Federal Register

Friday,
October 24, 2003

Part III

Environmental Protection Agency

Standards for the Use or Disposal of Sewage Sludge: Decision Not To Regulate Dioxins in Land-Applied Sewage Sludge; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7577–9]

Standards for the Use or Disposal of Sewage Sludge: Decision Not To Regulate Dioxins in Land-Applied Sewage Sludge

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is giving final notice of its determination that neither numerical limitations nor requirements for management practices are currently needed to protect human health and the environment from reasonably anticipated adverse effects from dioxin and dioxin-like compounds in land-applied sewage sludge.

DATES: In accordance with 40 CFR 23.2, this final decision is promulgated for purposes of judicial review as of 1 p.m. Eastern Time on November 7, 2003. Under section 509(b)(1) of the Clean Water Act, judicial review of this final action can be obtained only by filing a petition for review in the United States Court of Appeals within 120 days after the final action is considered promulgated for purposes of judicial review.

FOR FURTHER INFORMATION CONTACT: Robert Cantilli, U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460 (202) 566–1091. *cantilli.robert@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Interested Entities

Entities typically regulated by Standards for the Use or Disposal of Sewage Sludge are those that prepare sewage sludge (also called ‘‘biosolids’’) and/or use or dispose of the sewage sludge through application to the land, placement in a surface disposal unit, or incineration in a sewage sludge incinerator. Entities potentially interested by today's notice include those that prepare and/or use sewage sludge for land-application purposes. Categories and entities interested in today's action include:

Category	Examples of affected entities
State/Local/Tribal Government	Publicly owned treatment works and other treatment works that treat domestic sewage, prepare sewage sludge, and/or apply sewage sludge to the land.
Federal Government	Federal Agencies with treatment works that treat domestic sewage, prepare sewage sludge, and/or apply sewage sludge to the land.
Farmers and ranchers	Individuals who apply sewage sludge to land.
Industry	Privately-owned treatment works that treat domestic sewage, and persons who receive sewage sludge and change the quality of the sewage sludge before it is applied to the land.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this action. This table lists the types of entities that EPA is now aware could potentially be interested in this action. Other types of entities not listed in the table could also be interested. To determine whether your facility is affected by this action, you should carefully examine today's notice. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW–2002–0019. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official docket is the collection of materials that are available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ‘‘Federal Register’’ listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ‘‘search,’’ then key in the appropriate docket identification number. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section B.1.

C. Table of Contents

I. Abbreviations and Acronyms Used

AMSA—Association of Metropolitan Sewerage Agencies
CFR—Code of Federal Regulations

CWA—Clean Water Act
DMT—dry metric tons
EFH—Exposure Factors Handbook
EMS—Environmental Management System
EPA—U.S. Environmental Protection Agency
HQ—hazard quotient
HEI—highly exposed individual
LADD—lifetime average daily dose
MGD—million gallons per day
NBP—National Biosolids Partnership
ng TEQ/kg—nanograms toxic equivalence per kilogram body weight
NODA—Notice of Data Availability
NSSS—National Sewage Sludge Survey
PCBs—polychlorinated biphenyls
PCDDs—polychlorinated dibenzo-p-dioxins
PCDFs—polychlorinated dibenzofurans
pg TEQ/day—picograms toxic equivalence per day
pg TEQ/kg-d—picograms toxic equivalence 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
TBD—Technical Background Document
TCDD—2,3,7,8-tetrachlorodibenzo-p-dioxin
TEF—toxicity equivalency factor
TEQ—toxic equivalence
WHO—World Health Organization

II. What Is the Legal History of the Standards for the Use or Disposal of Sewage Sludge?

EPA promulgated Standards for the Use or Disposal of Sewage Sludge (40 CFR part 503) under section 405(d) and (e) of the Clean Water Act (CWA), 33 U.S.C. 1345(d), (e), as amended by the Water Quality Act of 1987. In these amendments to section 405 of the CWA, Congress, for the first time, set forth a comprehensive program for reducing the potential environmental risks and maximizing the beneficial use of sewage sludge. As amended, section 405(d) of the CWA requires EPA to establish numerical limitations and management practices, when appropriate, that protect public health and the environment from the reasonably anticipated adverse effects of toxic pollutants in sewage sludge. Section 405(e) prohibits any person from disposing of sewage sludge from a publicly owned treatment works (POTWs) or other treatment works treating domestic sewage for any use except in compliance with regulations promulgated under section 405.

Section 405(d) calls for two rounds of sewage sludge regulations and sets deadlines for promulgation. In the first round, EPA was to establish numerical limits and management practices for those toxic pollutants which, based on ''available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the environment.'' CWA section 405(d)(2)(A). The second round is to address toxic pollutants not regulated in the first round ''which may adversely affect public health or the environment.'' CWA section 405(d)(2)(B).

EPA did not meet the timetable in section 405(d) for promulgating the first round of regulations, and a citizen's suit was filed to require EPA to fulfill this mandate, (*Gearhart* v. *Reilly,* Civ. No. 89–6266–HO (D. Ore.)). A consent decree was entered by the court in that case, establishing schedules for both rounds of sewage sludge rules. EPA promulgated the first rule, codified at 40 CFR part 503, in 1993 at 58 FR 9248 (February 19, 1993) (''Round One''). For the second round (''Round Two''), EPA identified 31 pollutants and pollutant categories not regulated in Round One that EPA was considering for regulation. In November 1995, EPA narrowed the original list of 31 pollutants to polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like coplanar polychlorinated biphenyls (PCBs) for the second round of rulemaking (USEPA, 1996). The consent decree required the Administrator to sign a notice for publication proposing Round Two regulations no later than December 15, 1999, and to sign a notice taking final action on the proposal no later than December 15, 2001.

On December 15, 1999, the Administrator signed a proposal to establish numerical limits for dioxins, dibenzofurans, and co-planar PCBs (''dioxins'') in sewage sludge that is applied to the land and proposed not to regulate dioxins in sewage sludge that is disposed of in a surface disposal unit or fired in a sewage sludge incinerator (December 23, 1999, 64 FR 72045). On December 15, 2001, the Administrator signed a final notice of EPA's determination that numerical limitations or management practices are not warranted for dioxins in sewage sludge that are disposed of in a surface disposal unit or incinerated in a sewage sludge incinerator (66 FR 66228). In that notice, EPA also announced that a final action on the Round Two proposal to amend the Standards for the Use or Disposal of Sewage Sludge for sewage sludge that is applied to the land would be published at a later date. The consent decree in Gearhart was amended to extend the deadline for final action on the land application Round Two rulemaking from the original date of December 15, 2001, to a new date of October 17, 2003.

On June 12, 2002, EPA published a Notice of Data Availability (NODA) containing new information relating to dioxins in land-applied sewage sludge and requested public comments (67 FR 40554). The NODA provided a revised cancer risk assessment for dioxins in land-applied sewage sludge, newly collected data regarding concentration of dioxins in sewage sludge, and a new ecological screening risk analysis and solicited public comments.

III. What Did EPA Propose for Dioxins in Land-Applied Sewage Sludge?

A. Proposed Rule

EPA proposed a numeric limitation of 300 part per trillion (ppt) for ''dioxins'' measured as toxic equivalence (TEQ) in land-applied sewage sludge, and related monitoring, record-keeping and reporting requirements. EPA proposed a definition of ''dioxins'' to mean 29 specific congeners of PCDDs, PCDFs, and coplanar PCBs that have been found in sewage sludge. The proposed definition of ''dioxins'' specified seven 2,3,7,8-substituted congeners of PCDDs, ten 2,3,7,8-substituted congeners of PCDFs, and twelve coplanar PCB congeners.

The December 1999 proposal included a monitoring schedule for dioxins in land-applied sewage sludge that would have required wastewater treatment plants to monitor for dioxins in their sewage sludge for two consecutive years. EPA also proposed a modified frequency of monitoring based on analytical results from the first two years of monitoring.

EPA also proposed to exclude from the proposed numeric limit and monitoring requirements those treatment works having 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 proposed 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.

EPA's proposal was based on a deterministic risk assessment and data regarding dioxins in sewage sludge collected in the 1988–1989 National Sewage Sludge Survey (NSSS). See 64 FR 72045, 72048–72051 (December 23, 1999) and the National Sewage Sludge Survey (USEPA, 1990) for a full discussion of the proposed rule and supporting documentation.

