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Part IV

Environmental Protection Agency

Standards for the Use or Disposal of Sewage Sludge; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7120–5]

Standards for the Use or Disposal of Sewage Sludge

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is giving 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 at a surface disposal site or incinerated in a sewage sludge incinerator. In December 1999, EPA proposed to amend the Standards for the Use or Disposal of Sewage Sludge to limit dioxin and dioxin-like compounds in sewage sludge that is applied to the land. In that proposal, EPA also stated that the Agency was not proposing amendments to add numeric standards or management practice requirements for dioxins in sewage sludge that is placed in a surface disposal unit or incinerated in a sewage sludge incinerator. Final action on the proposal to amend the Standards for the Use or Disposal of Sewage Sludge for sewage sludge which is applied to the land will be published separately at a later date.

FOR FURTHER INFORMATION CONTACT: Arleen Plunkett, U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division (4304), 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. (202) 260–3418. *plunkett.arleen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Affected Entities

Entities typically regulated by Standards for the Use or Disposal of Sewage Sludge are those that prepare sewage sludge 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. Categories and entities affected by 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, that prepare sewage sludge and/or dispose of sewage sludge by placement in a surface disposal unit or incineration in a sewage sludge incinerator.
Federal Government	Federal Agencies with treatment works that treat domestic sewage, that prepare sewage sludge and/or dispose of sewage sludge by placement in a surface disposal unit or incineration in a sewage sludge incinerator.
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 disposed in a surface disposal unit or incinerated in a sewage sludge incinerator.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities affected by today's Notice pertaining to Standards for the Use or Disposal of Sewage Sludge.

II. 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 EB 57, 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 (4204), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001.

III. Historical and Legal Background

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 numeric limits and management practices 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 (POTW) or other treatment works treating domestic sewage through any use or disposal practice for which regulations have been established pursuant to section 405 except in compliance with the section 405 regulations.

Amended section 405(d) also established a timetable for the development of the sewage sludge use or disposal regulations. H. Rep. No. 1004, 99th Cong. 2d. Sess. 158 (1986). Section 405(d) calls for two rounds of sewage sludge regulations. In the first round, EPA was to establish numeric 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 was 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. *Whitman*, Civ. No. 89–6266–HO (D. Ore.)). In accordance with the consent decree entered by the court in this case, EPA promulgated the first round of sewage sludge regulations in 1993, 40 CFR part 503. 58 FR 9248 (Feb. 19, 1993) (''Round One''). The consent decree also established a schedule for EPA to identify additional toxic pollutants in sewage sludge and completing the second round of regulation under section 405(d)(2)(B) (''Round Two''). In May 1993, EPA identified 31 pollutants not regulated in Round One that EPA was considering for regulation. In November 1995, EPA notified the court that it was revising the original list of 31 pollutants and considering two pollutant groups for the second round rulemaking: polychlorinated dibenzo-p-dioxins/dibenzofurans (PCDDs/Fs) and dioxin-like coplanar polychlorinated biphenyls (PCBs) (USEPA, 1996a). 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 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. 64 FR 72045 (Dec. 23, 1999).

IV. What Did EPA Propose for Dioxins in Sewage Sludge?

EPA proposed a numeric standard for ''dioxins'' in sewage sludge that is land applied, measured as toxic equivalents (TEQs), and related monitoring, recordkeeping and reporting requirements. EPA proposed a definition of ''dioxins'' to mean 29 specific congeners of polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and coplanar PCBs that have been found in sewage sludge. The proposed definition of ''dioxins'' specifies seven 2,3,7,8,-substituted congeners of polychlorinated dibenzo-p-dioxins (PCDDs), ten 2,3,7,8-substituted congeners of polychlorinated dibenzofurans (PCDFs), and twelve coplanar PCB congeners. See 64 FR 72048–72051 for a full discussion of proposed requirements for land application.

EPA also assessed the risk of exposure to dioxins in sewage sludge that is disposed of by placement in a surface disposal unit or incinerated in a sewage sludge incinerator. EPA concluded that no numerical limits on dioxins or additional management practices are needed for sludge disposed of in either of these manners; i.e., that existing regulation of surface disposal and sewage sludge incinerators is adequate to protect public health and the environment from any reasonably anticipated adverse effects of dioxins. Therefore EPA did not propose any regulatory changes to 40 CFR part 503, subparts C and E.

