den Berg M, et al., 1998) for all 29 dioxin, furan and coplanar PCB congeners. EPA intends to use the 1998 WHO TEF scheme (or later, if the WHO adopts a revised scheme) for any final Part 503 TEQ numeric limit.

A 1997 WHO meeting of experts concluded that an additive TEF model remained the most feasible risk assessment method for complex mixtures of dioxin-like compounds. The WHO panel indicated that although uncertainties in the TEF methodology have been identified, one must examine this method in the broader context of the need to evaluate the public health impact of complex mixtures of persistent bioaccumulative chemicals. On this basis, EPA has used the 1998 WHO TEF methodology for the Agency's Draft Dioxin Reassessment, noting that it decreases the overall uncertainties in the risk assessment process.

A Panel of EPA's Science Advisory Board has reviewed the Agency's use of the 1998 WHO TEF scheme. The consensus of the Panel was that this is a reasonable and widely accepted way of dealing with the joint effects of dioxin-like compounds on human health. The majority of the Panel noted that the TEF approach is well accepted internationally.

IV. Why Did EPA Collect New Data and Revise the Land Application Risk Assessment?

The proposal to amend the Standards for the Use or Disposal of Sewage Sludge to limit dioxins in sewage sludge that is applied to the land was followed by a 90 day public comment period. During this time the risk assessment which supported the proposed rulemaking also was peer reviewed in accordance with EPA peer review procedures. Both the public comments and the peer review comments raised significant issues concerning the methodology and assumptions used for the land application risk assessment. The public and peer review comments also emphasized the need to collect new data on dioxins in sewage sludge. This data is used in the risk assessment, economic analysis, and other aspects of the rulemaking.

The data on dioxins in sewage sludge used for the proposal came from two separate sources. The data on dioxin and furan congeners was from the 1988 EPA National Sewage Sludge Survey

(USEPA, 1990). Since the National Sewage Sludge Survey (NSSS) did not include specific information on coplanar PCBs, EPA used a separate database to estimate the amount of coplanar PCBs found in sewage sludge (Green, *et al.,* 1995). In addition to developing a single database which includes information on all 29 dioxin-like congeners, EPA developed new data on dioxins in sewage sludge to test the Agency's assumption that dioxin levels in sewage sludge have changed over time, and to more accurately determine dioxin levels in sewage sludge using analytical methods with lower limits of detection. The Agency is also using this more recent data to more reliably estimate the risk, impacts, and costs associated with dioxins in land applied sewage sludge. A discussion of the sewage sludge sampling and data analysis is presented in Section V. of this Notice.

The principal comment concerning the risk assessment methodology was that the Agency should use a probabilistic approach instead of the deterministic approach that was used for the proposal. A probabilistic approach uses values for certain input variables over the range of available data, instead of the deterministic approach of determining, or setting, certain input variables at particular values. Conducting a risk analysis with a probabilistic approach can yield better information about sources of variability and uncertainty in the final risk estimates, compared to conducting a risk analysis with a deterministic approach.

Other comments on the risk assessment recommended that the Agency use an exposure analysis more consistent with that used in the Agency's current Draft Dioxin Reassessment (USEPA, 2000a); that the Agency use data from the current EPA Exposure Factors Handbook (USEPA, 1997); and that the risk assessment include a sensitivity analysis of the critical input variables.

The revised risk assessment is described in Section VI. of this Notice. The revised risk assessment was submitted for peer review. The consensus view of the peer reviewers agreed with the revised risk assessment methodology and assumptions on input parameters. The revised risk assessment, described below and available in the docket, incorporates revisions made in response to the peer review.

V. What Information Concerning Dioxins in Sewage Sludge Does the New Data Provide?

A. What Data Were Collected in the EPA 2001 Dioxin Update of the National Sewage Sludge Survey?

The EPA 2001 dioxin update of the NSSS provides data that support the calculation of unbiased national estimates (i.e., based on a random selection of publicly owned treatment works) for dioxin and dioxin-like compounds in sewage sludge (USEPA, 2002a). The publicly owned treatment works (POTWs) sampled in the EPA 2001 dioxin update survey were randomly selected from all POTWs in four size categories: <1 MGD, 1 MGD–10 MGD, 10 MGD–100 MGD and >100 MGD. This survey updates the 1988 NSSS. The updated survey includes coplanar PCBs, which had not been included in the 1988 NSSS because approved analytical methods for these analytes were not available at that time. The updated survey also uses the current TEFs, which have been revised since the 1988 NSSS. For the EPA 2001 dioxin update survey, EPA collected sewage sludge samples from 94 POTWs selected from the 174 POTWs which had been surveyed in the 1988 NSSS. The sample of 174 POTWs included in the 1988 NSSS were selected from the national population (as of 1988) of approximately 10,000 POTWs with secondary treatment. EPA used a survey design which accounted for the different numbers of POTWs in different size categories for both the 1988 NSSS and the EPA 2001 dioxin update survey. EPA conducted the sampling at the 94 POTWs in the first calendar quarter of 2001 and completed the laboratory analysis, data review, and database development by mid-2001.

B. What Techniques Were Used To Collect Samples?

Sewage sludge samples were collected, documented, preserved, and shipped to the laboratory where the analyses for dioxins were conducted using the protocol entitled ''Sampling Procedures for the 2001 National Sewage Sludge Survey'' (USEPA, 2001a). This document specifies the sampling procedures used for the sewage sludge samples obtained from the 94 POTWs that participated in the EPA 2001 dioxin update survey. The procedures were used on a number of different types of sewage sludge samples including liquids, samples with low solids content, dewatered sewage sludges from filter presses and centrifuges, composted products, and pellets. The sampling protocol specifies sample preservation methods, collection devices and apparatus, containers, types of labels, and label information. In accordance with the sampling protocol used for the EPA 2001 dioxin update survey, duplicate samples were collected for 15 percent of the samples collected for subsequent analysis to determine the precision of the analyses. At each treatment works sampled, a second sample aliquot was collected and archived for potential future analyses. Chain of custody forms were completed for the samples collected at each sampling site to ensure the integrity of the results of the survey.

C. What Analytical Methods Were Used?

EPA used analytical methods that are considered state of the art for the sewage sludge matrix. Dioxin and dibenzofuran congener concentrations were determined by EPA Method 1613B (USEPA, 1994b) using high resolution gas chromatography-mass spectrometry as the end point system of measurement. The coplanar PCB analyte concentrations were determined by EPA Method 1668A (USEPA, 1999a) which employs the same type of measuring instrumentation. Method 1613B is an official EPA analytical methodology codified at 40 CFR Part 136. EPA anticipates that Method 1668A will be codified in Part 136 within the next two years.

D. How Were the Concentrations of Dioxin Measured?

The sewage sludge samples were analyzed for 29 dioxin congeners consisting of the 7 dioxin congeners, 10 dibenzofuran congeners, and 12 coplaner PCB congeners that EPA proposed for the definition of ''dioxins'' (see Section III.B. above). For the EPA 2001 dioxin update survey, whole (wet) weight sample sizes were individually determined for each sewage sludge sample by considering the percent solids in each sample. Smaller whole weight sample sizes were used for the analyses when the percent solids content of the sewage sludge sample was greater, and vice versa. This approach led to lower and more consistent detection limits for concentrations of target analytes for all of the sewage sludge samples in the EPA 2001 dioxin update survey. This procedure was a significant improvement compared to the method used for handling the sewage sludge samples in the 1988 NSSS. For the 1988 NSSS, equal whole weight sample sizes were used regardless of the percent solids content of the samples. This led to higher and less consistent detection limits for the sewage sludge samples in the 1988 NSSS. In addition, other improvements in the analytical methodology and the analytical instrumentation also contributed to lower and more consistent detection limits than those obtained in the 1988 NSSS.

E. How Were the Concentrations Reported?

All of the individual 29 congener concentrations were converted to TEQ concentrations by multiplying the congener concentrations by the 1998 WHO TEFs. For comparison purposes, TEQs for total dioxin and dioxin-like compounds in the 1988 NSSS samples and the EPA 2001 dioxin update survey samples are reported in Table 1, Table 2 and Table 3 in nanograms per kilogram (ng/kg) dry weight basis.

F. How Were the Non-Detect Measurements Handled in Developing National Summary Statistics?

Where congeners were not detected in sample measurements, three different substitution methods were used in calculating national estimates of dioxin concentrations in sewage sludge: (1) Zero was substituted for a non-detect; (2) one-half the detection limit for the congener was substituted for a non-detect; (3) the detection limit for the congener was substituted for a non-detect. As a result of the small detection limits achieved in the EPA 2001 dioxin update survey, there were only small differences in the national summary statistics among the three substitution methods for the EPA update survey.

G. What Were the Results of the EPA 2001 Dioxin Update of the National Sewage Sludge Survey?

Table 1 presents the mean, standard deviation, maximum and 99th, 98th, 95th, 90th and 50th percentiles dioxin TEQ values for the sewage sludges from the 94 POTWs in the EPA 2001 dioxin update survey. Table 1 reports summary results separately for dioxins and furans, coplanar PCBs, and total dioxin-like compounds (i.e., 29 dioxin, furan and coplanar PCB congeners) using the three alternative substitution values for non-detects (i.e., zero, one-half the detection limit, and equal to the detection limit). In Table 1, the results obtained using zero, one-half the detection limit and the detection limit are shown in the rows denoted by ''0'', ''½ DL'' and ''DL'', respectively. The complete statistical analysis of the data from the EPA 2001 dioxin update survey is presented in Statistical Support Document for the Development of Round Two Sewage Sludge Use or Disposal Regulations (USEPA, 2002a).

TABLE 1.—EPA 2001 DIOXIN UPDATE SURVEY—NATIONAL TOXIC EQUIVALENT ESTIMATES (NANOGRAMS/KILOGRAM DRY MATTER BASIS)—TOTAL TOXIC EQUIVALENTS FOR POTWS

Method	Mean	Std. Dev.	Max.	99th %	98th %	95th %	90th %	50th %
Total Dioxin and Furan TEQs (nanograms/kilogram dry matter basis)								
0	21.70	47.5	682.00	100.00	54.40	33.30	31.40	15.50
½ DL	21.70	47.5	682.00	100.00	54.40	33.30	31.60	15.50
DL	21.80	47.5	682.00	100.00	54.40	33.30	31.70	15.50
Total Coplanar PCB TEQs (nanograms/kilogram dry matter basis)								
0	5.22	10.3	58.30	50.60	44.80	13.10	9.66	2.05
½ DL	9.87	14.0	58.30	55.10	54.50	49.40	19.20	6.04
DL	14.50	22.4	103.00	97.2	91.60	78.00	35.00	8.11
Total Dioxin and Dioxin-Like TEQs (nanograms/kilogram dry matter basis)								
0	26.90	49.6	718.00	114.00	76.60	59.30	42.80	19.70
½ DL	31.60	50.0	718.00	115.00	80.10	73.50	55.10	23.40
DL	36.30	52.7	718.00	138.00	96.00	113.00	69.10	24.00

Under the proposed rule, treatment works with a flow rate equal to or less than one MGD and certain sewage sludge-only entities that receive sewage sludge for further processing prior to land application would be excluded from the proposed numeric limit and monitoring requirements. The EPA 2001 dioxin update survey provides additional data with respect to dioxin concentrations from POTWs that would be excluded under the proposal. Table 2 below shows the results for dioxin concentrations in sewage sludge for POTWs with flows of less than and greater than one MGD. Results shown in Table 2 indicate very small differences in the median dioxin concentrations between small and large POTWs. At the upper percentiles, the differences between the small and large POTW values are substantial. However, the significance of these differences is difficult to assess due to the relatively small sample sizes, the sensitivity of the results to the treatment of non-detect measurements and the low precision typically associated with estimates of upper percentiles based on small sample sizes. An additional discussion of the proposed exclusion for small entities is presented in Section X. of this Notice. EPA requests comments on the significance of the differences in dioxin concentrations in sewage sludge measured at facilities with wastewater flows greater than one MGD compared to dioxin concentrations in sewage sludge at facilities with wastewater flows less than one MGD.

TABLE 2.—EPA 2001 DIOXIN UPDATE SURVEY—TOTAL DIOXIN AND FURAN AND DIOXIN-LIKE PCB NATIONAL TEQ (NANOGRAMS/KILOGRAM DRY WEIGHT BASIS) ESTIMATES—POTWS BY FLOW GROUPS

Method	Zero for Nondetects		½ DL for Non-detects		DL for Nondetects	
Estimate	≤1 MGD	>1 MGD	≤1 MGD	> 1 MGD	≤1 MGD	> 1 MGD
Mean	22.10	38.50	26.50	44.10	30.80	49.60
Std. dev	16.8	86.7	18.3	86.8	24.6	88.2 dev.
Maximum	78.60	718.00	78.6	718.00	118.00	718.00
99th %	71.80	401.00	76.40	403.00	109.00	406.00
98th %	65.10	265.00	74.20	269.00	101.00	276.00
95th %	46.00	62.60	67.10	94.80	77.00	134.00
90th %	37.20	54.00	46.10	64.20	46.60	86.90
50th %	19.90	18.90	22.90	22.60	23.80	25.80

H. How Do the Results of the EPA 1988 National Sewage Sludge Survey Compare with the EPA 2001 Dioxin Update Survey?

A comparison of results for dioxin and furan congeners obtained in the 1988 and 2001 surveys is presented in Table 3.