In addition, unrelated to dioxins in sewage sludge, EPA proposed technical amendments to the frequency of monitoring requirements for pollutants other than dioxins. 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. Notice of Data Availability (NODA)

Based on comments critical of both the proposal's use of a deterministic risk assessment and its use of more than decade-old data on dioxins concentrations in sewage sludge, in 2001 EPA collected and analyzed samples of sewage sludge nationwide in order to obtain new information on the levels of dioxins in sewage sludge. EPA also substantially revised the cancer risk assessment for dioxins associated with land application of sewage sludge. EPA used new dioxins concentration data in the revised risk assessment and conducted statistical analyses to better understand the fluctuation of dioxins concentrations in sewage sludge samples over time. In the NODA, EPA summarized the new sewage sludge data, the revised risk assessment, and presented an approach to assess potential non-cancer health effects of exposure to dioxins associated with land application of sewage sludge. EPA also presented a screening ecological risk analysis (SERA) of the effects of dioxins in land-applied sewage sludge on ecological species. EPA requested comments on the new data and risk analyses, additional dioxins exposure information, and comments on any impact the data and information might have on the 1999 proposed rule with respect to land application of sewage sludge. EPA also requested comment on whether monitoring requirements to measure dioxins in land-applied sewage sludge should be promulgated in lieu of a numerical limitation.

In the NODA, EPA also presented information from EPA's draft dioxin reassessment document, Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. EPA described implications of the draft dioxin reassessment for the final determination regarding regulation of dioxins in land-applied sewage sludge and requested public comment. EPA included this information in the NODA in order to be in a position to fulfill its obligations under the *Gearhart* v. *Whitman* consent decree. The consent decree requires EPA to take final action on or before October 17, 2003, regardless of whether EPA issues a final dioxin reassessment document, with some schedule adjustment allowed depending on the timing of EPA's issuance of a final dioxin reassessment document prior to October 17, 2003. EPA has not issued a final dioxin reassessment document; thus, the October 17, 2003 deadline applies. Regarding the draft dioxin reassessment documents discussed in the NODA, EPA has continued to revise these documents, and the science continues to be under review. Review by the National Academy of Sciences is the next review to be undertaken, as specified by Congress in the Conference Report accompanying EPA's fiscal year 2003 appropriation. H.R. Conf. Rep. No. 108–10, at 1445–46 (2003).

IV. What Final Action Is EPA Taking Today?

EPA has determined that no further regulation of land-applied sewage sludge is needed to protect public health and the environment from reasonably anticipated adverse effects from exposure to dioxins in land-applied sewage sludge. Therefore, no numeric limitations, monitoring, operational standards, or management practices are being established in 40 CFR part 503 for dioxins in land-applied sewage sludge.

While monitoring data could be useful to a local community to discover whether a significant increase is occurring in the dioxin concentration and assist in identifying the source of any such significant increase (see later discussion), the data indicate that such increases are short-term in nature, and the risk assessment showing low risk to the HEI takes these spikes into account. Therefore, EPA has determined that monitoring in lieu of a numerical limit is not warranted.

With respect to revisions to the existing requirements pertaining to frequency of monitoring of pollutants other than dioxins in land-applied sewage sludge, EPA is not taking final action at this time. Therefore, any comments on the proposed amendment to the footnote to Table 1 in 40 CFR 503.16 are not being addressed today. EPA may take final action on this proposed amendment in a subsequent rulemaking.

V. What Is the Basis for This Final Action for Dioxins in Land-Applied Sewage Sludge?

A. Overview

Sewage sludge is a residual mixture of solids and water as a result of wastewater treatment. Generally, sewage sludge consists of 2 to 28 percent solids in a water matrix. The solids component of sewage sludge typically contains microbial residue, microbes and trace quantities of chemicals such as metals and organic compounds, including dioxin and dioxin-like compounds. In the United States, approximately 8 million dry metric tons (DMT) of sewage sludge are produced annually by 16,000 wastewater treatment plants. Approximately 54 percent (4.32 million DMT) are applied to land to fertilize and condition soils; 28 percent (2.24 million DMT) are disposed of at municipal solid waste landfills; 17 percent (1.36 million DMT) are incinerated; and 1 percent (0.08 million DMT) is disposed of in lagoons or sewage sludge-only landfills. Of the total amount land-applied, an estimated 85 percent (3.7 million DMT) are applied to agricultural lands used to raise crops for human or animal consumption. Sewage sludge is applied to some 0.1 percent of available agricultural land in the United States. Other land application sites include forests, reclamation sites such as strip mines, and public-contact sites, such as parks, golf courses, highway median strips, and lawns.

EPA has decided not to regulate dioxins in land-applied sewage sludge because EPA considers the predicted risks to human health and the environment from dioxin and dioxin-like compounds in land-applied sewage sludge to be low. Based on recently collected data and assessment of risk, EPA has concluded that the existing regulation of sewage sludge in 40 CFR part 503 is adequate to protect human health and the environment from the reasonably anticipated adverse effects of dioxins in land-applied sewage sludge.

Risk is determined based on both toxicity and exposure. Regarding toxicity, dioxins have been shown to elicit both cancer and a variety of non-cancer effects in animals, and there is strong evidence to indicate that humans are susceptible to the same toxic effects. Although dioxins are found in extremely small quantities in water and soil, they persist in the environment and accumulate in the food chain. However, regarding exposure, EPA's evaluation of the effects on human health due to exposure to dioxins in land-applied sewage sludge shows the risks to be minimal.

This evaluation looked at the segment of the U.S. population that EPA identified as the most exposed to dioxins in land-applied sewage sludge: farmers (and their families) who apply sewage sludge to their land and consume a high percentage of their own products. This population was selected in part because of their proximity to the land where sewage sludge is applied and, more importantly, because of the portion of their diet grown on land where sewage sludge is applied. EPA's risk assessment shows that even these ''highly exposed individuals'' (HEI) are at low risk of cancer from dioxins in land-applied sewage sludge.

The risk assessment analyzed cancer risk from exposure to dioxins in land-applied sewage sludge. The risk assessment predicted an excess lifetime cancer risk to members of the highly exposed farm family that is in the range of cancer risks that does not warrant additional regulation of land-applied sewage sludge. Indeed, the number of cancer cases for this farm family population is extremely low, less than one cancer case per year.

Because the general population of the U.S. has lower exposure to dioxins from land-applied sewage sludge than the modeled farm family, the incremental cancer risk from exposure to dioxins in land-applied sewage sludge for the general population (*i.e.*, those not members of a highly exposed farm family) is lower than the risk to the HEI. Therefore, having found that the existing sewage sludge land-application regulations (*e.g.*, grazing restrictions, agronomic rate application limitation) are adequate to protect the highly exposed population from the cancer risks due to dioxins in land applied sewage sludge, EPA concludes that the existing regulations are adequate to protect the general population, which is subject to lower exposures.

With respect to non-cancer effects, EPA does not yet have a method to calculate the non-cancer risks that may occur to either the highly exposed modeled population or the general population. EPA used a model to predict the increased dioxin body burden over prolonged exposure to dioxins in land-applied sewages sludge. However, in the absence of an acceptable daily dose for dioxins (also referred to also as a reference dose, or RfD) or other measurement, EPA is not able to estimate the potential development of non-cancer effects in the modeled HEI population from the increases in dioxins body burdens. *See* section VII.B. for a discussion of the evolving science with respect to assessing non-cancer health risks from exposure to dioxins.

EPA also performed a Screening Ecological Risk Analysis (SERA) on the risks to wildlife due to exposure to dioxins from land-applied sewage sludge. The screen calculated the ratio of estimated doses of dioxins to wildlife as a result of the land application of sewage sludge to acceptable dioxin doses to wildlife (dioxin wildlife benchmarks). While not definitive risk estimates, the results of the SERA indicate that wildlife species should not be significantly impacted by dioxins in land-applied sewage sludge.

In addition, the results of EPA's 2001 Dioxin Update to the National Sewage Sludge Survey (USEPA, 2002b) indicate that dioxin levels in sewage sludge have declined since 1988, the last time that dioxins in sewage sludge were surveyed by EPA. There is reason to believe that this downward trend in dioxin concentration in sewage sludge will continue as additional regulatory controls are placed on additional sources of dioxin creation, especially on various types of combustion practices and their emissions, as well as effluent limitation guidelines for the pulp, paper, and paperboard point source category, 40 CFR part 430.

In summary, the information available today on dioxin exposures, toxicity and assessed cancer risks supports EPA's determination that no additional numeric limits or management practices are required to adequately protect human health and the environment from the adverse effects of dioxins in land-applied sewage sludge.

B. Assessment of Cancer Risk From Dioxins in Land-Applied Sewage Sludge

As EPA stated in the proposal and the NODA, EPA is basing its decision with respect to human health impacts on an assessment of the risk of cancer due to exposure to dioxins in land-applied sewage sludge. Both the risk assessment for the proposed rule and the revised risk assessment presented in the NODA were based on EPA's identification of cancer as the hazard to be assessed.