V. What Final Action Is EPA Taking Today?

EPA is providing final notice of its decision not to regulate dioxins in sewage sludge that is placed in a surface disposal unit or fired in a sewage sludge incinerator. As explained below in sections VI.B. and C., EPA has determined that no further regulation of sewage sludge that is placed in a surface disposal unit or incinerated in a sewage sludge incinerator is needed to protect public health and the environment from any reasonably anticipated adverse effects of dioxins. Therefore, no additional numeric limit, operational standard, or monitoring requirements are currently being established.

EPA will address at a later time the proposed provisions related to dioxin and dioxin-like compounds in sewage sludge that is land applied.

VI. Risk Assessment Methodologies and Results

A. Approach and Assumptions in EPA's Risk Assessments for Exposure to Dioxins Resulting From Surface Disposal and Incineration

As we explained in the proposal, EPA conducted separate risk assessments for surface disposal of sewage sludge and incineration of sewage sludge in a sewage sludge incinerator. (64 FR 72051–72055). The four steps of the risk assessment process include hazard identification, dose-response assessment, exposure assessment, and risk characterization. Both risk assessments used similar hazard identification and dose-response data and assumptions. However, the risk assessments examined different exposure pathways and have different risk characterizations. The following presents an overview of the approaches used for these risk analyses.

Today's final action is based on assessments of the risks to human health posed by dioxins that are in surface-disposed sewage sludge or sewage sludge incinerator emissions.[1] The hazard identified for these risk assessments is cancer as a human health endpoint from the compounds assessed. We took into account the impacts on human cancer risk nationwide. We examined the cancer risk of 2,3,7,8–TCDD and estimated several dose-response relationships for this congener (USEPA, 1994). The cancer risk of the other congeners included in the risk assessment are expressed in relation to the cancer risk of 2,3,7,8–TCDD (USEPA, 1994).

The risk assessments for the proposal evaluated cancer as the human health risk using the 1985 cancer slope factor for dioxin (USEPA, 1994). Because the Agency's Dioxin Reassessment has not yet been finalized, the final determination for surface disposal and incineration continues to be based on evaluation of cancer risk applying the 1985 cancer slope factor. Our conclusions on the protection of human health that support this no action decision would be the same even if we considered the 2000 Draft Dioxin Reassessment (USEPA, 2000a), since use of the pertinent information from the Draft Reassessment would increase the risks only slightly.

Regarding exposure pathways, our evaluation of surface disposal of sewage sludge considered the human health risks associated with drinking ground water contaminated by dioxins and breathing air containing volatilized dioxins. For incineration in a sewage sludge incinerator, we evaluated human exposure to dioxins directly through inhalation of gases and particles in the emissions from sewage sludge incinerators, and indirectly by consumption of crops and animal products produced on agricultural lands and home gardens affected by the

[1] Of the approximately 6.9 million dry metric tons produced annually in the United States, we estimate that less than two percent is placed in sewage sludge-only surface disposal units, and 19 percent is fired in sewage sludge incinerators (Bastian, 1997).

deposition of particles from sewage sludge incinerator emissions.

You will find below descriptions of routes of exposure (called the exposure pathways) through surface disposal and incineration of sewage sludge that we assessed. We then calculated risks associated with these pathways by comparing exposures with dose-response information for the pollutants.

B. Description of Surface Disposal Risk Assessment

We performed an exposure assessment in order to estimate the risk to humans from surface disposal of sewage sludge containing dioxins. In this exposure assessment we identified the population that may be exposed, determined the routes through which exposure to dioxins may occur, and estimated the magnitude, duration, and timing of dioxin doses that people may receive. This procedure resulted in a distribution of predicted individual exposures. We used this distribution of individual exposures to determine the types of individuals who may be at highest risk as well as those with average (''central tendency'') risks. High-end assumptions are intended to estimate risks that are expected to occur in small but definable ''high end'' portions of the subject population. This means that exposure is above the 90th percentile exposure in a population, but not higher than the individual in the population who has the highest exposure. To estimate high-end risk, we used some high-end parameters and some central tendency parameters. The central estimate of individual exposure was based on either the arithmetic mean or the median exposure. In addition to individual descriptors, we also estimated population risk to obtain an estimate of the number of health effects that might be expected in the population over a specific time period.

1. Overview of Risk Assessment Methodology for Surface Disposal

This risk assessment methodology focused on the last two steps of the risk assessment process, exposure assessment and risk characterization. The hazard identification and dose-response assessment portions of the risk assessment were taken from the External Review Draft Dioxin Reassessment Document (USEPA, 1994).