TABLE 3.—NATIONAL ESTIMATES (NANOGRAMS/KILOGRAM DRY MATTER BASIS) FOR DIOXIN AND FURAN CONGENERS IN THE EPA 2001 DIOXIN UPDATE SURVEY AND NSSS 1988

Method	Zero for nondetects		½ DL for nondetects		DL for nondetects	
Estimate	2001	1988	2001	1988	2001	1988
Mean	21.70	46.50	21.70	67.30	21.80	88.20
Std. dev	47.5	153.0	47.5	153.0	47.5	157.00
Maximum	682.00	1870.00	682.00	1870.00	682.00	1870.00
99th %	100.00	450.00	100.00	453.00	100.00	466.00
98th %	54.40	402.00	54.40	404.00	54.40	455.00
95th %	33.30	301.00	33.30	303.00	33.30	340.00
90th %	31.40	56.70	31.60	152.00	31.70	226.00
50th %	15.50	5.68	15.50	34.20	15.50	52.40

The values obtained in the EPA 2001 dioxin update survey for the upper percentiles are lower than those obtained in the 1988 NSSS. On this basis, the concentrations of dioxins in sewage sludge appear to have declined since 1988. However, the significance of these differences between the two surveys is not certain due to changes in the sampling procedures and analytic methods . These comparisons do not include coplanar PCB congeners because the 1988 NSSS did not collect coplanar PCB congener data. For the purposes of the December 1999 proposed rule, data on coplanar PCB levels in sewage sludge from a 1995 Association of Metropolitan Sewerage Agencies Survey (Green, *et al.,* 1995) were combined with the 1988 NSSS dioxin and furan results to provide an estimate of total dioxin levels in sewage sludge. EPA requests comments on the significance of the differences in dioxin concentrations in sewage sludge measured in the EPA 2001 dioxin update survey compared to dioxin concentrations in sewage sludge measured in the 1988 NSSS.

VIII.Why Is Temporal Variability of Dioxin in Sewage Sludge Important?

The variability of dioxins in sewage sludge over time is important for a number of reasons. First, understanding the temporal variability of dioxin concentrations in sewage sludge is important for establishing numerical limits for dioxins in sewage sludge which protect public health and the environment with an adequate margin of safety. Specifically, this information helps in assessing the likelihood that individuals will be exposed to higher levels of dioxins from land application of sewage sludge over time. A more complete discussion of this issue is presented in the risk characterization in Section VI.L. of this Notice. Second, information on the variability of dioxin concentration in sewage sludge is important for determining the appropriate frequency of monitoring for concentrations of dioxins in sewage sludge that will ensure that any numerical limit that is established will not be exceeded.

J. What Does the Variability of the Dioxin Levels Show?

It is not possible to draw general inferences with regard to the variability or differences in dioxin levels observed in the two surveys. This is due to a number of factors that include the large time interval between the surveys (i.e., 13 years), changes that may have occurred at the POTWs, and changes and improvements in analytical methods. It is possible, however, to make a number of observations with regard to changes in dioxin levels based on the data. Of the 94 POTWs participating in both the 1988 NSSS and the EPA 2001 dioxin update survey, a total of 14 POTWs have sewage sludge dioxin concentrations (dioxins and furans only) equal to or greater than 93 ppt TEQ from at least one of the surveys. These same 14 POTWs exhibited the greatest differences in the dioxins and furans concentrations when comparing the results of the 1988 and 2001 EPA surveys. The other 80 POTWs participating in both surveys have substantially smaller differences, as well as lower dioxin levels measured in both surveys. Of the 14 POTWs with the greatest differences between the two surveys, four had large increases in sewage sludge dioxin concentrations and ten had large decreases in sewage sludge dioxin concentrations from 1988 to 2001.

Based on these data, no POTWs had consistently high levels of dioxins in sewage sludge. It appears that sewage sludge samples with higher concentrations of dioxins may experience a greater variability in dioxin concentrations over time and that higher dioxin levels may not remain high for a significant period of time. Likewise, POTWs with moderate or low levels of dioxins in their sewage sludge may experience much less variability in dioxin concentrations over time. It is possible that in the group of POTWs where higher concentrations of dioxins were measured in their sewage sludge, there are unidentified sources with relatively high levels of dioxins entering the sewers intermittently. The second group of POTWs where lower concentrations of dioxins were measured in both surveys appear to be experiencing typical environmental background variation of dioxin levels. The possible sources of dioxins which contribute to higher levels of dioxins in sewage sludge are discussed in greater detail later in this Section and Section XII of the Notice. EPA's assessment of the variability in higher levels of dioxins in sewage sludge is discussed further as part of the risk characterization in Section VI.L. of this Notice.

K. What Does Month-to-Month Variability in the Concentration of Dioxins Show?

EPA also examined both long and short term variability in sewage sludge dioxin concentrations in three wastewater treatment plants that have routinely monitored for dioxins in their sewage sludge over relatively long periods of time and voluntarily submitted their data to EPA (USEPA, 2001b). EPA did this to better understand the extent of variability using data collected on a relatively frequent basis.

Of the three POTWs which provided their data to EPA, one of the POTWs provided data on two different sewage sludge products that they produce. These data were standardized using the WHO_{98} standard for TEQs to provide consistency.

The December 1999 proposal specified annual monitoring for land applied sewage sludges with dioxin concentrations between 30 ppt TEQ and the proposed limit of 300 ppt TEQ. Sewage sludges with two consecutive annual dioxin measurements less than 30 ppt TEQ would be required to monitor once every five years. These less frequent monitoring requirements were based on EPA's assumption that dioxin concentrations in sewage sludge remained relatively constant over time.

The data for the facilities where monthly data were available indicate that the dioxin concentrations are relatively consistent over time on a month-to-month basis. The maximum monthly concentration was within a factor of two to four times the average (mean) concentration for the same facility. Similar to the comparison data from the 1988 NSSS and the 2001 update, the variability appeared the greatest for the facility with the highest dioxin concentrations measured in its sewage sludge. A complete analysis of the month-to-month data is presented in the Statistical Support Document for the Development of Round Two Sewage Sludge Use or Disposal Regulations (USEPA, 2002a).

The month-to-month variability in the dioxins concentration observed in the sewage sludge for which the Agency had data, as well as the longer term variability observed in the small percentage of sewage sludge with higher concentrations of dioxins (discussed above), has led us to re-evaluate the proposed monitoring frequency. A more complete discussion of monitoring frequency is presented in Section IX. of this Notice.

L. What Other Data Did EPA Evaluate?

The Association of Metropolitan Sewerage Agencies (AMSA) voluntarily collected sewage sludge samples from 171 POTWs and analyzed these samples for dioxins using the same methods used for the 2001 EPA dioxin update survey. AMSA submitted the results of their survey to EPA in a report entitled ''AMSA 2000/2001 Survey of Dioxin-Like Compounds in Biosolids: Statistical Analyses (Final Report)'' (AMSA, 2001). The AMSA survey began in October 2000 and was completed in July 2001. The AMSA survey was designed to measure levels for the same 29 dioxin and dioxin-like congeners measured in the EPA 2001 dioxin update survey. AMSA also compared the results of their 2001 survey with the results of their 1994/1995 survey of dioxins in sewage sludge. Participation in AMSA's survey was on a voluntary basis.

Most participants in the AMSA survey were larger POTWs which make up the bulk of the AMSA membership. Some non-AMSA members also participated in the AMSA survey, including some smaller POTWs. Overall, 111 separate wastewater treatment agencies participated in the 2001 AMSA survey, providing 200 samples from 171 POTWs, located in 31 states. The sewage sludge dioxin concentrations measured in the AMSA survey generally ranged from 7.1 ppt TEQ to 256 ppt TEQ, with one sample measured at 3,590 ppt TEQ. The mean (average) concentration and the median dioxin concentrations in sewage sludge from the AMSA survey were 48.5 ppt TEQ and 21.7 ppt TEQ, respectively.

EPA has found the data from the AMSA survey to be useful in describing dioxins in sewage sludge from larger POTWs. The results of the AMSA survey tend to corroborate the results obtained from the EPA 2001 dioxin update survey. However, the AMSA results were not used by EPA to establish national estimates of dioxin concentrations in sewage sludges or for purposes of estimating risks from dioxins in land-applied sewage sludge. EPA did not use these results because the POTWs participating in the AMSA survey volunteered for this survey and were, therefore, not randomly selected, as were the POTWs in the EPA 2001 dioxin update survey. The final report from the AMSA survey and associated appendices are in the docket and can also be found on AMSA's web site at: *http://www.amsa-cleanwater.org/advocacy/dioxin/dioxin.cfm.*

VI. What Are the Principal Features and Assumptions of the Revised Land Application Human Health Risk Assessment?

The revised risk assessment is entitled ''Exposure Analysis for Dioxins, Dibenzofurans, and CoPlanar Polychlorinated Biphenyls in Sewage Sludge—Technical Background Document'' (USEPA, 2002b). The risk assessment methodology, assumptions, results and characterization are summarized below.

The revised risk assessment contains the following standard elements used in EPA human health risk assessments: hazard identification, dose-response assessment, exposure assessment, and risk characterization. The revised risk assessment includes a probabilistic methodology to determine the adult and child exposure to the 29 dioxin and dioxin-like congeners. For the proposed rule, the risk assessment depended on a deterministic analysis based on single value inputs and outputs. A probabilistic analysis was well-suited for this risk assessment because sewage sludge is generated nationwide and, therefore, may be used on agricultural fields anywhere in the United States. The probabilistic analysis not only captures the variability in sewage sludge application practices, it also captures the differences in the environmental settings (e.g., soils, meteorology and agricultural practices) in which sewage sludge may be land-applied.

In addition to a new methodology of analysis, the revised risk assessment uses new inputs which include a redefined ''highly exposed individual,'' new pathways and mechanisms of exposure consistent with EPA's Draft Dioxin Reassessment (USEPA, 2000a. See Part I, Vol. 3, Chap. 2.), a number of new exposure factors adopted from the latest EPA Exposure Factors Handbook (USEPA, 1997), and a sensitivity analysis to determine the relative importance of the input variables. In this Section, EPA describes the features of the revised risk assessment with emphasis on the new inputs used in the probabilistic analysis.

A. What Did the Hazard Identification Analysis Conclude?

The risk assessment that EPA used for the December 1999 proposal identified cancer as the human health endpoint, i.e., as the ''hazard'' (64 FR 72051). The revised risk assessment does not change this hazard identification and continues to assess the risk of cancer as the human health endpoint.

B. What Did the Dose-Response Assessment Conclude?

EPA's dose-response assessment evaluated the risk of the dioxin, dibenzofuran, and PCB congeners using cancer slope factors that are based on the toxicity of the most highly characterized of the dioxin congeners, 2,3,7,8-TCDD (USEPA, 2000a. See Part II, Chap. 7, Part A.). The cancer slope factor for TCDD used by EPA in recent assessments, including the revised sewage sludge land application risk assessment, is 1.56×10^{-4}/picograms toxic equivalents/kilogram body weight/day (pg TEQ/kg-d) (USEPA, 1994a). The cancer slope factor (also referred to as Q* or ''cancer potency'') is a numeric value which relates the incremental probability of developing a cancer from exposure to a particular substance. This cancer slope factor value is expressed as a lifetime excess cancer risk per unit exposure, and is usually quantified in terms of (milligrams of substance per kilogram of body weight per day)$^{-1}$. The greater the numeric value of the cancer slope is, the greater the carcinogenic potency of the substance. The same slope factor is used to estimate cancer risks for both children and adults. For this analysis, only the cancer endpoint was evaluated and a linear dose response relationship was used in the analysis.

An extensive discussion of the dose response mechanism for TCDD is provided in the Draft Dioxin Reassessment document (USEPA, 2000a. See Part II, Chap. 8.). The Draft Dioxin Reassessment also includes a revised cancer slope factor. Because the Draft Dioxin Reassessment is preliminary and does not state EPA policy conclusions or factual findings, the draft cancer slope factor was not used in the revised risk assessment. However, for purposes of discussion and public comment, this Notice includes a discussion of how the EPA Draft Dioxin Reassessment could apply to the analysis of impacts from dioxins in land-applied sewage sludge, including use of the revised cancer slope factor, in Section VII.A. of this Notice. EPA is seeking comment on the implications of this information in the event that, prior to taking final action on the Round Two rule, EPA finalizes a cancer slope factor or other policies or approaches currently reflected in the current Draft Dioxin Reassessment and discussed in this Notice.

C. How Was the Exposure Analysis and Risk Assessment Conducted?

The primary methodology for the exposure analysis was to estimate exposure to dioxins in land-applied sewage sludge using a probabilistic approach. A probabilistic exposure analysis produces a distribution of exposures which is then used to estimate the range of risks for the highly exposed population being modeled. The distribution of exposure is determined by varying parameter values where data is available over multiple iterations of the exposure model. Values were varied for such parameters as dioxin concentrations in sewage sludge, number of years on the farm, and number of applications. While ranges of data were available for the majority of input parameters, ''single point'' values were used for some key input parameters for the exposure analysis, including values for parameters used to define the highly exposed population, soil ingestion rates, and number of days per year of exposure. These assumptions are discussed in greater detail elsewhere in this Notice.