1. *Redefinition of the HEI and Assumptions Regarding the HEI:* For the December 1999 proposal, EPA modeled a ''rural family'' as the Highly Exposed Individual (HEI) population. In the 1999 risk assessment, EPA assumed that the modeled rural family's risk of adverse health effects resulting from exposure to dioxins in land-applied sewage sludge is greater than that of the general population because a higher percentage of the family's diet consists of food grown on sewage sludge-amended soil. At proposal, the rural family was assumed to consume 10 percent of their beef, beef liver, and lamb diet, three percent of their dairy diet, and 43–59 percent of their produce diet from crops raised on sewage sludge-amended soil (64 FR 72053).

In contrast, the revised risk assessment conducted in support of the final decision used a probabilistic method (Monte Carlo) to produce an estimate of the distribution of risk to the HEI. In general, the probabilistic risk assessment approach better characterizes the range of potential risks, and better accounts for uncertainty and variability. For the revised risk assessment, EPA retained the basic assumption from the proposal that the modeled HEI population is at greater risk than the general population. However, EPA revised a number of the exposure assumptions with respect to the modeled HEI population.

In the revised risk assessment, EPA assumed that members of the highly exposed farm family live on farms where sewage sludge is land-applied as fertilizer or a soil amendment on pasture land as well as crop land. In addition, in the revised risk assessment EPA assumed that a higher percentage of the farm family's diet consists of food grown on sewage sludge-amended soil. Specifically, EPA assumed that the farm family consumes 49 percent of the beef and 25.4 percent of the dairy products in their diet from products of their own farms. EPA also assumed, for the first time, that the adults on the farm consume fish caught from a nearby waterbody (stream) pond. As in the deterministic risk assessment, the revised risk assessment assumed that the farm family also raised a significant portion of its fruit and vegetable diet on sewage sludge amended soils. A description of the modeled HEI population and how its risk was estimated is presented in the Background Document, Standards for Use or Disposal for Sewage Sludge, Final Action (USEPA, 2003b).

In the NODA, EPA requested comments on the Agency's use of the farm family scenario described for the revised risk assessment. A few commenters agreed with EPA's definition of the HEI population as the farm family. Most commenters believed that EPA's hypothetical farm family risk scenario was unrealistic and would overestimate risk. They argued that no family would farm its land in the manner described, nor consume such a high percentage of food (up to 50 percent) grown on sewage sludge-amended land. They also believed it unlikely that every farm in America has a fish pond receiving dioxins runoff from land-applied sewage sludge. A few other commenters believe that EPA's assumptions were not sufficiently conservative, for example, that the percentage of home grown food in the diet was too low. Comments concerning the HEI also said that the risk assessment did not consider the possibility that farmland would be developed and that houses or schools could be built on farmland.

EPA disagrees with comments that assumptions for the modeled HEI population are too conservative and should be changed. Regarding the comment that the amount of food grown on sludge-amended land consumed by farm families as modeled in the revised risk assessment is too conservative, EPA disagrees. The values that EPA used to estimate the proportion of the farmer's diet that is home produced were taken from Table 13–71 (Fraction of Food Intake that is Home Produced) of the Exposure Factors Handbook (USEPA, 1997), a peer reviewed source of data for use in risk assessments. For similar reasons, EPA also disagrees with comments that EPA's estimates of home grown food consumption are not sufficiently conservative. In addition, as some commenters pointed out, the risk assessment should model the ''reasonably maximum exposed'' individual. EPA believes that the HEI modeled in the risk assessment meets this description, and that ''reasonably maximum exposed'' is not equivalent to ''maximum exposed.'' Although one could conceive of the possibility that someone may consume up to100% percent of their diet from home grown products, EPA does not believe it is reasonable to use this assumption in the risk assessment.

One commenter stated that houses could be built on farmland in the future and that EPA should factor this in (presumably to address families living on sewage sludge amended soil). However, because the risks associated with the scenario that EPA evaluated (the farm family as the highly exposed population) are greater than the risks EPA would estimate for a residential land use scenario, there is no need for EPA to evaluate residential exposure. In addition, the Agency evaluated the risks associated with a child's ingestion of sewage sludge amended soil, which could be typical of a residential scenario. Those risks are lower than those for a child's ingestion of contaminated beef and dairy products as in the modeled farm family described herein. (USEPA, 2003a).

Another commenter stated that it is unreasonable to assume that every farm has a fish pond receiving dioxins from runoff of land-applied sewage sludge. Fish consumption by an adult recreational fisher on the farm was one of the pathways used in the exposure model. EPA agrees that while it is unlikely that every farm will have a waterbody from which fish are caught and consumed, it is a possible scenario and a valid one to include in the analysis. In any case, the risk assessment indicates that the consumption of fish from a stream receiving dioxins runoff in land-applied sewage sludge results in minimal influence on the risk estimate.

2. *Other Assumptions in the Risk Assessment:* In addition to the revised modeled HEI population assumptions (USEPA, 2003a), other assumptions were used in the revised risk assessment. Again, these assumptions, to the extent possible, are presented as a range of values, which were modeled using a Monte Carlo probabilistic method. A number of assumptions concern farming practices and sewage sludge application rates. For sewage sludge application rates, EPA assumed a distribution ranging from 5 to 10 metric tons of sludge per hectare applied every other year for a period of time ranging from once to 40 years (that is, EPA assumed that there would be from one to 20 applications of sewage sludge). Half the acreage on the modeled farm was assumed to be in tilled crop production and half permanently in untilled pasture. EPA assumed that row crops are tilled three times per year, and that tilling incorporates sewage sludge into the top 20 cm of soil. EPA assumed that sewage sludge that is applied to pasture is not tilled. We used these assumptions because they are typical of agricultural application situations for soil amendment products by convention.

Many of the assumptions and values used in the revised risk assessment differed from those in the 1999 risk assessment for the proposed rule. The revised risk assessment includes new exposure pathways and mechanisms to more accurately portray farm conditions for the modeled HEI population. For example, the 1999 risk assessment assumed that pastured animals only eat sewage sludge-amended soil containing dioxins; this was assumed to be the animals' only route of exposure. In contrast, the revised risk assessment assumed that cattle ingest dioxins from several sources: leaf surfaces containing dioxins volatilized from the top two centimeters of soil; sewage sludge particles that remain on the leaf surfaces; and direct ingestion of sewage sludge-containing soil. The revised risk assessment also included chickens and assumed that they ingest soil from a buffer area that receives dioxins through erosion of surface soils from adjacent sewage sludge-amended pasture and crop.

EPA requested comments on the specific assumptions outlined in the revised risk assessment, and received a variety of public comments. Some commenters believed that these assumptions, like those concerning the HEI, were too conservative and reflected a worst-case scenario. Others wanted EPA to evaluate additional exposure pathways and scenarios (*i.e.*, dermal exposure, risks for breast-fed infants combined with risks for child and adult receptors, and soil ingestion rates that reflect potentially different soil contact behavior for crops and pasture). Other commenters believed EPA underestimated risk of cancer from exposure to dioxins in land-applied sewage sludge. EPA received several comments on the conceptual site models and exposure scenarios. These comments included statements that the risk assessment did not account for harvesting and land-use restrictions, or variation in sludge application rates among different crops and regions. Other commenters stated that modeling assumptions such as the HEI modeled farm family being exposed to dioxins from multiple pathways were questionable (uncertainty inherent in application of models and use of many ''average'' values imbedded in the assessment) and the vapor dispersion model may underestimate vapor concentration.

The revised risk assessment for dioxins in land-applied sewage sludge does not include additional exposure pathways, however, EPA has summed the risk from all pathways to estimate the overall risk to a given receptor. As explained later in this notice, EPA evaluated the risks to the adult, child, and nursing infant in the farm family. In addition to ingestion of breast milk for the infant, the risk assessment evaluated up to six additional exposure pathways and exposure routes: (1) Inhalation of ambient air; (2) incidental ingestion of soil in the buffer; (3) ingestion of above- and below-ground produce grown on the crop land; (4) ingestion of beef and dairy products from the pasture; (5) ingestion of home produced poultry and eggs from the buffer; and (6) ingestion of fish from the nearby waterbody. More detailed descriptions of the revised risk assessment assumptions and methodologies are presented in the TBD, Section 5.

No data were available on the variation in sludge application rates for specific crops or regions. Had these data been available, they could have been considered in the analysis. In the revised probabilistic risk assessment, however, EPA placed the conceptual farm scenario in 41 different meteorological and agricultural soil regions in the U.S. to account for variations in different crop harvesting and land use restrictions. The analysis as conducted is conservative and the risks estimated using these conservative use assumptions for the crops requiring the greatest fertilizer application still demonstrate low risks to even the HEI (members of a farm family that apply sewage sludge to their own land and consume products from their land).