A receptor is the entity exposed to a physical, chemical or biological source which can cause an adverse effect. In this case the receptors are infants, children, and adults in highly exposed farm families living on farms where sewage sludge is applied. ''Highly exposed'' farm families are defined as farm families whose diets consist of 50 percent of products produced on their own farm. EPA estimates that the maximum number of individuals in this highly exposed population would be less than 11,000 even if all of the Nation's sewage sludge were applied to family farms (see Section VI.L.). Since the general population consumes only a small fraction of their diets from products grown on farms with land-applied sewage sludge, EPA assumed that a regulatory decision that is protective of this highly exposed family is also protective of the general population.

The probabilistic analysis was performed using a Monte Carlo simulation. In a Monte Carlo simulation, the model is run for a number of iterations, each producing a single result (e.g., a single estimate of cancer risk). For this assessment, 3,000 iterations were run in the Monte Carlo simulation; therefore, the output of the probabilistic analysis was a distribution of 3,000 values. This distribution represents the distribution of possible outcomes, which reflects the underlying variability in the data used in the analysis. These results were then used to identify risk to the highly exposed population at various percentile levels (e.g., 90th percentile risk value). As noted above, the corresponding percentile risk values to the general population would be significantly lower.

Some model input parameters used in the Monte Carlo simulation, such as the concentrations of dioxin congeners in sewage sludge samples, were drawn from statistical distributions. For others, variability was associated with variable locations; thus, location variability was explicitly considered in the setup of the data used for the probabilistic analysis. For location-dependent parameters, locations were first selected at random with equal probability of occurrence [2] based on the 41 climate regions. These regions defined a set of related environmental conditions (e.g., soil type, hydrogeologic environment) that characterized the environmental setting. All location-specific parameters (e.g., rainfall) thus remained correlated, while non-location-specific parameters were varied both within and among locations.

D. How Did the Framework Change?

In the exposure analysis, the risk assessment evaluated a revised scenario for exposure to sewage sludge: exposure

[2] Information was not available to allow the weighting of these 41 climate regions based on the number of farm families in each region.

of a farm family that consumes 50% of its diet from home-produced crops and animal products grown on their own sewage sludge-amended land. For the December 1999 proposal, a rural family consuming a smaller proportion of home-grown products derived from sewage sludge-amended soil was modeled in the original risk assessment. EPA selected the new scenario specifically to address groups of individuals who may have high levels of exposure to dioxins in sewage sludge. EPA assumed that the farm family lives immediately adjacent to the sewage sludge-amended field and is exposed to a combination of agricultural products produced on the farm, including beef and dairy products. The farm family also is assumed to raise free-range chickens near their house (in the buffer area). On the opposite side of the house from the field and pasture is a fishable stream where a recreational fisher is assumed to catch fish for personal consumption. There are four types of people who were assumed to be representative of the individuals who would be exposed to dioxin from sewage sludge: an infant of a farmer, a child of a farmer, an adult farmer, and an adult recreational fisher. The exposure to the adult fisher was combined with that of the adult farmer, when the total exposure to the adult was calculated. Therefore, the fisher and farm adult can be considered as the same adult. Table 4 summarizes the exposure pathways for each type of individual.

TABLE 4.—RECEPTORS AND EXPOSURE PATHWAYS

Receptor	Inhalation of ambient air	Ingestion of soil	Ingestion of above- and below-ground produce	Ingestion of beef and dairy products	Ingestion of poultry and egg products	Ingestion of fish	Ingestion of breast milk
Adult	✔	✔	✔	✔	✔	✔	
Child	✔	✔	✔	✔	✔		
Infant							✔

The new scenario includes new exposure pathways and exposure mechanisms, incorporating updated scientific analysis for dioxin, which is also reflected in EPA's Draft Dioxin Reassessment (USEPA, 2000a. See Part I, Vol. 3, Chap. 2.). For the proposed rule, the risk assessment evaluated pastured animals eating sewage sludge containing dioxins after sewage sludge land application. The revised risk assessment assumes tilled soil only for production of vegetables, fruits, and root crops and untilled soil for pasturage to which sewage sludge is applied. Half the acreage on the modeled farm is assumed to be used for crop production (tilled) and half permanently used for pasturage (untilled). Rather than assuming that cattle are exposed to dioxins only by eating sewage sludge-containing soil, the Agency now assumes that cattle are exposed to dioxins in sewage sludge by three mechanisms: ingesting dioxins from the leaf surfaces of plants containing dioxins which have volatilized from the top two centimeters of the soil to which sewage sludge has been applied; ingesting dioxins from sewage sludge particles which remain on the leaf surfaces of plants after land application; and direct ingestion of sewage sludge-containing soil by the grazing cattle. Of these three mechanisms of dioxin transfer to cattle from the sewage sludge, the predominant mechanism is ingestion of dioxins from leaf surfaces containing dioxins which have volatilized from the sewage sludge-soil mixture. The dioxins from land-applied sewage sludge that does not erode away from the land application site are assumed to reside permanently in the top two centimeters of the soil. Another new assumption reflecting the latest science on dioxin and consistent with EPA's Draft Dioxin Reassessment documents is that chickens will be ingesting dioxins from the buffer area which receives dioxins from the pasture and crop fields through erosion. EPA requests comments on the Agency's use of the farm family scenario described for the revised risk assessment. EPA also requests comments on the specific assumptions outlined above.

E. What Are the Factors in Estimating How Much Dioxin is Released to the Environment?

Various inputs for sewage sludge characteristics were used in the exposure analysis to determine how much dioxin is available for volatilization, erosion or leaching. These included: concentrations of each of the 29 congeners in sewage sludge (empirical distribution of concentrations for each dioxin congener varied by sample), bulk density of sewage sludge (single value), porosity of sewage sludge (single value), percent moisture of sewage sludge when applied to agricultural fields (single value), and fraction of organic carbon of sewage sludge (single value). The use of the congener concentrations was different in the revised exposure analysis. Rather than using point estimates for the 29 congeners for the probabilistic analysis, all of the congener concentrations measured in the 94 samples from the EPA 2001 dioxin update survey were used. Specifically, for each iteration of the Monte Carlo analysis, one of the 94 sewage sludge samples from the EPA 2001 dioxin update survey was randomly selected and the concentrations of all congeners from that sample were considered in that iteration of the analysis. For each iteration, the concentration of dioxins in the sludge was assumed to remain constant for the entire period of application since family farms would likely receive sewage sludge from a single POTW.

When the chemical content of a substance is analyzed, the assumption used to address non-detected chemicals can have a significant impact on the reported results if the detection limits are relatively large. Non-detects can be reported as zero, one-half the detection limit, or the detection limit. Because of the excellent sensitivity and limits of detection achieved by the analytical procedures used in the EPA 2001 dioxin update survey, the reported values for dioxin congeners in the samples of sewage sludge are relatively unchanged whether non-detects are treated as zero, one-half of the detection limit, or at full detection limit. For this risk assessment, EPA assumed that non-detects are equal to one-half of the detection limit. This assumption is prevalently used by EPA for risk assessments based on data sets for non-detects, including the Draft

Dioxin Reassessment for calculating TEQ concentrations for dioxins in environmental media (i.e., air, soil, water) and in exposure media (i.e., food). Furthermore, it appears that there would be no quantifiable difference in the estimated risk regardless of the assumption made for non-detects for the reasons discussed above. EPA requests comment on the treatment of non-detects in the revised risk assessment and the effect on estimating risk.

Another sewage sludge characteristic, bulk density of sewage sludge as it is applied to the agricultural field, was used to estimate the loading of constituents to the soil in the model. Sewage sludge is assumed not only to add constituents to the soil, but also to add volume when mixed with the existing soil. Thus, bulk density is a required parameter for the modeling scenario used in the exposure analysis. Bulk density of the land-applied sewage sludge may be a direct measurement or may be estimated using the dry bulk density, the percent moisture, and the porosity of the sewage sludge.

F. What Are the Factors in Estimating How Much Dioxin Is Being Transported in the Environment to the Individual in the Farm Family?

A conceptual site model was used to represent exposures to the highly exposed modeled population from land application of sewage sludge. To capture some of the variability in environmental settings across the United States, the conceptual site model was placed in different regions throughout the continental United States.

The risk assessment was intended to be representative of a national distribution of environmental conditions. The 48 contiguous states (excluding Hawaii, Alaska, and the off-shore possessions) were divided into 41 meteorologic regions. These regions were selected to represent the national variation of location-specific variables. Each area is assumed to represent a single climate region (i.e., conditions within that area can be modeled using the meteorologic data from a single meteorologic observation station). Meteorologic and climate data were used in air modeling, partitioning in the source model, and surface and subsurface fate and transport modeling.

In addition, farm areas were assumed to be linked to geographic area. Large farms are more common in the Midwest and western parts of the United States, and smaller farms are more common in the eastern and southern parts of the United States. Thus, a regional estimate for a median farm size was developed and was used in this risk assessment. The U.S. agricultural census contains estimates for the distribution of farms within each county. These data were used to develop a median farm size for each county. These county-wide median farm sizes were classified according to the 41 geographic areas and the median of the median farm sizes was estimated for each of the 41 regions. The median area was then used in the air modeling and the erosion to surface water modeling. This methodology was used to account for the regional variation in agricultural practices throughout the nation, but it did not consider variation in size within a single region.

A series of models was used to estimate concentrations of the congeners in the environment with which a farm family may come into contact. The revised risk assessment assumes that there are six direct and indirect exposure pathways that the models describe:

- Inhalation of ambient air;
- Incidental ingestion of soil in the buffer area;
- Ingestion of above- and below-ground produce grown on the crop land;
- Ingestion of beef and dairy products from the pasture;
- Ingestion of home-produced poultry and eggs from the buffer area; and
- Ingestion of fish from the nearby water body.

As indicated above, a regional approach was used to define the area surrounding the agricultural application site. A source partition model was then used to estimate environmental releases of each constituent. These estimated environmental releases in turn provided input to the fate and transport models to estimate media concentrations in air, soil, and surface water. A food chain model was used to estimate constituent concentrations in produce, beef, dairy products, poultry, eggs, and fish.

The source partition model determines the initial release of congeners into the environment. Sewage sludge application to pastures or crop land is assumed to be different and these differences affect the behavior of constituents in the environment. The model uses information described above on sewage sludge characteristics (e.g., moisture content and congener concentrations), and environmental setting (e.g., precipitation, temperature, and soil characteristics) to estimate environmental releases.

Fate and transport modeling procedures describe the mechanism by which the congeners move from the source through the environment. As described above, a source partition model was used to determine the amount and nature of congener released from the agricultural field. A multimedia approach was used to characterize the movement of the dioxins through the environment. This approach considered atmospheric concentrations, atmospheric deposition, soil concentrations, and sediment concentrations in potentially impacted water bodies.

Air modeling procedures estimated air concentrations and deposition of vapors and particles on the agricultural farm, onto the buffer area, directly into the surrounding water bodies, and onto the regional watershed. Air dispersion and deposition of vapors and particles were modeled using the Industrial Source Complex Short Term Model. Soil erosion comes from the crop fields and pastures, the buffer area containing the house and chicken yard, and the remaining portion of the watershed. Erosion was modeled using the Universal Soil Loss Equation. All impacts in the same period of time were summed to estimate the concentration in the stream sediment and water column.

The exposure pathways included inhalation of dioxins in ambient air during tilling of agricultural fields, incidental ingestion of soil, ingestion of aboveground and belowground produce (i.e., root crops), ingestion of beef and dairy products, ingestion of eggs and poultry products, and ingestion of fish. EPA's preliminary analysis indicated that exposure to dioxins from the consumption of ground water was insignificant due to the extremely low solubility of dioxins in water and negligible leaching of dioxins to ground water (USEPA, 1999b).

With concentrations of the congeners determined for water and air, the concentrations being delivered to humans from aboveground produce, belowground produce, poultry, eggs, beef, dairy products, and fish were then calculated. This was accomplished using food chain models. The food crops (vegetables, fruits, and root vegetables) were assumed to be grown on the sewage sludge-amended fields, and cattle (beef and dairy) were assumed to be raised on pastures receiving sewage sludge. These processes were modeled using a multi-pathway exposure model and the fate and transport parameters and modeling procedures reflecting the latest scientific knowledge on the fate and transport of dioxin. The exposure pathways considered the transport of constituents from the soil to plants (vegetables, fruits, roots, and pasture grass) and ingestion of these materials by humans and animals. The transport to plants may occur through the root system, but most occurs through air-to-plant transfer mechanisms. The contaminated plants are in turn consumed by cattle and humans.

The latest scientific knowledge with respect to the methodology of estimating concentration of congeners in beef and/or dairy products is also described in the Draft Dioxin Reassessment document. This methodology has been developed based on the transfer of congeners from the total diet of the cattle into the fat. The method described in the Draft Dioxin Reassessment emphasizes the importance of the differences in diet between beef and dairy cattle in explaining different food concentrations. While the same equation was used for all cattle, whether they are beef cattle or dairy cattle, the differences were in the dietary fraction assumptions. These assumptions were based on how much of the time the cattle are pastured and how much of the time they are confined with supplemental feed. Forage was assumed to be raised on the sewage sludge-amended pasture where the sewage sludge was assumed to remain on the top two centimeters of the soil and to volatilize onto the forage. The soil was assumed to be the soil in the sewage sludge-amended pasture. The supplemental feed for the cattle was assumed to be grown on sewage sludge-amended crop land where the sewage sludge was tilled into the soil. Half of the supplemental feed was assumed to be vegetation and half was assumed to be grains. Supplemental feed was assumed to contain a lower dioxin concentration than forage because it was assumed to contain less volatilized dioxins (due to tilling), and the grain portion was assumed to be free of contamination due to stripping of the outer leaves where dioxins accumulate.

To determine the dioxin concentrations in poultry and eggs, the risk assessment starts with the assumption that sewage sludge is not to be applied directly to the chicken yard. The chickens are assumed to be free range within a confined area of the buffer near the farm residence. The chicken diet is assumed to consist of 90 percent store bought chicken feed (uncontaminated by dioxins in sewage sludge applied on the farm land) and 10 percent buffer soil.

As already indicated, the receptors included in the modeling are adults and children living and working on farms where fruits, vegetables, root crops, and farm animals are raised, and half of these food items consumed by the adults and children living on the farm are produced on the farm. The farm family also is assumed to be exposed to inhalation risks from windblown and tilling emissions from the agricultural field. Soil ingestion risks are also assessed for both adults and children. Children are assumed to ingest soil from the buffer area, and the adult farmer is assumed to ingest soil from the tilled field. In addition, risks to recreational fishers who catch and consume fish from the stream adjacent to the agricultural field is considered and summed with the other exposure pathways on the assumption that farmers are also recreational fishers.

EPA requests comment on the assumptions and values used in this Section to estimate how much dioxins are being transported to individuals in the modeled farm family (e.g., the sources (store-bought versus farm-produced) and dioxin contamination levels of poultry feeds).

G. What Additional Factors Are Applied to Dioxin Concentrations To Determine How Much of the Congeners are Being Ingested or Inhaled by a Farm Family Member?

To determine how much of the congeners adults and children are inhaling and ingesting, exposure factors were applied to the concentrations of the contaminants from air, produce, cattle, dairy, poultry, eggs, and fish. The exposure factors used in this analysis were taken from the Exposure Factors Handbook (USEPA, 1997). The Exposure Factors Handbook summarizes data on human behaviors and characteristics related to human exposure from relevant key studies and provides recommendations and associated confidence estimates on the values of exposure factors.[3]

The proportion of home produced food commodities eaten by highly exposed farm families was assumed to be 50% of their diet for all iterations. This assumption defined the modeled population. Specific distributions of other exposure factors for the general population of farm residents were compiled from the Exposure Factors Handbook. These include ingestion rates for adults and children for aboveground vegetables, root vegetables, fruits, beef, dairy products, poultry, and eggs. Distributions have been developed for adults and for three age groups of children for these dietary categories.

Exposure factors are related to the pathways in that they describe the rates at which dioxin doses are ingested or inhaled from the various sources noted above (e.g., air, soil, beef, and diary, by the highly exposed farm family adults and children). The exposure factors used in this risk assessment are represented by a distribution or a fixed value in the Monte Carlo probabilistic analysis.

For the probabilistic exposure analysis, probability distribution functions were developed from the values in the Exposure Factors Handbook. The intake factors, for which either single values or distributions were used from the Exposure Factors Handbook, are: soil ingestion (one value for children aged 1 to 6 and another value for all other receptors); and fruits and vegetables ingestion, beef and dairy ingestion, fish ingestion, and inhalation rates (all of which are distributions of values.)

H. How Did EPA Calculate the Range of Exposure Levels?

For cancer effects, where the biological response is described in terms of lifetime probabilities, dose is presented as a ''lifetime average daily dose'' (LADD). Because exposure duration varies from person to person (i.e., may not occur over the entire lifetime), calculation of exposure produces a distribution of exposure levels (or doses). In addition to exposure duration, the LADD takes a number of variable factors into account, including when exposure begins, how often and in what amounts sewage sludge is applied to the land, and the length of time over which land application occurs. For this risk assessment, the LADD takes into account: (1) A distribution of randomly selected times when land application begins, i.e., either when the highly exposed farm family begins applying sewage sludge to their land or moves onto a farm where sewage is being or has been applied; (2) a distribution of exposure durations ranging from one year to 70 years;[4] (3) a distribution of sewage sludge application duration, ranging from a minimum of one year up to a maximum of 40 years (i.e., a minimum of one application to a

[3] EPA carefully reviewed and evaluated the quality of the data before their inclusion in the Exposure Factors Handbook. EPA's evaluation criteria included peer review, reproducibility, pertinence to the United States, currency, adequacy of the data collection period, validity of the approach, representativeness of the population being modeled (in this case, farm families), characterization of the variability, lack of bias in study design, and measurement error (USEPA, 1997).

[4] Exposure durations representing the residence time in the same house were also determined using the Exposure Factors Handbook. The lifetime of the individual was assumed to be a fixed value of 70 years. A fixed value for exposure frequency was assumed to be 350 days per year, accounting for two weeks away from the farm for vacation (USEPA, 2002b). These single values were selected to be protective and yet representative of realistic scenarios.

maximum of 20 applications based on a fixed application frequency of once every two years), and (4) a distribution of sewage sludge application rates (i.e., amount of sludge applied to the land) ranging from 5–10 metric tons per hectare per application. The LADD also includes doses from each exposure route (i.e., inhalation and ingestion) and body weight. A distribution of body weights for the adult and child were taken from the Exposure Factors Handbook.

The purpose of the exposure assessment is to estimate the dose to an exposed individual by combining media intake estimates with media concentrations. Estimates of exposure are based on the potential dose (e.g., the dose ingested or inhaled) rather than the applied dose (e.g., the dose delivered to the gastrointestinal tract) or the internal dose (e.g., the dose delivered to the target organ). Doses from individual pathways (e.g., soil, exposed vegetables) were calculated by multiplying the contaminant concentration in the food product or other exposure media (e.g., air or soil) by the respective intake rate on a per kilogram body weight basis. Doses received from the various ingestion pathways (e.g., soil and food) were then summed over the period of time in which exposure occurs, resulting in an average daily dose received from ingestion exposure.

I. How Was Childhood and Infant Exposure Evaluated in the Exposure Analysis?

Children are an important sub-population to consider in a risk assessment because they may be more highly exposed than adults; compared to adults, children may eat more food and drink more fluids per unit of body weight. This higher intake-rate-to-body-weight ratio can result in a higher average daily dose of dioxins than adults experience. The risk assessment performed for sewage sludge application to agricultural land includes an analysis of exposures to 3,000 individuals whose exposures begin in childhood. To account for intake rates varying over different childhood age groups, parameters characterizing exposures beginning in childhood were developed.

The first step in developing the time-weighted parameters is to define the start age for the child and the length of exposure for that individual. These two values then determine how long the individual is in each age group. Four age groups were defined as follows: age group 1 (1–5 years of age); age group 2 (6–11 years of age); age group 3 (12–19 years of age); and age group 4 (over 20 years of age). After the individual is defined, age appropriate consumption rates are chosen for each age group which are selected from the age specific consumption rate distribution for each item considered in the analysis. For example if the exposure begins at age 3 and continues for 20 years, a consumption rate for each age group was selected and weighted to represent the number of years spent in each age group to get an average intake rate for the entire exposure duration of 20 years (i.e., age group 1= 3 years of exposure; age group 2 = 6 years; age group 3 = 7 years; and age group 4 = 4 years, for a total of 20 years exposure.) This time weighted intake rate is then used with the average concentration of dioxins for the food item over the entire exposure duration, to yield an average daily dose.

Infants are also an important sub-population to consider in this risk assessment because they may be exposed to dioxin-like compounds via the ingestion of breast milk. While risks to children and adults were integrated to incorporate individuals for whom exposure first occurs during childhood but continues into adulthood, the lifetime risks to infants were calculated separately from the risks to older children (i.e., ages 1 year or older) and adults. For infants, exposure during the first year of life was averaged over an expected lifetime of seventy years to derive a LADD that was then used to calculate risk. The ''lifetime'' risk to infants thus should be thought of as the contribution to lifetime risk that occurs during the first year of life through ingestion of breast milk for individuals born into a farm family exposed to dioxins from land-applied sewage sludge.

J. How Was the Cancer Risk Estimate Calculated?

Cancer risk is calculated using lifetime excess cancer risk estimates to represent the excess probability of developing cancer over a lifetime as a result of exposure to the constituent of interest. Lifetime excess cancer risk estimates are the product of the lifetime average daily dose for each of the four types of individuals exposed to dioxin and for each exposure pathway, and the corresponding cancer slope factor.

The exposure assessment estimates delivered doses for each of the 29 congeners to a farm family individual. Each of these congener doses were then converted to TEQ doses by multiplying each congener dose by its TEF. These TEQ doses for each of the 29 congeners were then summed to yield an overall TEQ dose to the individual for that exposure pathway (e.g., inhalation or ingestion). Finally this TEQ dose was multiplied by the cancer slope factor to estimate the excess cancer risk to the individual for that pathway of exposure.

Using all samples from the EPA 2001 dioxin update survey, the estimated risks and corresponding daily exposure to dioxins for the highly exposed farm adult and child are given below in Table 5 for various percentiles of exposure within this population. ''Adult'' means individuals whose exposure begins when they are adults, and ''child'' means individuals whose exposure begins when they are children. In most cases exposure which begins during childhood also ends during childhood. However, in some instances, exposures which begin when individuals are children continued into their adult years.

Additional risk calculations were performed to estimate the impact on the risk if sewage sludge with 300 ppt TEQ dioxin and 100 ppt TEQ dioxin were restricted from being land applied. Eliminating sewage sludge samples with higher concentrations of dioxins did not change the estimated risk. The distribution of risk estimates for scenarios excluding samples with dioxin concentrations greater than 300 ppt TEQ and 100 ppt TEQ are the same as the distribution below shown in Table 5, which includes data from all sewage sludge samples.

TABLE 5.—RISKS AND DAILY EXPOSURE FOR HIGHLY EXPOSED FARM ADULT AND CHILD FOR ALL EXPOSURE PATHWAYS—($Q^*=1.56 \times 10^{-4}$/PG TEQ/kg-d)

Percentile	Adult *		Child **	
	Risk	Daily Exposure pg TEQ/kg-d	Risk	Daily Exposure, pg TEQ/kg-d
50th	1×10^{-6}	7.3	1×10^{-6}	7.3
75th	4×10^{-6}	7.3	3×10^{-6}	7.3
90th	1×10^{-5}	7.3	7×10^{-6}	7.3
95th	2×10^{-5}	7.3	1×10^{-5}	7.3
99th	4×10^{-5}	7.3	2×10^{-5}	7.3

* Initial exposure begins when the individual is an adult.
** Initial exposure begins when the individual is a child.

K. How Did EPA Analyze the Relative Importance of Inputs to the Risk Model?

In addition to the revised risk assessment, EPA conducted a sensitivity analysis to identify the effects of variability and uncertainty in the risk model on the risk estimates. These steps are performed on the inputs and outputs of the Monte Carlo analysis. In the Monte Carlo analysis, probability distributions were assumed for each of the variable input parameters, and a distribution of 3,000 media concentrations and risk results were generated as outputs in the analysis. In the sensitivity analysis, statistical methods were applied to this sample of inputs and outputs to evaluate the influence of the individual inputs on the model outputs. Several different indices of sensitivity were derived from the simulated sample to quantify the influence of the inputs and identify the most influential parameters. Finally, a regression analysis was applied to a linear equation to estimate the relative change in the output of a Monte Carlo simulation relative to the changes in the input parameters.

Table 6 presents the results of the sensitivity analysis for the beef and dairy products exposure pathways. The consumption of beef and dairy products by the farm family represent over 90 percent of dioxin exposure and subsequent cancer risk associated with land application of sewage sludge. For the beef products pathway, exposure duration and beef consumption rate combine to account for 86 percent of the variation in the estimation of dioxin exposure. The two variables which account for the next highest contributions to variation in the estimation of exposure (i.e., sewage sludge application rate and average year that the farm family moves in) combined for 2 percent of the variation. Similarly, for dairy products, exposure duration and dairy products consumption rate also represent 86 percent of the variation in the estimation of exposure, with the next two highest variables again representing a combined 2 percent of the variation. A detailed discussion of the entire sensitivity analysis can be found in the land application risk assessment Technical Background Document (USEPA, 2002b).

TABLE 6.—RESULTS OF SENSITIVITY ANALYSIS

Pathway and Sensitivity variables	Percent of risk accounted for by variable
Beef:	
Exposure Duration	60
Consumption Rate	26
Sewage sludge Application Rate.	1
Average year that the farm family moves in.	1
Dairy products:	
Exposure Duration	54
Consumption Rate	32
Average year that the farm family moves in.	1
Sewage sludge Application rate.	1

L. How Does EPA Characterize the Risk?

As previously noted, EPA developed a revised risk assessment using a probabilistic approach as a basis for the Agency final action on development of a numerical standard for dioxins in sewage sludge applied to agricultural land. In order to protect the general public from adverse health impacts from dioxins in land-applied sewage sludge with an adequate margin of safety, the risk assessment calculates the risk to the most highly exposed population (i.e., a farm family consuming 50 percent of their diet from products grown on sewage sludge amended soil) . The following discussion characterizes the key elements of EPA's risk assessment and compares them according to the principles in EPA's guidance for exposure assessment and for risk characterization (USEPA, 1992 and USEPA, 2000b).