EPA disagrees with comments that the risk assessment does not appropriately consider volatilization of dioxins from sewage sludge. First, the equations that EPA used (USEPA, 2003a) to represent the sewage sludge's environmental fate and transport in soil included volatilization as a fate and transport mechanism. While EPA assessed volatilization as a dioxin transport mechanism for several exposure pathways, volatilization is an important component only for the critical pathway of the contamination of forage crops grown on the agricultural field with subsequent ingestion of these crops by beef and dairy cattle. This is so because volatilization is the main mechanism of dioxin transport from the sewage sludge soil mixture to the receiving surfaces of the forage crop, which is a component of the mechanism of dioxin exposure to grazing animals. Volatilization of dioxins via other exposure pathways does not significantly contribute to the exposure of dioxins to the HEI.

To address the vapor concentration question (*i.e.*, dioxins concentrations on the surfaces of forage crops), the mixing height values used in this analysis are contained in the Industrial Source Complex Short-Term Model, Version 3 (ISCST3), the air model used in this analysis. This is an approved method for modeling area sources such as agricultural fields. This model has been validated with measurement data and is less conservative than the box model used in the proposed rule, which did not include dispersion and deposition of sewage sludge. A conservative modeling assumption is that land applied sewage sludge remains in the top two centimeters (cm) of the receiving soil for the pasture where the animals are grazed. This is an unlikely assumption since weathering and natural soil organism (*e.g.* earthworms) activity would naturally incorporate the sewage sludge into the soil at greater depths. This assumption creates an upper end dioxin transport from the sewage sludge soil mixture to the surface of the forage crop.

3. *Cancer Slope Factor (Q1*):* The cancer slope factor is used to calculate the incremental cancer risk attributable to the exposure to a pollutant. The cancer slope factor (also referred to as Q1*) is a numeric value which relates the incremental probability of developing cancer from exposure to a particular substance. The cancer slope factor is expressed as excess lifetime cancer risk per unit exposure, and is usually quantified in terms of milligrams or picograms toxic equivalents of substance per kilogram of body weight/day ((pg TEQ/kg-d)$^{-1}$). The greater the numeric value of the cancer slope, the greater the carcinogenic potency of the substance. For example, 1×10^{-5} is greater than the numeric value 1×10^{-6}. The same slope factor is used to estimate cancer risk for both children and adults. The cancer slope factor represents the upper bound 95th percentile confidence limit of the excess cancer risk from a lifetime exposure to a pollutant (*i.e.*, the dose for which increased risk of cancer is predicted for the most sensitive five percent of the population).

For calculating cancer risk from exposure to dioxins, in the revised risk assessment EPA used a cancer slope factor for TCDD of 1.56×10^{-4} picograms toxic equivalence/kilogram body weight/day ((pg TEQ/kg-d)$^{-1}$) (USEPA, 1985). Thus, the estimate for the 95th percentile excess lifetime cancer risk to the modeled HEI population (*i.e.*, the five percent of the HEI population that is most exposed) is 2×10^{-5}, or 2 in 100,000.

Cancer risk can also be expressed in terms of the number of additional cases of cancer annually attributable to exposure to dioxins in land-applied sewage sludge. This requires an estimation of the number of people in the United States that fall into the farm family scenario that EPA modeled. As explained in the NODA (67 FR 40554) population could be no more than some 11,000 people. By assuming that all sewage sludge produced in the U.S. is land-applied, and by including all farm families whose diets consist of 50 percent of products produced on their farms, EPA took the approach of calculating a very high estimate of the size of the highly exposed population. A more realistic estimate of the HEI population takes into account the fact that only about half of the sewage sludge produced in the U.S. is land applied, and that the number of individuals who consume both home-grown dairy and beef can, by definition, be no greater than the smaller of the number of individuals who consume either home-produced dairy or home-produced beef. This approach results in an estimate of 1,600 persons in the HEI population, which is number of persons estimated to consume home-produced diary products. Because it is unlikely that all of those who consume home-produced dairy products also graze their dairy cows on sewage sludge-amended pastures, even this number may overestimate the size of the highly exposed population. See Background Document, USEPA, 2003b for a detailed explanation of calculating the HEI population. In order to present both the more realistic evaluation as well as a high estimate of the number of excess cancer cases in this population attributable to exposure to dioxins in land-applied sewage sludge, EPA calculated these estimates as a range.

Using this range of 1,600 to 11,200 individuals in the HEI population, EPA estimates that there could be between 0.002 to 0.01 total excess cancer cases in the HEI populations attributable to land application of sewage sludge. This corresponds to additional annual cancer cases of between 0.00003 and 0.0001 that would be attributable to land application of sewage sludge. Thus, whether the HEI population in the U.S. is estimated to be some 1,600 individuals or 11,200 individuals, or whether the maximum 95th percentile or more accurate 50th percentile risk is used, the number of excess lifetime cancer cases attributable to dioxins in land-applied sewage sludge approaches zero. EPA's methodology for reaching this estimate is explained as follows:

EPA estimates individual excess lifetime cancer risk as the product of an individual's lifetime average daily dose (LADD) of dioxins (expressed as a TEQ) and the cancer slope factor for TCDD (see Table 1). EPA summed individual exposure and subsequent cancer risks from all pathways relevant to an exposed individual to estimate the total individual lifetime cancer risk from all pathways. The estimate of the total number of lifetime cancer cases expected within a population is the product of the individual excess lifetime cancer risk estimates for all individuals in the population and the number of individuals in the population. Because this estimate looks at the HEI population as a whole, it is more accurate to apply the 50th percentile risk (1×10^{-6}) than the 95th percentile risk, which actually overestimates the predicted number of cancer cases for this population group. The estimate of annual cancer cases within a population is the total number of excess lifetime cancer cases divided by a 70-year lifetime.

EPA used this procedure to derive the results of the revised risk assessment. Specifically, in the exposure assessment EPA estimated the HEI's dose of each 29 dioxin-like congeners detected in sewage sludge. The dose of each congener was converted to a TEQ dose by multiplying the congener's dose by the congener's toxicity equivalency factor (TEF). The TEQ doses for each of the 29 congeners were then summed to yield an overall TEQ dose to the individual for each exposure pathway (*e.g.*, inhalation, ingestion). Finally, the TEQ dose was multiplied by the cancer slope factor (Q1*) to estimate the excess lifetime cancer risk to the individual for each pathway of exposure. EPA estimated total lifetime average daily dioxins exposure and excess lifetime risk to the HEI by summing lifetime average daily dioxins exposures and excess lifetime cancer risks across all of the exposure pathways relevant to each modeled individual (adult, child, infant).

Many commenters questioned EPA's use of the 1985 guidance Q1* rather than the slope factor presented for TCDD in the September 2000 Draft Dioxin Reassessment (USEPA, 2000). They argued that it made no sense to assess cancer risk based on the 1985 cancer slope factor when EPA itself had developed an alternate value. Another commenter said that given the uncertainties in the assessment of the carcinogenicity of dioxin and dioxin-like compounds, quantifying a cancer slope factor and adopting a linear extrapolation model only magnified the uncertainty. EPA conducted its risk assessment utilizing the cancer slope factor from the 1985 guidance. Because of the terms of the Consent Decree, in the NODA we also evaluated the cancer risks to the modeled population by considering the cancer slope factor for dioxins in the Draft Dioxin Reassessment (USEPA, 2000). EPA's final decision not to regulate dioxins in land applied sewage sludge is in harmony with either cancer slope. One commenter believed EPA's existing slope factor was outdated and that the ongoing dioxin reassessment, or perhaps the Great Lakes Initiative (GLI) cancer slope factor (USEPA, 1995) reflected more current science.

EPA believes that use of the 1985 guidance Q1* is reasonable. While alternative cancer slope factor calculations have been under review, there remains sufficient uncertainty as to whether a different Q1* should be used for assessing cancer risk from dioxins exposure and what the new Q1* should be. EPA reevaluated the 1985 cancer slope in 1990 in the GLI (USEPA, 1995), by examining the pathological data from the study upon which the cancer slope factor was derived. From this reevaluation, both new tumor incidences and a new scaling factor were employed to produce a new cancer slope factor. The GLI cancer slope is approximately one half the value of the 1985 cancer slope factor. The GLI cancer slope factor was used to establish water quality standards for those water bodies. The Agency never officially adopted the GLI cancer slope factor in its risk assessments for other programs because by 1995 the Dioxin Reassessment was underway and additional science on the carcinogenic mechanism for 2,3,7,8-TCDD was evolving. In addition, the difference between the cancer risk estimate using the 1985 guidance Q1* and other proposals (*e.g.*, the GLI, alternate Q1* used in the NODA) would not lead EPA to reach a different conclusion with respect to whether the predicted adverse health effects (cancer) from dioxins in land-applied sewage sludge requires EPA to regulate dioxins in land-applied sewage sludge. A more detailed discussion of the cancer slope factor is provided in section VII (''Discussion of Scientific Information Presented in the NODA'').

4. *Method of Calculating Risk to the Modeled HEI Population:* As explained previously, using the results of all samples from the EPA 2001 dioxin update survey, EPA modeled all 29 dioxin and dioxin-like congeners individually, and then summed the results for all congeners to arrive at the risk for dioxins expressed as TEQ. EPA estimated excess lifetime cancer risks and corresponding average lifetime daily exposure to dioxins for a highly exposed farm adult and child (see section V.D. for a discussion of the EPA 2001 dioxins update survey).

As described in the NODA, the revised risk includes an analysis of exposures to individuals using 3,000 iterations of the Monte Carlo analysis. Individuals were subdivided into two exposure scenarios, those whose exposures begin during childhood and those whose exposures begin in adulthood. To account for the fact that children's intake rates vary with age, the analysis used separate sets of exposure parameters for four age cohorts: ages 1–5, ages 6–11, ages 12–19, and ages 20–70. To capture the higher intake-rate-to-body weight ratio of children, a start age between the ages of 1 and 6 was randomly selected for all children for each iteration in the probabilistic analysis.

Children (defined as between one year and six years of age) are an important sensitive population in risk assessment because they may be more highly exposed than adults. This age range was selected because this represents the highest consumption rate (intake/body weight) for most of the exposure pathways evaluated in this risk assessment. 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 dioxins dose per body weight for children as compared to adults. The estimated excess lifetime cancer risk for individuals whose exposure begins in childhood is less than or equal to the estimated excess lifetime cancer risk for adults whose exposure begins later in life. The reason for this is that children's mobility generally is greater than that of adults. That is, overall, the period of time that a child will occupy a given residence is shorter than the period of time an adult will occupy a given residence. Therefore, individuals whose exposures to dioxins from land-applied sewage sludge in home-produced foods begins in childhood are, in general, assumed to be exposed for a shorter duration than those whose exposure begins in adulthood (USEPA, 2003a).

Infants are also an important sensitive population considered in the revised risk assessment. Infants may be exposed to dioxin-like compounds via the ingestion of breast milk. The characterization of risks to infants of farmers and home gardeners was considered separately from the characterization of risks to older children (*i.e.*, aged 1 year or older). While risks to children and adults were integrated to assess 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 an individual's lifetime risk that is due to ingestion of breast milk from a mother exposed to dioxins in home-produced foods derived from land-applied sewage sludge.

Table 1 below provides percentiles of the distribution of estimated excess lifetime cancer risk to a farm family adult and child who consume home-produced foods derived from land on which sewage sludge has been applied.

TABLE 1.—RISKS AND DAILY EXPOSURE FOR HIGHLY EXPOSED INDIVIDUALS FOR ALL EXPOSURE PATHWAYS

[Q1*=1.56 × 10^{-4} (pg TEQ/kg-d^{-1}]

Percentile	Adult *		Child **	
	Risk	Daily exposure, pg TEQ/kg-d	Risk	Daily exposure, pg TEQ/kg-d
50th	1×10^{-6}	0.0086	1×10^{-6}	0.0094
75th	4×10^{-6}	0.026	3×10^{-6}	0.021
90th	1×10^{-5}	0.064	7×10^{-6}	0.042
95th	2×10^{-5}	0.11	1×10^{-5}	0.062

* Initial exposure begins in adulthood.
* Initial exposure begins during childhood.

As Table 1 shows, the median exposed HEI (at the 50th exposure percentile), even with the conservative assumptions built into the definition of the HEI, has a one in a million excess lifetime risk of cancer. An HEI at the high end of the exposure distribution (*i.e.*, one at the upper 5 percent exposed or the 95th percentile) has a 2 in 100,000 excess lifetime cancer risk from exposure to dioxins in land-applied sewage sludge. Both the lifetime and annual excess cases of cancer are considered conservative based on the assumptions used to model the HEI. EPA's reference to the 95th percentile exposure scenario and risk estimate is accompanied by the understanding that only five percent of the total number of individuals modeled in the HEI population (estimated to be 80 to 560 individuals nationwide) has an estimated lifetime cancer risk of 2 in 100,000 or greater. This risk estimate is considered to be unlikely based on the conservative assumptions used in constructing the HEI in a farm family. The remainder of the modeled HEI population will have a lower potential cancer risk because they are less exposed to dioxins than at the 95th percentile exposure scenario.

Certain commenters expressed concern that the 1999 human health risk assessment was limited to characterization of cancer risks, stating that the non-cancer health effects of dioxins may be a more serious concern than cancer because non-cancer health effects may occur at lower doses and may affect more body systems. Commenters recommended that non-cancer endpoints be considered in Round 2 or that draft reference doses be used to evaluate non-cancer endpoints.

EPA based the revised risk assessment for dioxin-like constituents in sewage sludge applied to agricultural land and its decision not to regulate dioxins in land-applied sewage sludge on the cancer endpoint because it is the most scientifically well-established and well-supported endpoint. Although EPA and others have been studying non-cancer human health effects from exposure to dioxins, a methodology to adequately assess those risks has not yet been established. Details of this assessment and developments in the study of assessing non-cancer risks are discussed further in section VII. Discussion of Scientific Information Presented in the NODA.

C. Findings Concerning Ecological Effects

In response to public and peer review comments received on the 1999 proposal, EPA performed a screening ecological risk analysis (SERA) (USEPA, 2003a). The SERA used a two-phased approach that includes: (1) an initial screening assessment to determine whether the dioxins concentrations in land-applied sewage sludge warranted further assessment. This effort was an initial bounding estimate to assess the upper bound potential for ecological effects at the high end of exposure, and (2) a more refined assessment using a combination of higher end central tendency exposure assumptions regarding environmental media concentrations, receptor-specific dietary preferences, and ecological benchmarks. EPA used a hazard quotient (HQ) approach to assess the potential for adverse ecological effects. For the SERA, the HQ was the ratio of the modeled exposure and an exposure (an ecological benchmark) that is expected to be without adverse ecological effects. When HQs are greater than one, exposures exceed ecological benchmarks, suggesting the potential exists for adverse ecological effects. When HQs are less than one, exposures are less than ecological benchmarks, suggesting that there is minimal potential for adverse ecological effects. In the SERA, EPA determined that all HQs were less than one.

In the NODA, EPA discussed the SERA and requested comments on the methodology, the data used, and the results derived from the SERA. As with the revised cancer risk assessment, the SERA used the concentrations of dioxins obtained from new sampling data in the 2001 Dioxin Update (USEPA, 2002b) of the National Sewage Sludge Survey (NSSS). As explained in section V.D., the 2001 dioxin update survey data consist of sewage sludge samples obtained from 94 municipal wastewater treatment facilities, and are considered a nationally representative sample.

The SERA addresses risks to mammals and birds, the receptors that are expected to have the highest exposure to dioxins. The assessment does not address risks to other receptor groups such as invertebrates and plants. The potential for dioxins to bioaccumulate in wildlife receptors is specifically addressed through analysis of the ingestion pathway. The analysis includes receptors exposed through ingestion of both aquatic and terrestrial food items and thus addresses the potential for bioaccumulation of dioxins from soil, surface water, and sediment.

The bioaccumulation factors (BAFs) for terrestrial invertebrates used in the analysis were derived from empirical data and assume a linear relationship between the concentrations of dioxins in soil and in food items. However, the BAFs are relatively conservative, and EPA considers them adequate for a screening level analysis.

There was disagreement among commenters concerning the adequacy of the SERA and whether dioxins in land-applied sewage sludge posed a risk to wildlife. Some commenters agreed with EPA's conclusion that there was no serious ecological risk, while others said that the uncertainty in the model's applications, and the many ''average'' values in the assessment, made the low HQs questionable. Other commenters indicated there was a potential for bioaccumulation in several forms of wildlife.

EPA believes the SERA is adequate to predict hazards to wildlife species from dioxins in land-applied sewage sludge. The SERA was designed to be consistent with EPA's Guidelines for Ecological Risk Assessment (USEPA, 1998). See the Technical Background Document (TBD) for a discussion of the SERA (USEPA, 2003a). Because the ecological analysis was a screening analysis intended only to indicate the potential for adverse ecological effects, EPA considers the qualitative uncertainty analysis to be adequate. The uncertainty discussion identifies sources of uncertainty, discusses their implications for the outcome of the analysis, and, where possible, indicates whether the uncertainty is likely to cause an over or underestimation of risk. Screening-level ecological risk assessments are designed to provide, for those chemicals and receptors that pass the screen (as in dioxins), a high level of confidence that there is a low probability of adverse effects to ecological receptors.

The SERA provides insight into the potential for ecological effects from dioxins in land-applied sewage sludge. The approach used shows that the exposures to animals in terrestrial and water body margin habitats do not exceed protective ecological benchmarks (that is HQs do not exceed one), suggesting that dioxins in land-applied sewage sludge do not pose a high potential for adverse ecological effects.