Approximately 95 percent of the U.S. population's exposure to dioxins results from the consumption of animal products in the diet where dioxin is concentrated in the fatty portion of the meats and dairy products (USEPA, 2000a. See Part I, Vol. 3, Chap. 3.). EPA chose the farm family as the highly exposed population to be modeled, using a key assumption that their diets have significant percentages of meat and dairy products from their own farms where sewage sludge is land applied as a fertilizer or soil amendment. Members of such a farm family are at greater risk from exposure to dioxins associated with land application as compared with the overall U.S. population because their diets would be based on products from their farm. As previously noted, a decision that is protective of this highly exposed modeled population is thus protective of the general population from the same pathways of dioxin exposure with a greater margin of safety since the diet of the general population contains only a small fraction of meat and dairy products grown on farms with land-applied sewage sludge.

The following discussion characterizes the three principal components of the risk assessment: the exposure scenario; key assumptions and data used in the exposure assessment modeling; and the cancer slope factor (Q1* or potency factor). Each of these components is characterized as either ''high end'' or ''central tendency.''

As previously noted, sewage sludge is assumed to be applied at agronomic rates to tilled crop land used for the production of vegetables, fruits, and root crops, and to pasture land which is not tilled. Fifty percent of the farm family's agricultural land is assumed to be tilled crop land and the other fifty percent untilled pasture. An important assumption in terms of characterizing the risk is that the dioxin in each application of sewage sludge to pasture is assumed to permanently remain in the top two centimeters of the land surface and is not diluted over time. This is a key assumption since volatilization from soil to the leaf surfaces of crops consumed by animals and humans is the principal mechanism by which dioxins are transported from sewage sludge applied to the land. This assumption predicts a maximum amount of transport of dioxins for subsequent consumption by pastured animals. In addition, this pasturing scenario is not varied; EPA assumes that the farmer does not rotate the pasture to grow row crops where tilling of sewage sludge in the soil would mitigate dioxin volatilization transport. Thus, this assumption is likely to contribute to an overestimation of risk.

Another important assumption contributing to the risk estimate is that the family is simultaneously exposed to a combination of agricultural products produced on the farm. For the purpose of the exposure assessment and risk assessment, all pathways of exposure to dioxins are summed.

As previously noted, the cancer slope factor used in the revised risk assessment is 1.56×10^{-4}/pg TEQ/kg–d. This value is characterized as the upper bound (i.e., at the 95th percentile confidence level) on the slope of the dose-response curve in the low-dose region and is generally assumed to be linear. Use of upper bound slope factors also results in calculation of high-end risks of cancer for individuals in the target population of highly exposed farm families (i.e., 95% likelihood that risk to such highly exposed individuals is lower) (USEPA, 2000a. See Part III, Chap. 6).

As described above in the description of the risk assessment, most of the parameters used in the Monte Carlo simulations were distributions of a range of observed values for each parameter. Where a range of data was not available, ''fixed'' data points or assumptions were used. The sources of information for the fixed point inputs necessary to conduct the risk assessment include the EPA Exposure Factors Handbook (USEPA, 1997), peer reviewed scientific literature, and other assumptions specifically related to land application of sewage sludge based on actual practice.

The following is a listing of some of the key fixed parameters used in the Monte Carlo simulations and their characterizations. Some of the fixed assumptions characterized as ''high end'' have the greatest impact on the risk estimate based on the results of the sensitivity analysis discussed above (see Section VI.K.). These assumptions include the farm family simultaneously exposed to multiple pathways including a certain percentage of their own products; dioxin remaining in the top two centimeters on pasture lands; and the upper bound Q1*. The following ''fixed'' parameters are important to note, but have a lesser impact on the risk estimate.

Other ''High End'' Assumptions

- Exposure Frequency—350 days per year.
- Fraction of diet for home-caught fish—100%.
- Fraction of soil ingested that is contaminated—100%.
- Fraction of ingested dioxin absorbed by the mother—100%.
- Use of potential dose rather than applied or internal dose.

Mean or Central Tendency Values from EPA Exposure Factors Handbook

- Fraction of food preparation loss for exposed fruit, exposed vegetables, and root vegetables.
- Percent cooking and percent post-cooking loss for beef and poultry.
- Fraction of home-caught fish that are at trophic levels 3 and 4 (high dioxin bio-accumulating fish).
- Soil ingestion rates for children and adults.

Values from Scientific Literature [5]

- Biological half life of dioxin in lactating women.
- Concentration of dioxin in aqueous phase of maternal milk.
- Fraction of fat in maternal breast milk. (mean value)
- Fraction of ingested dioxin absorbed by the infant.
- Fraction of mother's weight that is fat. (mean value)
- Proportion of dioxin stored in maternal fat.

The probabilistic methodology facilitates risk estimates for individuals in any percentile of the assessed population. The revised land application risk assessment reports high-end estimates of risks for individuals at the 50th, 75th, 90th, 95th and 99th percentiles of exposure within the population defined for this analysis as ''highly exposed.'' USEPA, 2002b. It may also be acceptable to characterize the risk assessment as the ''high end of the high end'' within this modeled population of highly exposed farm families.

[5] USEPA, 1998a. Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure To Combustor Emissions. These values were gathered from various sources and are either mean values or representative ranges (not high end).

The incremental cancer risk for land application of sewage sludge was estimated considering all exposure pathways for three scenarios: baseline (all samples from the EPA 2001 dioxin update survey); 300 ppt TEQ cutoff (samples greater than 300 ppt TEQ excluded); and 100 ppt TEQ cutoff (samples greater than 100 ppt TEQ excluded). The estimated lifetime risks for adults using this cancer slope factor range from 4×10^{-5} at the 99th percentile to 1×10^{-6} at the 50th percentile for multi-pathway exposure to dioxins through land-applied sewage sludge (see Table 5). (As indicated in Table 5, the estimated risks for children are less than or equal to the estimated risks for adults.) No quantifiable decrease in risk is calculated if sewage sludge with greater than 300 ppt TEQ dioxins or greater than 100 ppt TEQ dioxins were restricted from being land applied. The reason that the estimated risk does not decrease when sewage sludge limits of 300 ppt TEQ dioxins or 100 ppt TEQ dioxins are assumed is that, based on the representative sampling, there is so little sewage sludge that contains dioxin at or above these concentrations.

Continual application of sewage sludge with significantly higher concentrations of dioxins than currently measured would be necessary to predict quantifiable increases in risk. However, comparison of data from the 1988 NSSS (USEPA, 1990) and the EPA 2001 dioxin update survey (USEPA, 2002a) indicate that ''spikes'' (i.e., higher concentrations) of dioxins in sewage sludge appear to be transient. Specifically, all ten sewage sludge samples with the highest concentrations of dioxins and furans measured in the 1988 Survey (concentrations ranging from 97 ppt TEQ to 827 ppt TEQ) had greatly reduced concentrations of dioxins and furans in the 2001 dioxin update survey (concentrations ranging from 2 ppt TEQ to 53 ppt TEQ) (USEPA, 1990 and USEPA, 2002a). Conversely, the four sewage sludge samples with the highest concentrations of dioxins and furans measured in the 2001 dioxin update survey (concentrations ranging from 93 ppt TEQ to 682 ppt TEQ) had markedly lower concentrations of dioxins and furans in the 1988 Survey (concentrations ranging from 2 ppt TEQ to 41 ppt TEQ) (USEPA, 2002a and USEPA, 1990).

[**Note:** These comparisons are based on dioxin and furan concentrations since only dioxins and furans were measured in the 1988 Survey.] Thus, it is highly unlikely that a single family would be exposed to one of these sewage sludges with a high concentration of dioxin long enough to produce a quantifiable increase in risk.

Finally, the Agency calculated the maximum number of cancer cases in the highly exposed population that could be predicted from exposure to dioxins in land applied sewage sludge (USEPA, 2002c). To make this calculation the Agency used data from the EPA Exposure Factors Handbook (USEPA, 1997) that indicates that 2 percent of the United States population are in farm families whose diets consist of 50 percent of products produced on their own farm (5.6 million people). The Agency then estimated the maximum percentage of farmland to which sewage sludge could be applied annually is 0.2 percent. This estimate was derived by dividing the amount of farmland which could receive sewage sludge if all 8 million metric tons of sewage sludge produced annually in the United States (USEPA, 1999c) were land-applied at an agronomic rate of 10 metric tons/hectare (800,000 hectares) by the total amount of farmland in the United States (377 million hectares; USDA, 1997). On this basis EPA estimates that the highly exposed farm family population is no greater than 11,000 (i.e., 0.2% of the 5.6 million people whose diets consist of 50% percent of products produced on their own farm). The number of lifetime cancer cases is estimated by multiplying the risk by the number of individuals in the modeled population. The estimated lifetime cancer cases for the modeled population is 0.224 if the 95th percentile adult risk from land application of sewage sludge (2×10^{-5}, see Table 5) is used for this calculation, and 0.112 using the 90th percentile adult risk (1×10^{-5}, see Table 5). The number of annual cases is estimated by dividing the lifetime cancer cases by 70 years of exposure. The estimated annual cancer cases is 0.006 if the 99th percentile adult risk is assumed, 0.003 if the 95th percentile adult risk is assumed, and 0.002 if the 90th percentile adult risk is assumed.

EPA requests comments on the Agency's characterization of the key elements of the revised land application risk assessment. EPA will consider these comments to characterize the overall estimate of risk to the modeled population.

VII. What Are the Implications of EPA's Dioxin Reassessment Process for This Rulemaking?

Since 1991 EPA has been conducting a scientific reassessment of the health risks of exposure to dioxin and dioxin-like compounds. EPA began this task in light of significant advances in the Agency's scientific understanding of mechanisms of dioxin toxicity, significant new studies of dioxin's carcinogenic potential in humans, and increased evidence of other adverse health effects. These efforts have included the involvement of outside scientists as principal authors of several chapters, frequent public meetings to report progress and take public comment, and publication of early drafts for public comment and peer review. The review process for the Dioxin Reassessment has also involved extensive use of outside scientists from other federal agencies and the general scientific community.

As previously stated, aspects of the Agency's Draft Dioxin Reassessment that are considered state of the science or the best available information about dioxin have been incorporated into the revised exposure analysis and risk assessment for dioxins in land-applied sewage sludge. (See Section VI.D. of this Notice). However, the Agency has not finalized its policy and/or factual conclusions with respect to other aspects of the Draft Dioxin Reassessment, and any decisions on these policy and factual conclusions made in part as a result of the Dioxin Reassessment could affect the sewage sludge land application exposure analysis and risk assessment, and therefore could affect the Agency's decisions with respect to this rulemaking. Therefore, EPA is seeking comment on the implications of this information in the event that, prior to taking final action on the Round Two rule, EPA finalizes a cancer slope factor, an approach to assessing risk of non-cancer health effects from dioxins, or other aspects of the current Draft Dioxin Reassessment. If EPA issues a final Dioxin Reassessment that is substantially similar to the current draft as discussed in this Notice, EPA does not expect to provide further notice and opportunity for public comment with respect to the effect of the Dioxin Reassessment on this rulemaking. The following is a brief summary of the EPA Dioxin Reassessment process, and a discussion of how the Agency may integrate key decisions on dioxins policy resulting from the Dioxin Reassessment into the Round Two rulemaking.

EPA first released the external review drafts of the Dioxin Reassessment health effects and exposure documents in September 1994 (USEPA 1994a). The Agency took public comment on the drafts, followed by the Agency's Science Advisory Board (SAB) review of the Draft Dioxin Reassessment in May 1995. The documents were revised based on these reviews and were again released for external peer review. EPA made additional revisions to the documents based on the external peer review and submitted them once again to the SAB. After a public meeting on May 15, 2001, the SAB's Executive Committee endorsed a review report of the Draft Dioxin Reassessment contingent upon changes to address some of the differing scientific opinions raised in the review report.

Based on the overall endorsement of the content of the Draft Dioxin Reassessment by the SAB, EPA used many aspects of the Reassessment in the revised Part 503 exposure analysis and risk assessment. These include the TEQ approach based on the toxicity of 2,3,7,8-TCDD, the use of the current WHO_{98} TEQs, and the numerous physical, chemical, occurrence, and exposure factors used in the Dioxin Reassessment to evaluate and characterize human health risks from dioxins.

Two of the key areas which the SAB identified as having differing scientific opinions are the cancer slope factor for 2,3,7,8-TCDD and the use of a margin of exposure (MOE) approach to evaluate the likelihood that non-cancer effects may occur in the human population at environmental exposure levels. The Draft 2000 Dioxin Reassessment notes that, while major uncertainties remain, efforts to bring more data into the evaluation of cancer potency have resulted in an estimate of 1×10^{-3}/pg TEQ/kg-d. According to the Draft 2000 Dioxin Reassessment, this cancer slope factor represents a plausible upper bound on risk based on evaluation of human and animal data. These values are approximately six times higher than previous estimates (USEPA, 1985 and USEPA, 1994a) which were based on fewer data. However, the EPA SAB panel was not able to reach consensus on a single value for a dioxin potency factor. The SAB panel cited differences of opinion on the adequacy of data and modeling approaches and assumptions as their reasons for not reaching consensus on a dioxin cancer slope factor.