D. Indications From the 2001 Survey of Dioxins in Sewage Sludge

In response to comments on the proposal that EPA needed data more current than the 1988 National Sewage Sludge Survey (NSSS) data, EPA conducted a national sampling and analysis effort to measure dioxins in sewage sludge in 2001 (USEPA, 2002b). The EPA 2001 Dioxin Update of the NSSS provides data that support the calculation of unbiased national estimates (*i.e.*, based on a stratified random selection of publicly owned treatment works) for dioxin and dioxin-like compounds in sewage sludge. In addition to being more recent, the 2001 data also include concentrations of coplanar PCB congeners, along with dioxin and furan congeners. Coplanar PCB congeners were not analyzed in the 1988 NSSS.

EPA sampled sewage sludge from a stratified random sample of 94 POTWs selected from the sample of 174 POTWs surveyed in the 1988 NSSS, stratified into four size categories: those with a daily flow of less than one million gallons per day (MGD), 1–10 MGD, 10–100 MGD, and greater than 100 MGD. The 174 POTWs selected in 1988 had been selected from the approximately 11,000 POTWs in existence at that time that had secondary treatment. The 11,000 were sampled according to stratified probability design (*i.e.*, by size based on wastewater design flow). The sample for the 2001 Dioxin Update to the National Sewage Sludge Survey was a subset of the sample for the 1988 NSSS and thus resulted in a statistically valid national estimate of dioxin congener concentrations in the Nation's sewage sludge. EPA considers dioxin and dioxin-like congener concentrations used in the revised risk assessment to be representative of dioxins congener concentrations in sewage sludge nationwide because of the sample design. See Section III, Statistical Support Document for the Development of Round 2 Biosolids Use or Disposal Regulations (USEPA 2002b).

The sewage sludge samples were processed to produce a single representative sample for each facility. In addition, the data reflect probability-based survey weights based on the numbers of POTWs in the four strata defined on the basis of quantity of flow. Since the few POTWs in the flow group receiving more than 100 MGD of influent wastewater produce the largest amounts of sewage sludge, the probability-based sample design incorporated an over-sampling of large POTWs. The survey weights reflect this feature.

The 2001 dioxins update survey was designed based on the 1988 NSSS in order to allow comparability of statistically valid national estimates, although, as explained later, a number of factors limit the degree of comparison that is possible. A comparison of results for dioxin and furan congeners obtained in the 1988 and 2001 surveys is presented in Table 2. This table summarizes the results using alternative methods for handling non-detect measurements. These comparisons do not include coplanar PCB congeners because the 1988 NSSS did not collect coplanar PCB congener data.

TABLE 2.—NATIONAL ESTIMATES (NANOGRAMS/KILOGRAM DRY MATTER BASIS) FOR DIOXIN AND FURAN CONGENERS IN THE EPA 2001 DIOXIN UPDATE SURVEY AND 1988 NSSS

Method for handling nondetects (estimate)	Zero for nondetects		½ minimum level of quantitation (ML) for nondetects		ML for nondetects	
	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 EPA 2001 dioxin survey suggests that dioxins levels in sewage sludge have decreased from 1988 to 2001. In addition, the upper percentile values obtained in the EPA 2001 dioxins update survey are lower than those obtained in the 1988 NSSS. See Statistical Support Document for the Development of Round 2 Biosolids Use or Disposal Regulations (USEPA, 2002b) for a full discussion of the 2001 updated dioxins survey.

It is not possible to draw firm conclusions with regard to changes in dioxin concentrations in sewage sludge nationally, due to differences in the two surveys caused by changed circumstances since 1988 (13 years between surveys). During this time, changes may have occurred at POTWs, and there have been changes and improvements in analytical methods. Nevertheless, as discussed in the NODA, EPA has made a number of observations regarding changes in dioxins concentrations in sewage sludge based on a comparison of the data in the two surveys. As mentioned previously, the 94 POTWs participating in the EPA 2001 dioxin update survey also participated in the original 1988 NSSS. Samples from 14 of the POTWs showed dioxins 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 dioxins levels measured in both surveys. Of the 14 POTWs with the greatest differences between the two surveys, four had large increases in sewage sludge dioxins concentrations and ten had large decreases in sewage sludge dioxins concentrations from 1988 to 2001.

No sampled POTW with high levels of dioxins in sewage sludge in the 1988 NSSS showed high levels in the 2001 update survey. Based on these data, EPA infers that POTWs with higher concentrations of dioxins in their sewage sludge may experience a greater variability in dioxins concentrations over time, and that higher dioxins levels may not remain high for a significant period of time. It is possible that POTWs with higher concentrations of dioxins in their sewage sludge intermittently receive dioxins from unidentified but specific sources via the sewer system. Likewise, POTWs with moderate or low levels of dioxins in their sewage sludge may experience much less variability in dioxins concentrations over time. This second group of POTWs appears to be experiencing typical environmental background variation of dioxins levels.

EPA requested comments on the significance of the differences in dioxins concentrations in sewage sludge measured in the EPA 2001 dioxin update survey compared to dioxins concentrations in sewage sludge measured in the 1988 NSSS. Several commenters noted that dioxin levels had decreased between the 1988 survey and the 2001 survey. One commenter was unsure of the implications of the finding, because analytical methods have improved and PCBs were not analyzed in earlier surveys, but felt that both dioxin and PCB levels have most likely declined because of changes in their use.

Three commenters said that the results indicated that attendant risks were also decreasing; one went on to say that EPA should use the findings to promote public confidence in land application of sewage sludge and dioxins regulatory limits. Another respondent said that the decrease made stringent regulatory requirements for sewage sludge unnecessary and that existing dioxins controls are having a noticeable effect on environmental releases. One commenter said that the findings should give regulatory agencies and the public confidence that decisions based on current data sets will provide adequate protection under reasonably anticipated future conditions.

One commenter endorsed EPA's response to previous public comments by obtaining new data in the 2001 dioxins update survey to the 1988 NSSS, saying that the initiative demonstrated EPA's commitment to use reliable data to provide accurate risk assessments of sewage sludge. Another commenter felt that EPA had inappropriately weighted data from the NSSS by giving greater weight to samples from small-production POTWs and thereby understating risk estimates. Another commenter was unsure whether the study was designed to test the hypothesis that there might be differences in dioxins concentrations between small and large facilities. Finally, some commenters felt that the survey data support taking no action for dioxins in land-applied sewage sludge.

EPA believes that appropriate consideration of data from small POTWs was made in the design of the sample for the survey. A simple random sample of POTWs, without regard to the amount of influent wastewater, would not have provided adequate representation of the POTWs receiving the larger amounts of influent wastewater. In fact, a simple random sample, drawn without regard to size, would have been dominated by POTWs in the less than 1 million gallons per day (MGD) flow group.

Regarding indications from the data, EPA believes that the data suggest an overall decrease in dioxins. New or revised pretreatment requirements and pollution prevention measures adopted since 1988 would be expected to have reduced dioxins in the influent to POTWs. The decrease of dioxins in sewage sludge observed in the two surveys supports the Agency's conclusion that new regulatory requirements for dioxins in land-applied sewage sludge are unnecessary.

VI. Environmental Justice

Environmental justice and equity concerns involve consideration of the potential for minorities and people of lower economic status to be impacted by dioxins exposures to a greater degree than the rest of the general population. EPA believes the HEI analysis addresses reasonable high end exposures that could represent a subsistence low income farm family. The HEI analysis addresses exposure regardless of minority or economic status.

VII. Discussion of Scientific Information Presented in the NODA

For the past 12 years, EPA has been conducting a reassessment of the human health risks associated with dioxin and dioxin-like compounds. This reassessment is not a final document. In this decision the Agency continued its practice of using the best available data published from a variety of sources that meet the Information Quality Guidelines. The Agency considered all such data and associated uncertainty to determine the strength of the evidence in finalizing this regulatory action related to dioxin and dioxin-like compounds.

A. Assessing Cancer Risk

1. Incremental Cancer Risk

As explained in section V.A. of this Notice, the revised risk assessment for dioxins in land-applied sewage sludge supporting today's final action uses the 1985 Q1* of 1.56×10^{-4} (pg TEQ/kg-d)$^{-1}$. The estimated upper bound lifetime risks for highly exposed farm family adults using this Q1* range from 2×10^{-5} at the 95th percentile exposure to 1×10^{-6} at the 50th percentile exposure for multi-pathway exposure to dioxins through land-applied sewage sludge (see Table 1). There are two exposure scenarios for adults living in the farm family exposed to dioxins in land-applied sewage sludge: (1) Individuals whose exposure begins in adulthood referred to as ''Adult'' in Table 1, and (2) individuals whose exposure begins in childhood referred to as ''Child'' in Table 1. As explained in section V.A., the estimated lifetime cancer risks for the child are less than or equal to the estimated lifetime cancer risks for the adult. These risks correspond to estimated daily exposures for the latter group of adults ranging from 0.11 at the 95th exposure percentile to 0.0086 pg TEQ/kg-d at the 50th exposure percentile.