The revised Round Two land application risk assessment uses the cancer slope factor currently used by EPA in risk assessments (USEPA, 1994a). If EPA adopts a different cancer slope factor for assessing the risk of cancer from dioxin prior to taking final action on the proposed Round Two rule, EPA will evaluate the risk of cancer from land-applied sewage sludge using any such revised cancer slope factor. Similarly, to the extent EPA adopts a policy regarding risks of non-cancer health effects from dioxin prior to the final decision on the proposed Round Two rule, the Agency will evaluate non-cancer effects associated with dioxins in land-applied sewage sludge using any such policy.

In order to give the public an opportunity to understand and comment on how the particular approaches contained in the Draft Dioxin Reassessment could potentially affect the proposed Round Two rulemaking, EPA is presenting a discussion of the potential impacts of the revised cancer slope factor and approaches for estimating non-cancer effects contained in the Draft Dioxin Reassessment on EPA's revised land application risk assessment. This includes a discussion of background exposures and risks based on information in the Draft Dioxin Reassessment, such as existing body burden, although EPA has not made a final decision regarding these findings or adopted any policy with respect to regulating dioxins in light of background exposures and existing body burden.

A. How Would the Dioxin Cancer Risk from Land Application Compare to Background Dioxin Cancer Risk?

Dioxin and dioxin-like compounds always exist in nature as complex mixtures. These compounds can be quantified in environmental media and their potential effects assessed as a mixture. As previously noted, the contribution of the other ''dioxin-like'' compounds is quantified by treating each as having a defined ''toxicity equivalence'' to dioxin (toxicity equivalent factor, TEF). The TEQ concentration is calculated by multiplying the concentration of each congener in the sewage sludge by its corresponding TEF, and then summing the resulting products from this calculation for all 29 congeners.

The significance of the incremental exposure and risk due to a specific source such as land application of sewage sludge is best understood by discussing it in the context of general population background exposure to dioxins. The fact that background exposures and body burden of dioxins are currently high for the general population means that any incremental exposure from a particular source needs to be considered in context of its contribution to overall risk. The following is a comparison of the dioxin cancer risk the EPA calculated from the Agency's revised risk assessment to the background dioxin cancer risk estimated from the Agency's 2000 Draft Dioxin Reassessment. This comparison considers both the current cancer slope factor the Agency has been using since 1985 and the revised cancer slope factor contained in EPA's 2000 Draft Dioxin Reassessment.

The revised risk assessment for land application of sewage sludge uses the current cancer slope factor of 1.56×10^{-4}/pg TEQ/kg–d. The estimated upper bound lifetime risks for highly exposed farm family adults using this cancer slope factor range from 4×10^{-5} at the 99th percentile to 1×10^{-6} at the 50th percentile for multi-pathway exposure to dioxins through land-applied sewage sludge (see Table 5). As indicated in Table 5, the estimated risks for children are less than or equal to the estimated risks for adults. These risks correspond to an estimated daily exposures (adult) ranging from 0.3 pg TEQ/kg–d at the 99th percentile to 0.006 pg TEQ/kg–d at the 50th percentile. Use of the 1×10^{-3}/pg TEQ/kg–d cancer slope factor being considered in the 2000 Draft Dioxin Reassessment would result in estimated high-end multi-pathway lifetime risks for highly exposed farm family adults ranging from 2.4×10^{-4} at the 99th percentile to 6×10^{-6} at the 50th percentile (see Table 7, below). These estimated risks using a 1×10^{-3}/pg TEQ/kg–d cancer slope factor are based on the same daily exposures indicated in Table 5. Again, the estimated risks for children would be less than or equal to the estimated risks for adults (see table 7).

TABLE 7.—RISKS FOR HIGHLY EXPOSED FARM ADULT AND CHILD FOR ALL EXPOSURE PATHWAYS—($Q^*=1 \times 10^{-3}$ PG TEQ/kg=d)

Percentile	Adult *	Child **
50th	6×10^{-6}	6×10^{-6}
75th	2×10^{-5}	2×10^{-5}
90th	6×10^{-5}	4×10^{-5}
95th	1×10^{-4}	6×10^{-5}
99th	2×10^{-4}	1×10^{-4}

* Initial exposure begins when the individual is an adult.

** Initial exposure begins when the individual is a child.

For this comparison EPA considered ''background risk'' to be the upper bound risk for the general population. Using the current cancer slope factor of 1.56×10^{-4}/pg TEQ/kg–d and current body burden and exposure levels, the background risk for the general population is estimated to be approximately 1×10^{-4}. By comparison, EPA's 2000 Draft Dioxin Reassessment estimates that the upper bound risk for the general population exceeds 1×10^{-3} using a revised cancer slope factor of 1×10^{-3}/pg TEQ/kg–d. Note that actual risks for individuals are a function primarily of dietary habits and could be higher or lower. Thus, high-end incremental risk estimates for highly exposed farm families from land application of sewage sludge are approximately an order of magnitude (i.e., ten times) lower than background risks for the general population.

These risk calculations are a function of dioxin TEQ dietary intake. Adult daily intakes of dioxins, furans and coplanar PCBs are estimated to average 65 picograms toxic equivalents per day (pg TEQ/day) from all sources for the general population. By comparison, land application of sewage sludge results in an estimated incremental intake for a highly exposed adult farmer of 0.45 pg TEQ/day at the 50th percentile of exposure; 1.7 pg TEQ/day at the 75th percentile; 4.5 pg TEQ/day at the 90th percentile; 9.1 pg TEQ/day at the 95th percentile; and 19.6 pg TEQ/day at the 99th percentile. These estimates of total intake of dioxin for highly exposed adult farmers are calculated by multiplying the estimated daily exposures from land application of sewage sludge (in pg TEQ/kg–d; see Table 5) by an assumed adult body weight of 70 kg.

B. How Would the Non-Cancer Dioxin Risk from Land Application Compare to Background Non-Cancer Dioxin Risk?

EPA traditionally uses a ''reference dose'' (RfD) for evaluating the potential for non-cancer effects for an incremental exposure that results from a specific source of contamination. The RfD is an estimate of a daily oral exposure to the human population that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime. RfDs for a particular contaminant are a useful health benchmark when background exposures are low or nonexistent. Background exposures for dioxin-like compounds have been quantified by EPA as being in the range of 1 pg TEQ/kg body weight-day for adults. On a body burden basis, the background exposure for adults in the United States has been quantified at 5 ng TEQ/kg whole weight basis (USEPA, 2000a. See Part I, Vol. 3, Chap. 4.). The Draft Dioxin Reassessment concluded that traditional approaches for setting an RfD would result in an RfD for dioxin TEQs that is likely to be substantially below current background intakes. For this reason, EPA believes that establishment of an RfD that is below typical background exposures is uninformative in judging the significance of incremental exposures. Consequently, EPA has not developed an RfD in the Draft Dioxin Reassessment (USEPA, 2000a. See Part III, Chap. 6.)

Instead, the Draft Dioxin Reassessment promotes the concept of evaluating an incremental percentage increase over background approach for assessing potential non-cancer risk. There are two approaches to evaluating the incremental percent increase. One is based on dose or intake, and the second is based on body burden. The Draft Dioxin Reassessment states that body burden, rather than daily dose, is a more appropriate metric for quantifying risks of cancer as well as non-cancer health effects. For long-term exposures to a steady dose (i.e., 15–20 years or more), dose and body burden are correlated since the body burden will tend to approach a steady state with long term steady exposures. However, a short term change in dose will not result in the same relative change in body burden. For example, a short term elevated exposure to dioxin, say an exposure ten times higher on average for one year, will not result in a proportional increase in body burden, a ten-fold increase in body burden in this example. However, over long periods of time, 20 years or more for example, a ten-fold increase in an average dose will result in a ten-fold increase in body burden.

High-end incremental dioxin body burdens to the modeled highly exposed farm population associated with land application of sewage sludge are estimated to be 0.019 ng TEQ/kg body weight at the 50th percentile of exposure, 0.072 ng TEQ/kg body weight at the 75th percentile of exposure, 0.19 ng TEQ/kg body weight at the 90th percentile of exposure, 0.39 ng TEQ/kg body weight at the 95th percentile of exposure, and 0.84 ng TEQ/kg body weight at the 99th percentile of exposure (Lorber 2002). These body burden estimates are based on the estimated daily exposure from land application of sewage sludge for highly exposed adult farmers (see Table 5) and an assumed exposure time of at least 20 years. As described in the Draft Dioxin Reassessment, the general population body burden spans a range of younger to older adults. Evidence clearly indicates that older individuals have body burdens that are higher than younger individuals, mainly because of much higher exposures in past decades. The average body burden of younger adults is more likely to be approximately 3 ng TEQ/kg body weight, while the body burden of older adults would be higher than the overall population average of 5 ng TEQ/kg body weight. Women of childbearing age, a population of concern, would more likely have body burdens in the range of 3 ng TEQ/kg body weight. (USEPA, 2000a. See Part I, Vol. 3, Chap. 6.). Using this background body burden and the high-end incremental exposures associated with land application of sewage sludge, the percentage increases in body burdens of dioxins for highly exposed adult farmers from land application of sewage sludge are estimated to be 0.6 percent at the 50th percentile of this modeled population, 2 percent at the 75th percentile, 6 percent at the 90th percentile,13 percent at the 95th percentile and 28 percent at the 99th percentile.

VIII. What Is EPA's Assessment of Effects on Ecological Species?

A. What Approach Did EPA Use for the Screening Ecological Risk Analysis of Dioxins in Land-Applied Sewage Sludge?

In response to public and peer review comments EPA performed a screening ecological risk analysis (SERA) since the December 1999 Round Two proposal. The SERA uses a two-phased approach that includes (1) an initial bounding estimate to assess the upper bound potential for ecological effects at a high-end of exposure and (2) a deterministic assessment focused on representative ecological receptors.

The risk measurement chosen for this SERA is the hazard quotient (HQ), the ratio of the exposure (in dose or concentration) to an ecological benchmark. Media concentrations (e.g., sediment, soil) from the human health risk assessment modeling simulations were used to predict exposure doses, and HQs were calculated on a dioxin TEQ basis. Calculation of HQs has a binary outcome: either the chemical concentration (or dose) is below the protective ecological benchmark (HQ<1), or it is equal to or greater than the benchmark (HQ≥1). Given the assumptions and data inputs for each stage, the HQ results are presumed to progress from highly uncertain and highly conservative in the first phase to somewhat less conservative and more certain in the second phase.

Screening-level ecological risk assessments are designed to provide, for those chemicals and receptors that pass the screen, a high level of confidence that there is a low probability of adverse effects to ecological receptors (U.S. EPA, 2001c). The SERA was not designed or intended to provide definitive estimates of risk; rather, the SERA provides insight into the potential for ecological risk. The SERA was designed to be consistent with EPA's Guidelines for Ecological Risk Assessment (USEPA, 1998b).

B. How Did EPA Conduct the Screening Ecological Risk Analysis?

The screening ecological risk analysis addresses the 29 dioxin congeners modeled in ''Exposure Analysis for Dioxins, Dibenzofurans, and Coplanar Polychlorinated Biphenyls in Sewage Sludge'' (USEPA, 2002b) and was based on media concentrations generated in that assessment.

The analysis phase of the SERA began with a highly conservative approach to determine whether any of the habitats, receptor categories, and exposure routes might be of concern. The second phase consisted of more refined deterministic analyses based on somewhat more representative exposure scenarios. Both phases predicted exposure doses and compared those estimates to ecological benchmarks (i.e., the HQ). HQs greater than 1 in the first phase analysis indicated that a more refined analysis was needed to determine whether ecological effects are expected.

The exposure estimates were derived from modeled media concentrations generated in the human health risk assessment (USEPA, 2002b). For the SERA, annual soil, sediment, and surface water concentrations were used as the basis for estimating exposure in all phases of the analysis. Thus, the SERA inherently assumes a one-year exposure duration for ecological receptors. The model calculates average annual exposures. We use these values as high end representations of exposures over the lifetimes of the evaluated receptors.

Table 8 compares the values and assumptions used in each phase of the analysis.

TABLE 8.—VALUES AND ASSUMPTIONS FOR THE SCREENING ECOLOGICAL RISK ANALYSIS

Parameter	Phase 1—High end exposures	Phase 2—deterministic exposures
Cogeners addressed	All	All.
Receptors	Four highly exposed mammals and birds	35 representative mammals and birds.
Dietary composition	Diets reflecting maximum exposure	Representative diets.
Biouptake factors	Fixed values.	Fixed values

TABLE 8.—VALUES AND ASSUMPTIONS FOR THE SCREENING ECOLOGICAL RISK ANALYSIS—Continued

Parameter	Phase 1—High end exposures	Phase 2—deterministic exposures
Percent of diet taken from contaminated area	100%	100%.
Ecological benchmarks	NOAELs	Maximum allowable toxicant level, calculated as the geometric means of the NOAELs and LOAELs.
Media concentrations used to estimate exposure.	50th and 90th percentiles and maximum for sewage sludge.	90th percentile for modeled concentrations in environmental media.

The exposure scenarios considered in the SERA include the agricultural application of sewage sludge in crop fields and pastures, silvicultural application, and application to reclaimed lands. However, only the agricultural application in crop fields and pastures was assessed quantitatively; the other scenarios were addressed qualitatively through comparison with agricultural application. For agricultural application, the SERA addressed two types of habitats. The first habitat consisted of receptors feeding and foraging in the agricultural fields where sewage sludge is applied (i.e., terrestrial habitat). These receptors are terrestrial vertebrates that eat the crops and pasture vegetation (e.g., the white-tailed deer), or that eat small birds and mammals that live and feed in the fields (e.g., the red fox). In addition, the agricultural field includes soil invertebrates that are exposed through direct contact with the land-applied sewage sludge.