Use of the alternative Q1* of 1×10^{-3} (pg TEQ/kg-d)$^{-1}$ that was considered in the NODA would result in estimated high-end multi-pathway excess lifetime cancer risks for the latter group of adults in the highly exposed farm family ranging from 1×10^{-4} at the 95th exposure percentile to 6×10^{-6} at the 50th exposure percentile. These estimated risks in the NODA are based on the same daily exposures indicated in Table 1. Again, the estimated excess lifetime cancer risks expressed for individuals born on the farm (see discussion above and in USEPA, 2003b) would be less than or equal to the estimated risks for individuals exposed to dioxins on the farm starting some years after birth (*i.e.*, the corresponding values are 6×10^{-5} at the 95th exposure percentile and 6×10^{-6} at the 50th exposure percentile).

2. Background Cancer Risk

The significance of the exposure and cancer risk due to a specific source such as dioxins in land-applied sewage sludge can be understood in the context of general population background exposure to dioxins from all sources. In other words, the exposure attributed to a particular source can be considered in the context of its contribution to the overall risk.

The background lifetime cancer risk to the general population from exposure to dioxins (all sources) is approximately 2×10^{-4} using the 1985 Q1* of 1.56×10^{-4} (pg TEQ/kg-d)$^{-1}$. The background risk to the HEI is identical to the background risk to the general population, since it is the risk associated with exposure to dioxins from all sources.

As previously explained, the estimated cancer risk for the HEI from exposure to dioxins in land-applied sewage sludge is 2×10^{-5} using the 1985 Q1*. However, excess lifetime cancer risk associated with dioxins in land-applied sewage sludge is very low compared to the background lifetime cancer risk from dioxins. At the 95th percentile, the increase in risk of the HEI (farm family estimated to be no more than 11,200 persons in the US) is about 10 percent of their background risk. As previously explained, excess cancer cases for this modeled population from exposure to dioxins in land-applied sewage sludge are estimated to be 0.002 to 0.01, again depending on the HEI analysis chosen (USEPA, 2003b), using the 1985 Q1*. Further, EPA estimates that the excess lifetime cancer risk to the overall U.S. general population from exposure to dioxins in land-applied sewage sludge is likely to be much lower than the excess lifetime cancer risk to the HEI, and as such, correspondingly lower relative to the general population's background risk from dioxins. This is because the general population's exposure to dioxins from dietary items grown on farms that use sewage sludge as a fertilizer or soil conditioner is significantly lower than the modeled HEI farm family's exposure to dioxins from the crops that they consume from their farms that use sewage sludge. (USEPA, 2003b).

Note that actual risks for individuals are a function of dietary habits, as well as a particular individual's susceptibility to develop cancer, and may be higher or lower. Thus, high-end incremental excess lifetime cancer risk estimates for highly exposed farm families from dioxins in land-applied sewage sludge are approximately an order of magnitude (*i.e.*, ten times) lower than background risks.

Based on this evaluation of the range of cancer risks to the modeled HEI , EPA believes the projected cancer risks to the HEI from dioxins in land-applied sewage sludge are reasonable.

B. Assessing Non-Cancer Risk

EPA generally 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 unlikely to cause an appreciable risk of deleterious non-cancer effects over a lifetime. RfDs for particular contaminants are useful health benchmarks when background exposures are low or nonexistent.

As discussed in section VII of the NODA, background exposures for dioxin-like compounds have been quantified by EPA as being in the range of 1 pg TEQ/kg/d for adults. On a body burden basis, the background body burden for dioxin TEQs for adults in the U.S. has been estimated to be 5 nanograms toxic equivalence per kilogram body weight (ng TEQ/kg), on a whole body weight basis (USEPA, 2002a). As the NODA suggested, conventional approaches to calculating an RfD for dioxins would result in an RfD 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 dioxins exposures on human health and therefore not useful for subsequent risk management decisions for dioxins. Consequently, EPA has not developed an RfD for dioxins.

VIII. Public Comments and Other Considerations

EPA received over 200 comments on the 1999 proposed amendments to the Standards for the Use and Disposal of Sewage Sludge and 27 comments on the 2002 June 12, 2002 NODA regarding the land application of sewage sludge. The majority of the comments were addressed by the NODA or are addressed earlier in this Notice. A summary of other major comments is presented below, along with a summary of EPA's responses. A complete copy of all public comments and EPA's response to comments can be found in the Response to Comments Document in the docket (USEPA, 2003c).

A. Definition of "Dioxins"

Several comments were received concerning the proposed definition of dioxins. Commenters indicated a preference for two separate and distinct definitions for "dioxin" and "coplanar PCBs" (*i.e.*, dioxins would mean tetra through octa chlorinated dibenzo-p-dioxin and furan congeners; and coplanar PCBs would mean the 12 coplanar PCB congeners).

EPA Response: As previously mentioned, EPA defined "dioxins" in the proposed rule as 29 specific congeners of PCDDs, PCDFs, and coplanar PCBs that have been found in sewage sludge. The proposed definition of "dioxins" specifies seven 2,3,7,8,-substituted congeners of PCDDs, ten 2,3,7,8-substituted congeners of PCDFs, and twelve coplanar PCB congeners. EPA had proposed a definition of dioxins using TEF values for dibenzo-p-dioxins and furans described in USEPA 1989 and the WHO 98 TEF scheme for coplanar PCBs. As explained in the NODA (67 FR 40556), EPA now uses the WHO 98 system of TEFs to account for the overall toxicity of complex mixtures of all 29 congeners. The TEF system is accepted worldwide as the most scientifically defensible and most easily implemented method to assess these mixtures in risk assessments.

B. The Need for Regulating Dioxins in Land-Applied Sewage Sludge

EPA received a number of comments regarding the need, or lack of need, to regulate dioxins in land-applied sewage sludge. There was disagreement among the comments premised on dioxins levels in the environment and perceived or real risks. Comments in favor of regulation (including setting numerical limits) included suggestions that: (1) A regulatory program is needed to ensure that dioxins are not land-applied, (2) it is illogical not to have a regulatory limit for dioxins when EPA regulated various metals in sewage sludge, (3) a risk-based limit is necessary, (4) sewage sludge is a significant source of dioxins and should therefore be regulated, (5) EPA should establish a risk-based limit and not a limit based on the 95th percentile concentration of dioxins measured in the 2001 dioxins update survey, and (6) EPA has traditionally used a one-in-one-million risk as acceptable for regulation, and that there is no justification for setting less stringent standards for sewage sludge.

Commenters in favor of not regulating dioxins in sewage sludge felt that there was no need for numeric limits or other requirements, because the overall risks were well within EPA acceptable limits, that the data supported no further regulation, and that EPA failed to address the issue of whether further reductions in exposure were necessary or cost-effective.

EPA Response: For the reasons discussed elsewhere in this **Federal Register** notice, EPA has decided not to regulate dioxins in sewage sludge that is land applied. These decisions are based on the revised cancer risk assessment, the SERA, and 2001 Dioxin Update Survey data. Weighing risks using the collective body of scientific information, EPA has concluded that the increased risks of humans developing cancer from exposure to dioxins in land-applied sewage sludge, as well as effects to the environment, are reasonable, and that no further regulation is warranted. Therefore, neither numeric limitations nor management practices for dioxins in land-applied sewage sludge are being imposed.

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 the highly exposed farm family is also protective of the general population. EPA's risk analysis has shown that when dioxins TEQ concentrations in sewage sludge are modeled, only five percent of the population was at a risk level of 2×10^{-5}. EPA believes that the actual risk is likely to be lower, due to the many conservative assumptions used in constructing the HEI risk characterization.

Regarding comments that there is no justification for setting less stringent standards for sewage sludge than one-in-one-million risk, the revised risk assessment for dioxins in land-applied sewage sludge indicates that an individual in the highly exposed modeled population (estimated to be between approximately 1,600 and 11,200 people) has an estimated excess lifetime cancer risk ranging from 1×10^{-6} to 4×10^{-5} (50th to the 99th percentile exposure) for exposure by multiple pathways. EPA further notes that the lifetime cancer risk ranging from 1×10^{-6} to 4×10^{-5} may be overestimates due to the substantial number of conservative assumptions used in the revised risk assessment. As a result, the Agency does not agree that the risks discussed here warrant further regulation.

C. Groundwater Exposure

Certain commenters stated that EPA did not take into consideration the potential exposure to groundwater impacted by dioxins in land-applied sewage sludge.

EPA Response: The Agency did not analyze a groundwater contamination pathway because dioxins are hydrophobic and they bind very tightly to the sewage sludge/soil matrix. Our analysis found that transport of dioxins through the soil to groundwater, in the subsurface environment, was minimal. Details are provided in the TBD (USEPA, 2003).

D. Synergistic Effects

Some public comments indicated that EPA did not consider synergistic effects. They asserted, for example, that dioxins can be mobilized by solvents and surfactants, which are common in sewage sludge. Commenters also asserted that exposure to dioxins may increase susceptibility to other carcinogens and that this dimension should be analyzed.

EPA Response: There are no models or data available to address synergistic effects with respect to the fate and transport of diverse types of pollutants. Therefore, EPA could not assess such effects from other pollutants acting in combination with the 29 dioxin, dibenzofuran, and coplanar PCB congeners modeled by EPA. While such effects are always possible, EPA is not aware of scientific evidence to date suggesting that any such effects are likely to be significant for dioxins interacting with other pollutants in sewage sludge. The TEF/TEQ approach as outlined in today's notice allows EPA to assess the toxic effects from exposure to the sum of all 29 dioxin and dioxin-like congeners.

E. Voluntary Program

EPA received a wide variety of comments on methodologies to reduce dioxins sources and contamination. Two commenters agreed with EPA's suggested methodology for identifying dioxins sources (*i.e.*, identifying dioxins sources by tracing their congener ''fingerprints''). Some supported the use of voluntary programs in combination with regulatory standards and monitoring programs. Others suggested that a voluntary program only is sufficient, but that EPA should develop guidance to provide additional details and explain how communities can utilize the voluntary methodology. There was concern about who would define ''high'' concentrations of dioxins in sewage sludge or ensure that adequate steps would be taken to reduce high dioxins concentrations if such a program were voluntary. Some commenters asserted that EPA should positively encourage facilities with a history or likelihood of elevated dioxins levels in sewage sludge to monitor and investigate possible sources contributing to high dioxins levels. One commenter noted that the suggested EPA methods would be expensive and perhaps beyond the means of POTWs.

Another commenter said that EPA should require management practices to lessen human exposure to sewage sludge in which dioxins are below the numeric limit and should require POTWs to develop pretreatment programs to reduce dioxins in sewage sludge and minimize dioxins discharges into sewer systems.

EPA Response: With today's final notice EPA is imposing no regulatory requirements on small or large facilities, including monitoring. However, EPA believes that there may be local benefits from establishing a voluntary monitoring and source investigation and identification program for dioxins in land-applied sewage sludge for some POTWs.

EPA believes that voluntary monitoring for dioxins in sewage sludge, combined with a source identification program when high concentrations of dioxins in sewage sludge are encountered, could identify dioxins sources that contribute to any elevated levels of dioxins in sewage sludge. Mixtures of the 29 dioxin congeners have distinct patterns (*i.e.*, profiles or fingerprints) depending on the dioxins source. For example, a congener profile that is dominated by chlorinated dibenzofurans is often characteristic of a chemical manufacturing source. Voluntary monitoring and source identification, and perhaps a follow-up source reduction program, utilizing these fingerprints, could assist in the identification and subsequent mitigation or elimination of dioxins sources when relatively high dioxins concentrations in sewage sludge are detected.

EPA encourages POTWs to consider implementing a voluntary sewage sludge dioxins monitoring and dioxins source identification program through an Environmental Management System (EMS) approach. An EMS for a wastewater utility that generates sewage sludge is a voluntary program that encourages a utility to perform above and beyond mandatory Federal and State sewage sludge requirements and, thereby, improve their environmental performance in all areas of wastewater management including the use or disposal of sewage sludge. EMS participants involve citizens in their communities to assist in defining improved environmental performance. EMS status is awarded to participating utilities only after a rigorous review and subsequent certification by a third party. A voluntary dioxins monitoring and source investigation program, and suggestions for reducing and eliminating sources of dioxins in sewer service areas, could help contribute to reducing concentrations of dioxins in the community's sewage sludge.

The biosolids industry most likely will be implementing an EMS through the National Biosolids Partnership (NBP). The NBP is a partnership formed in 1997 with AMSA (Association of Metropolitan Sewerage Agencies), WEF (Water Environment Federation), and EPA (U.S. Environmental Protection Agency). Through partnering with sewage sludge producers, sewage sludge service contractors such as sewage sludge land application companies, sewage sludge users, regulatory agencies, universities, the farming community, and environmental organizations, the goal of the NBP is to advance environmentally sound and accepted biosolids management practices.

Through a voluntary EMS, being developed for biosolids by the NBP, EPA continues to provide the public with educational information, based on the best science, about the recycling and disposal of biosolids. EPA strongly supports the ongoing efforts of the NBP to develop the EMS and to provide correct and timely information and community-friendly practices that could be followed via its new communications system. The EMS program supports local authorities to find ways to meet and go beyond what is required in State and Federal regulations. About 54 municipalities are now pilot-testing their biosolids EMS programs based upon a blueprint developed by the NBP.

In 2003, the first two municipal wastewater treatment authorities, Orange County (CA) Sanitation District and the Department of Public Works from the City of Los Angeles, CA were awarded entry into the EMS Program by certification from an independent third party auditor. Several additional municipalities will be ready to undergo an independent third party audit of the EMS program later this year (2003). Municipalities involved in the voluntary EMS program are reporting benefits they have achieved. They report that their participation in the EMS program has resulted in more efficient operation, reduced odors from biosolids, less intrusive transport of the sewage sludge to land application sites, better communication, and meaningful involvement of the public. The Agency plans to continue supporting NBP activities and working with municipalities on expanding the use of EMS programs in biosolids management. Two NBP Web site addresses that present relevant biosolids information are *http://www.biosolids.org* and *http://biosolids.policy.net/emsguide/manual/goodpractmanual.vtml.*

IX. List of References

Lorber, M.N. 2002. Evaluating Non-Cancer Risk from Land Application of Sewage Sludge Using an Increment Over Background Approach. Memorandum from Matthew Lorber, National Center for Environmental Assessment, Office of Research and Development, USEPA, Washington, DC to Alan B. Hais, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, USEPA, Washington, DC, April 2002.

USEPA, 1985. Health Assessment Document for Polychlorinated Dibenzo-p-Dioxins. EPA/600/8–84/014F. Final Report. Office of Health and Environmental Assessment. Washington, DC. September, 1985.

USEPA, 1990. National Sewage Sludge Survey; Availability of Information and Data, and Anticipated Impacts on Proposed Regulations; Proposed Rule. **Federal Register** 55 (218): 47210–47283.

USEPA. 1995. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Human Health. Washington, D.C. EPA–820–B–95–006. Office of Water.

USEPA. 1996. Technical Support Document for the Round Two Sewage Sludge Pollutants. EPA–822–R–96–003. Office of Water. Washington, DC. August 1996.

USEPA. 1997. Exposure Factors Handbook. National Center for Environmental Assessment. Washington, DC. EPA/600/P–95/002F(a–c). Vol. I: 208 pp. Vol. II: 336 pp. Vol. III: 340 pp. Also available at NTIS (Vol. I PB98–124225, Vol. II PB98–124233, Vol. III PB98–124241, The Set PB98–124217). See also *http://www.epa.gov/ncea/exposfac.htm.*

USEPA. 1998. Guidelines for Ecological Assessment (Final). EPA/630/R–95/002F. Risk Assessment Forum. Washington, DC.

USEPA. 2000. Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Part III: Integrated Summary and Risk Characterization for 2,3,7,8–Tetrachorodibenzo-p-Dioxin (TCDD) and Related Compounds (SAB Review Draft). EPA/600/P–00/001Bg. Prepared by the National Center for Environmental Assessment, Office of Research and Development, Washington, DC. September 2000. Available online at *http://www.epa.gov/ncea.*

USEPA. 2002a. Notice of Data Availability, 67 FR 40554, June 12, 2002.

USEPA. 2002b. Statistical Support Document for the Development of Round 2 Biosolids Use or Disposal Regulations, Office of Science and Technology, Washington, DC.

USEPA, 2003a. Exposure Analysis for Dioxins, Dibenzofurans, and Coplanar Polychlorinated Biphenyls in Sewage Sludge, Technical Background Document, The Office of Water, Washington, DC.

USEPA, 2003b. Highly Exposed Population Background Document, Office of Water, Office of Science and Technology. Washington, DC.

USEPA, 2003c. Response to Public Comments. Office of Science and Technology. Washington, DC.

Van den Berg M, *et al.* 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, and PCDFs for Humans and Wildlife. Environ. Health Perspect. 106(12): 775–792.

Dated: October 17, 2003.

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[FR Doc. 03–26923 Filed 10–23–03; 8:45 am]

BILLING CODE 6560–50–P