The second type of habitat consisted of receptors exposed through living in or feeding from nearby surface water bodies that receive dioxin loads through runoff (i.e., waterbody margin habitat). Aquatic species, such as fish and aquatic invertebrates, were assumed to be exposed through direct contact with dioxins in water and sediment and through ingesting sediment and aquatic prey items. Terrestrial species, such as the raccoon or the osprey, were assumed to be exposed when they eat aquatic prey, such as fish, mussels, and snails from contaminated water bodies.

Exposure in both of these habitat types was based on the common characteristics of terrestrial and waterbody margin habitats, respectively. Exposure in waterbody margin habitats is influenced by variables such as water body size, position in the landscape, water flow rate, bed sediment composition, periodicity of flood events, and the presence of aquatic vegetation. Exposure in terrestrial systems is dependent upon many important factors such as regional location, vegetative cover type, wildlife community structure, and adequacy of food sources. While the generalized representative habitats are a simplification of exposure scenarios, they capture the basic elements characteristic of most terrestrial and waterbody margin habitats. The use of generalized terrestrial and waterbody margin habitats provided a screening-level context for this analysis.

Given the generalized habitat types for the SERA, the exposed ecological species were selected based on the following criteria: (1) Represent all trophic levels and relevant feeding guilds (e.g., herbivores, carnivores), (2) represent receptors with the potential to be highly exposed to dioxins in land-applied sewage sludge, and (3) include receptors with as wide a geographic distribution as possible, avoiding local receptors or those with narrow ecological niches because sewage sludge is land applied throughout the United States. Since adequate data were identified only for mammals and birds, assessment endpoints (i.e., HQs) were quantitatively screened only for these wildlife species populations.

The most significant pathway for vertebrate exposures to dioxins (e.g., mammals, birds, amphibians) is ingestion, and exposure/risk are expressed in terms of ingestion dose. Ingestion risk estimates for terrestrial vertebrates reflect risk to an individual in a species population, and risk to a population of that species is inferred through the selection of endpoints relevant to population viability.

C. What Are the Results of the Screening Ecological Risk Analysis?

Each phase of the SERA was designed to provide insight into the potential for adverse ecological effects. Phase 1 was a high-end bounding analysis, and Phase 2 was a deterministic analysis based on somewhat more representative exposure parameters and somewhat less protective benchmarks. In the Phase 1 analysis, HQ values greater than 1 were calculated, indicating that a more refined analysis was needed.

For the Phase 2 analysis, no HQ values exceeded the target HQ of 1; values range from a minimum of 0.0035 (Canada goose) to a maximum value of 0.36 (short-tailed shrew). The median HQ for the receptors assigned to waterbody margin habitats was 0.015, and the median HQ for receptors assigned to terrestrial habitats was 0.044, indicating that the potential for effects on terrestrial receptors may be somewhat higher than for receptors in waterbody margin habitats. The results of the Phase 2 analysis are summarized below in Table 9.

TABLE 9.—PHASE 2 RESULTS FOR SCREENING ECOLOGICAL RISK ANALYSIS

Species	HQ: Terrestrial habitats	HQ: Waterbody margin habitats
American kestrel	3.5E–02	not assigned.
American robin	1.2E–02	not assigned.
American woodcock	1.8E–01	not assigned.
Bald eagle	not assigned	2.8E–03.
Beaver	not assigned	2.5E–02.
Belted kingfisher	not assigned	9.0E–03.
Black bear	8.1E–02	not assigned.
Canada goose	3.5E–03	not assigned.
Cooper's hawk	2.9E–02	not assigned.
Coyote	2.2E–01	not assigned.
Deer mouse	3.0E–01	not assigned.

TABLE 9.—PHASE 2 RESULTS FOR SCREENING ECOLOGICAL RISK ANALYSIS—Continued

Species	HQ: Terrestrial habitats	HQ: Waterbody margin habitats
Eastern cottontail rabbit	4.4E–02	not assigned.
Great blue heron	not assigned	3.5E–03.
Green heron	not assigned	6.3E–03.
Herring gull	not assigned	8.8E–03.
Least weasel	1.6E–01	not assigned.
Lesser scaup	not assigned	2.1E–02.
Little brown bat	6.2E–02	not assigned.
Long-tailed weasel	2.2E–01	not assigned.
Mallard	not assigned	1.0E–02.
Meadow vole	1.7E–02	not assigned.
Mink	not assigned	2.3E–02.
Muskrat	not assigned	8.1E–02.
Northern bobwhite	1.3E–02	not assigned.
Osprey	not assigned	3.6E–03.
Prairie vole	2.3E–02	not assigned.
Raccoon	4.4E–02	1.3E–01.
Red fox	1.7E–01	not assigned.
Red-tailed hawk	1.9E–02	not assigned.
River otter	not assigned	2.6E–02.
Short-tailed shrew	3.6E–01	not assigned.
Short-tailed weasel	1.8E–01	not assigned.
Tree swallow	2.8E–02	not assigned.
Western meadowlark	1.7E–02	not assigned.
White-tailed deer	6.1E–02	not assigned.

As noted above sewage sludge application to reclaimed lands and silvicultural application of sewage sludge were addressed qualitatively through comparison with agricultural application. In general, reclamation and silviculture applications of sewage sludge are not well characterized. Reclamation applications can consist of spreading sewage sludge on reformed land surfaces as an amendment to support re-vegetation or as fill material deposited in excavations. In the former case, some tilling may occur with landscaping operations; for the latter case, tilling is unlikely. In either case, the dioxins would be expected to bind to soil particles and to display fate and transport behavior similar to that in agricultural fields. While the application rates and frequency are not necessarily comparable, ecological exposures are likely to occur in a manner similar to that for agricultural fields. Terrestrial vertebrates feeding at reclaimed sites would generally be similar to those in an agricultural setting. Receptors and pathways of exposure through aquatic systems would also be expected to be similar to those modeled in the SERA.

For silvicultural application of sewage sludge, EPA assumed that sewage sludge is land-applied once per site. Tilling is less likely to occur except in reforestation projects where site preparation for new plantings could include tilling of sewage sludge into the soil. Many of the avian and mammalian species considered in the agricultural analysis for the field habitat are also expected to feed and forage in forests and, therefore, the screening results for field habitats are considered relevant to the forest habitats. Although there are forest species that are not represented in the agricultural scenario, the major trophic elements are substantially represented. For these reasons, EPA believes that the results of the SERA also provide a useful indicator for the potential for adverse ecological effects at reclamation and silvicultural sites.

Finally, EPA notes the following considerations that should be recognized due to the screening nature of this analysis:

- Because the screening methodology is based on the exceedance of a target HQ of 1, the outcome of the screen is binary: HQ < 1 or HQ ≥ 1. Although large exceedances suggest a greater potential for ecological damage, an HQ of 50 is not necessarily five times worse than an HQ of 10.
- The potential for adverse ecological effects (as indicated by an HQ exceedance) should not be confused with the ecological significance of those effects. Regardless of the magnitude of an HQ exceedance, screening results can only suggest ecological damage; they do not demonstrate actual ecological effects, nor do they indicate whether those effects will have significant implications for ecosystems and their components.
- Ecological receptors for the screening methodology were chosen to represent relatively common species populations. Threatened and endangered species and/or habitats were not included in the analysis because a different type of spatial resolution would have been required (i.e., co-occurrence of threatened and endangered species/habitats with sewage sludge application sites). Consequently, the screening results do not indicate whether endangered species/habitats are at risk.

EPA requests comments on the methodology and data used for the screening ecological risk assessment. The Agency also requests comments on the results derived from the screening ecological risk analysis summarized above.

IX. How Might the New Data and Revised Risk Assessment Affect EPA's Proposed Dioxin Concentration Limit for Land-Applied Sewage Sludge and the Proposed Monitoring Requirements?

A. Possible Implications for Proposed Concentration Limit for Land-Applied Sewage Sludge

As indicated above, the revised risk assessment (probabilistic) for land application of sewage sludge estimates that the high-end individual excess lifetime risk to the highly exposed modeled population using the current cancer slope factor could range from 2×10^{-5} to 1×10^{-6} (''two in one-hundred thousand'' to ''one in one million'') for exposure by multiple pathways. Use of the cancer slope factor being considered in the 2000 Draft Dioxin Reassessment would result in estimated high-end multi-pathway lifetime cancer risks ranging from 1.2×10^{-4} to 6×10^{-6} for this same highly exposed modeled population. By comparison, the risk assessment for the December 1999 proposal (which used a deterministic methodology and a number of different assumptions; see Section VI.D. of this Notice), estimated a high-end cancer risk of 1.7×10^{-5} (USEPA, 1999b). As noted in the December 1999 proposal, the Agency considers risks in the range of 1×10^{-6} to 1×10^{-4} (''one in one million'' to ''one in ten thousand'') to be acceptable levels of risk. The revised high-end risk estimates continue to fall within this range of acceptable risks. The revised risk assessment also shows no measurable change in risk from requiring all sewage sludge to meet a 300 ppt TEQ limit.

B. Effect on Proposed Monitoring Requirements

In the December 1999 proposal, the Agency proposed two alternative monitoring schedules based on the level of dioxins in sewage sludge to be land applied. Specifically, treatment works and other sewage sludge preparers that measure the level of dioxin in their sewage sludge to be between 300 ppt TEQ and 30 ppt TEQ would be required to monitor annually. Treatment works and sewage sludge preparers that measure dioxin levels of 30 ppt TEQ or less for two consecutive years would be required to monitor every five years thereafter. The proposed monitoring schedule was based on the Agency's assumption that the level of dioxins in sewage sludge, both nationally and from specific sources, is relatively constant over time and may be decreasing. The Agency noted that since the concentration of 30 ppt TEQ which would allow less frequent monitoring is a full order of magnitude less than the proposed numeric standard of 300 ppt TEQ (i.e., one-tenth), the chances that such a sewage sludge would exceed the limit are small. Furthermore, the Agency noted that any health risks associated with dioxin exposure from land application of sewage sludge at these levels would require long-term exposure (i.e., significantly greater than five years) to potentially present unreasonable health risks.

As noted in Section V.H. of this Notice, the EPA 2001 dioxin update survey indicates that dioxin levels in sewage sludge appear to have decreased from 1988 to 2001. The new data also indicate that for most POTWs, dioxin levels appear to not fluctuate greatly over time. However, the sewage sludge samples which had the highest levels of dioxins in either the 1988 NSSS or 2001 EPA update survey appeared to evidence greater fluctuations in dioxin concentrations than the other sewage sludges. As also previously noted, the data for facilities where monthly data were available indicate that dioxin concentrations tend to corroborate these observations from the EPA 2001 dioxin update survey. The data for the facilities where monthly data were available indicate that the dioxin concentrations are relatively consistent over time on a month-to-month basis, but the variability appeared the greatest for the facility with the highest dioxin concentrations measured in its sewage sludge (see Section V.K.).

The Agency continues to believe that if it sets a dioxin limit of 300 ppt TEQ, this two-tier monitoring schedule in line with the December 1999 proposal may be appropriate. For facilities where longer term monitoring data was available, the maximum monthly concentration of dioxin was within a factor of two to four times the average concentration for that facility. By comparison, the proposed monitoring schedule would allow reduced monitoring frequency only when two consecutive measurements were a factor of ten less than the specified limit. Furthermore, no POTWs in the EPA 2001 dioxin update survey had consistently high levels of dioxins in their sewage sludge; and the revised risk assessment predicts that even long term exposure to dioxins in land-applied sewage sludge would result in negligible increases in risk.

Based on the data from the EPA 2001 dioxin update survey, approximately 31 percent of POTWs produce sewage sludge with dioxin levels between 30 ppt TEQ and 300 ppt TEQ (USEPA, 2002a). These POTWs would be required to monitor annually for dioxin under the proposed monitoring schedule if their sewage sludge is land applied. (By comparison, approximately 61 percent of POTWs previously were estimated to produce sewage sludge with dioxin levels between 30 ppt TEQ and 300 ppt TEQ based on the data available to EPA at the time of the December 1999 proposal (USEPA, 1999d).)

The costs associated with monitoring for dioxin annually at facilities with sewage sludge concentrations between 30 ppt TEQ and 300 ppt TEQ previously was estimated to be $1,224,000 based on the sewage sludge dioxin data available to EPA at the time of the December 1999 proposal (USEPA, 1999d). EPA now estimates the costs associated with monitoring for dioxin annually at facilities with sewage sludge dioxin concentrations between 30 ppt TEQ and 300 ppt TEQ would be approximately $656,000 (USEPA, 2002d).

Based on the new data, EPA is considering whether alternatives to the proposed monitoring scheme would be more appropriate. Because the data continue to show periodic ''spikes,'' and the data indicates that these higher levels of dioxin may not remain for long periods of time, a different monitoring schedule may be indicated. Similarly, the data indicates that sewage sludge with lower levels of dioxins may not fluctuate as greatly, which may indicate a different threshold or monitoring frequency than those proposed. For example, monitoring every two years rather than annually; or at some other interval may be more appropriate.

The percentage of land-applied sewage sludge which would have to be monitored annually would be reduced if the threshold for annual dioxin monitoring was set at a higher concentration than 30 ppt TEQ. Likewise, the percentage of land-applied sewage sludge which would have to be monitored annually would be greater if the threshold for annual dioxin monitoring was set at a lower concentration than 30 ppt TEQ. As an example, 13 percent of POTWs produce sewage sludge between 50 ppt TEQ and 300 ppt TEQ based on data from the EPA 2001 dioxin update survey (USEPA, 2002a). This compares to 31 percent of POTWs with sewage sludge dioxin concentrations between 30 ppt TEQ and 300 ppt TEQ, as noted above.

The Agency requests comments on the proposed monitoring schedule and the threshold concentration of dioxin that would allow for more or less frequent monitoring. Specifically, EPA requests comments on whether other schedules which would require more or less frequent monitoring would be more appropriate. EPA also requests comment on whether a monitoring requirement in lieu of a numeric limit should be considered.

X. How Might the New Data and Revised Risk Assessment Affect EPA's Proposal for Small Entities?

EPA proposed to exclude from the proposed land application requirements relating to dioxins, sewage treatment works with a wastewater flow of *one* MGD or less and sewage sludge-only entities which prepare 290 dry metric tons or less of sewage sludge annually for land application. (EPA estimates that a one MGD treatment works produces approximately 290 dry metric tons of sewage sludge annually.) Sewage sludge from these small preparers would be excluded from the limitation on dioxins in sewage sludge. Such preparers could continue to land apply their sewage sludge with no further restriction due to the sewage sludge's dioxin content.

The December 1999 proposal indicated that EPA believes that this exclusion is appropriate for several reasons. First, less than eight percent of the total sewage sludge that is land applied is produced by sewage treatment works with flow rates of one MGD or less (USEPA, 1990). Second, the probability that this small amount of sewage sludge (i.e., 42 dry metric tons per facility annually, which is the average amount of sewage sludge produced by POTWs less than one MGD) could unreasonably increase health risks for any individual is extremely small. EPA specifically requested comment on the Agency's proposal to exclude small preparers from any requirements relating to dioxins in sewage sludge to be land applied.

The new data that EPA collected on the levels of dioxins found in sewage sludge (USEPA, 2002a) and the revised land application risk assessment (USEPA, 2002b), provide additional information which the Agency believes supports the proposal to exclude sewage treatment works with a wastewater flow of one MGD or less and sewage sludge-only entities which prepare 290 dry metric tons or less of sewage sludge annually for land application.

The levels of dioxins in sewage sludge from treatment works with a wastewater flow of one MGD or less was measurably less than the levels of dioxins in sewage sludge from facilities with a wastewater flow greater than one MGD (USEPA, 2002a). The highest observed level of dioxins from treatment works with a wastewater flow of one MGD or less was 78.6 ppt TEQ. This compares to the highest observed value of 718 ppt TEQ for dioxins for facilities with a wastewater flow greater than one MGD. The average (mean) and 95th percentile values dioxins for treatment works with a wastewater flow of one MGD or less also were measurably less compared to treatment works with flows greater than one MGD: 26.5 ppt TEQ and 67.1 ppt TEQ, respectively for treatment works with a wastewater flow of one MGD or less compared to 44.1 ppt TEQ and 94.8 ppt TEQ, respectively for treatment works with a wastewater flow greater than one MGD.

The revised risk assessment methodology does not allow EPA to make a separate risk estimate for treatment works with wastewater flows of one MGD or less because, other than the dioxin levels in sewage sludge discussed above, there are no relevant factors considered in the risk assessment which vary specifically based on the capacity of the treatment works . However, the Agency believes the revised risk assessment provides further indication that the minimal amounts of sewage sludge from treatment works with wastewater flows of one MGD or less would be very unlikely to produce an unreasonable increase in health risks for any individual.

The revised risk assessment estimates that the high-end incremental adult lifetime risk for highly exposed farm families associated with dioxins in land-applied sewage sludge ranges from 4 x 10^{-5} at the 99th percentile to 1 x 10^{-6} at the 50th percentile, which equates to less than 0.006 cancer cases annually. The key variable in this risk estimate that can be related to treatment facility size is the distribution of farm sizes to which the sewage sludge is land-applied. The revised risk assessment used a distribution of median farm sizes for 41 meteorologic regions ranging from 24.2 acres to 1241.7 acres (USDA, 1997). For this distribution, the average farm size is 487 acres and the median farm sizes is 120 acres. By comparison, the average amount of sewage sludge produced by a treatment works with a wastewater flow of one MGD or less (i.e., 42 dry metric tons annually) would be applied to approximately 10 acres of farmland when applied at agronomic rates (i.e., 4 metric tons per acre annually). Thus, the acreage impacted by treatment works with a wastewater flows of one MGD is significantly less than that which would result in an estimated risk of 1 x 10^{-6}. On this basis, EPA believes that the amount of sewage sludge produced by treatment works with a wastewater flow of one MGD or less is not sufficient to result in an unreasonable risk to potentially exposed populations. Again, EPA specifically invites comment on the Agency's proposal to exclude small entities from any limit for dioxins in sewage sludge to be land applied.

XI. How Does the New Data and Revised Risk Assessment Affect EPA's Cost Estimates?

As noted in the December 1999 proposal, the increased costs which would be imposed by the proposed regulation are the costs for initially monitoring for dioxins by all land-applying treatment works greater than one MGD, annual monitoring at those facilities with dioxin levels between 30 ppt TEQ and 300 ppt TEQ, and switching to co-disposal with municipal solid waste for current land appliers whose sewage sludge contains over 300 ppt TEQ of dioxins. The Agency assumed that the cost of measuring dioxins in sewage sludge is $2,000 per sample and the cost to switch to co-disposal with municipal solid waste was $189 per dry metric ton in 1998 dollars. For the proposal, EPA estimated that the annualized cost of this regulation nationwide would be approximately $18 million. Of this amount, 13 percent was for monitoring, and the balance is for switching use or disposal practices (USEPA, 1999d).

EPA has updated these cost estimates (USEPA 2002d). The Agency assumes that the cost to switch to co-disposal with municipal solid waste has risen to $197 per dry metric ton in year 2000 and that the cost of measuring dioxins in sewage sludge remains at $2,000 per sample. On this basis, EPA now estimates that the annualized cost of this regulation Nationwide would be approximately $4.5 million if the dioxin limit for land application of sewage sludge is 300 ppt TEQ. The decrease in the estimated cost results from the smaller percentage of sewage sludge that would exceed a 300 ppt TEQ dioxin limit based on the data from the EPA 2001 dioxin update survey (i.e., 1% vs. 5%). The estimated benefits of a 300 ppt limit would be very low, since such a limit would not likely produce a detectable change in lifetime cancer risk, even to highly exposed farm families and using conservative assumptions, and no species in the SERA has a HQ above 1, even in the baseline with no limits.

XII. Identification and Control of Dioxin Sources that Contribute to Elevated Dioxin Levels in Sewage Sludge.

Both the EPA 2001 dioxin update survey and the 2001 AMSA Survey found a small percentage of sewage sludge samples with dioxin concentrations which were significantly higher than most of the other the sewage sludge samples in the survey. The EPA 2001 dioxin update survey found only 1 percent of the samples with a dioxin concentration greater than 100 ppt TEQ (compared to an average (mean) of 31.6 ppt TEQ). The AMSA 2001 survey found less than 5 percent of the samples analyzed in their survey with a dioxin concentration greater than 100 ppt TEQ (compared to an average (mean) of 48.6 ppt TEQ.)

Even though relatively few sewage sludge samples have elevated concentrations of dioxins, those that do can have levels which are much higher than the values typically observed. The highest dioxin concentration measured in the 2001 EPA and AMSA surveys were 718 ppt TEQ and 3,590 ppt TEQ, respectively. In addition, as discussed previously in this Section of today's notice, higher levels of dioxins in sewage sludge appear to be transient and may not be consistently identified. While the revised risk assessment shows no measurable change in the risk from eliminating these spikes to individuals exposed through land application of sewage sludge, the Agency believes it may be beneficial to develop a procedure to identify the sources contributing to higher levels of dioxins in sewage sludges. Relatively high levels of dioxin in sewage sludge may be an indication of sources in the treatment works' service area with even higher levels of dioxins.

The Agency is requesting comments on a methodology to assist communities in identifying sources of elevated dioxins in their sewage sludge. This methodology relies on two complementary elements to identify sources of dioxin: (1) Identification of sources known to be generators or sinks for dioxin (e.g., specific chemical manufacturing operations, combustion sources or contaminated landfills); and (2) comparison of the mix of the 29 dioxin congeners measured in a particular sewage sludge sample to the ''fingerprint'' of 29 dioxin congeners for known sources of dioxins. The methodology would be used by communities to reduce levels of dioxins in their sewage sludge by eliminating these sources of dioxins from the collection system or remediating contaminated sites.

The first element of this methodology is identification of local industrial, commercial and other sources with inputs to municipal sanitary sewers which have a potential to contain significant levels of dioxins. The primary database used to make these identifications would be the Agency's updated 2001–2002 Toxics Release Inventory. The Toxics Release Inventory is a valuable source of nationwide information regarding toxic chemicals that are being used, manufactured, treated, transported or released into the environment. Toxics Release Inventory data includes the local discharges of chemicals to sanitary sewers by industrial and commercial establishments. Other potential local sources of dioxins in sewage sludge include leachate from landfills, contaminated manufacturing and disposal sites, and scrubber water from combustion operations.

Identification of possible sources of dioxins in sewage sludge also will be aided by reviewing data available from local pretreatment programs and the results of detailed studies conducted in any communities which have attempted to identify sources of dioxins in their sewage sludge. Industry listings for local pretreatment programs will be reviewed to determine which are likely sources of elevated dioxins in sewage sludge. With respect to community-specific studies, EPA has received information which indicates that elevated concentrations of dioxins in the sewage sludge may be due to non-point source contamination. Non-point source contamination comes from erodible soils that contain elevated levels of dioxins and periodically enter either sanitary sewers as a result of infiltration during precipitation, or combined sewers through normal stormwater flows.

The second element of a methodology to identify sources which contribute to elevated dioxins in sewage sludge is to compare the mix of dioxin congeners in a particular sewage sludge to the mix of dioxin congeners in known sources of dioxins. Mixtures of the 29 congeners of dioxins have distinct patterns (profiles or ''fingerprints'') of relative proportions for each of the congener classes (i.e., dioxins, dibenzofurans and coplanar PCBs) depending on the source of dioxins. For example, dioxins produced by combustion have a different ''fingerprint'' than dioxins produced by chemical processes such as pulp and paper mill bleaching with chlorine or pentachlorophenol manufacturing. By examining these congener ''fingerprints'', it is possible to identify likely manufacturing, chemical or combustion processes that produced that particular profile. Dioxin congener profiles from the sewage sludge samples with elevated dioxin concentrations from the 2001 EPA and AMSA surveys will be compared against known dioxin profiles of samples from various manufacturing, chemical and combustion and chemical processes. These comparisons can be used in the source identification portion of the methodology described above.

EPA is inviting comments on this overall methodology to identify and reduce or eliminate sources of dioxins entering wastewater treatment plants that contribute to elevated levels of dioxins in sewage sludge. In particular, comments are invited on the two phase approach to identify these sources described above. Note that EPA is not proposing use of this methodology in a regulatory context, but rather developing it as a tool for use by POTWs and/or communities on a voluntary basis.

XIII. Request for Public Comments

While EPA is requesting comments on all of the information discussed in this Notice, the Agency hopes that public comments will also focus specifically on the following aspects of this Notice:

(1) The significance of the differences in dioxin concentrations in sewage sludge measured at facilities with wastewater flows greater than one MGD compared to dioxin concentrations in sewage sludge at facilities with wastewater flows less than one MGD (V.G.).

(2) The significance of the differences in dioxin concentrations in sewage sludge measured in the EPA 2001 dioxin update survey compared to dioxin concentrations in sewage sludge measured in the 1988 NSSS (V.H.).

(3) Choice of the highly exposed farm family as the modeled population for the revised risk assessment and the assumptions related to this choice of modeled population. (VI.D.).

(4) All of the assumptions related to exposure, fate and transport used in the revised risk assessment , including the specific assumptions related to the farming and grazing practices used by the modeled farm family (VI.D.),

(5) The treatment of non-detects in the revised risk assessment and the effect on estimating risk (VI.E.).

(6) The assumptions and values used to estimate how much dioxins are being transported to individuals in the modeled farm family (*e.g.,* the sources [store-bought versus farm-produced], types and dioxin contamination levels of poultry feeds.) (VI.F.)

(7) The methodology and data used for the screening ecological risk assessment (VIII.A. and VIII.B); and the results derived from the screening ecological risk analysis (VIII.C.).

(8) The significance of the finding that setting a 300 ppt TEQ limit would make no detectable difference in the risk of cancer to the highly exposed farm family.

(9) Taking no action with respect to regulating dioxins for land application (IX.).

(10) The proposed monitoring schedule and the threshold concentration of dioxin that would allow for less frequent monitoring, and specifically, on whether other schedules which would require more or less frequent monitoring would be more appropriate (IX.).

(11) Excluding small entities from the limit for dioxins in sewage sludge to be land applied (X.).

(12) A methodology to assist communities in voluntarily identifying and reducing or eliminating sources of dioxins entering wastewater treatment plants that contribute to elevated levels of dioxins in sewage sludge (XII.).

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