The purpose of this analysis was to estimate the total concentration of dioxins, furans, and coplanar PCBs that can be present in sewage sludge and still be protective of human health when sewage sludge is managed by surface disposal in monofills (i.e., sludge-only landfills) or surface impoundments. In order to assess the potential exposures from dioxins in sewage sludge placed in a surface disposal unit, we characterized the management practices associated with surface disposal facilities. This included ascertaining the environmental settings where surface disposal of sewage sludge may occur and identifying scenarios under which contaminants in sewage sludge may be transported through the environment to a human receptor.

We considered two possible exposure pathways: volatilization of dioxins from the surface disposal facility with subsequent inhalation of these pollutants and the leaching of dioxins to groundwater with subsequent consumption of this groundwater. Based on the general requirements and management practices for surface disposal under subpart C of the 40 CFR part 503 standards and the fact that dioxin congeners have an extremely low water solubility, we concluded that there is an insignificant chance that dioxins would be released to groundwater or surface water even during extreme wet weather conditions. Part 503, subpart C includes management practices designed to prevent groundwater and surface water contamination. For example, 40 CFR 503.24(d) prohibits the siting of an active sewage sludge surface disposal unit within 60 meters of an active seismic fault to prevent or significantly mitigate contamination of groundwater as a result of seismic events. These management practices also include requirements that prevent or significantly mitigate contamination of surface water. 40 CFR 503.24(b), (g). These requirements specify that an active sewage sludge surface disposal unit shall not restrict the flow of a base flood; runoff from an active sewage sludge unit shall be collected and disposed under applicable requirements; and the runoff collection system employed for the active sewage sludge unit shall have the capacity to handle runoff from a 24 hour, 25 year storm event. These requirements in part 503, subpart C for surface disposal units, therefore, serve to either prevent or significantly mitigate dioxin transport to and subsequent contamination of groundwater and surface waters.

2. Key Assumptions for the Surface Disposal Risk Assessment

There are two principal configurations used for surface disposal today (USEPA, 1990). We considered each to determine which had the highest potential for dioxin exposure to the modeled population. We then modeled the worse case (USEPA, 1999a).

The first surface disposal configuration that we considered is a monofill that is an unlined, sewage sludge-only trench fill receiving dewatered sludge with a solids content greater than 20%. Operating procedures for monofills established in 40 CFR 503.25 require vector control, which may include application of daily cover, and § 503.22 requires a written closure and post closure plan, including final cover provisions.

The second surface disposal configuration that we considered is a surface impoundment for which we assumed a continuous inflow of sewage sludge with a solids content of between 2% and 5%. For surface impoundments, a vertical outflow pipe maintained the surface liquid level at a constant height, and liquid was assumed to leave the impoundment both in the outflow (possibly for return to the treatment works) and in seepage through the floor of the impoundment. Over time, particulate settling would occur and a denser layer of solids accumulated on the floor of the impoundment. Eventually, this layer of solids reached the top of the impoundment and no further inflow was possible.

In order to assess the maximum level of risk for the surface disposal, surface impoundments were the modeled configuration. Surface impoundments are considered to be the worse of the two cases for dioxin transport and subsequent human exposure for the following reasons. With respect to exposure from volatilized dioxins, we assumed that, unlike monofills, there was no daily cover applied to the surface impoundment to reduce volatilization of dioxins to the ambient air. However, upon closure, we assumed that the surface impoundment was covered under the applicable requirements of part 503, subpart C. Pollutants, including dioxins, also can more readily leach to groundwater from surface impoundments than from monofills. This results from a greater hydraulic head in surface impoundments to transfer pollutants through the bottom of the unit.

Our exposure evaluation and risk assessment for surface impoundments (USEPA, 1999a) concluded that there is an insufficient flux of dioxins to ambient air from volatilization and to groundwater from leaching to result in a significant risk to exposed individuals. Therefore, placement of sewage sludge in a monofill also was determined not to result in a significant risk from dioxins to exposed individuals.

The following were the major assumptions used in the surface disposal risk assessment:

—Pollutant mass was assumed to enter the surface impoundment through continuous inflow of sewage sludge and leave through four loss processes: degradation within the impoundment; seepage through the floor; liquid overflow to a treatment facility; and volatilization.
—Rates of pollutant loss (including volatilization) were assumed to be ''first-order'' (i.e., the higher the concentration of the pollutant, the greater the rate of loss).
—Pollutants were assumed to be either attached to the surface of the sludge particles or dissolved in the surrounding water and to be at equilibrium (i.e., in a state of balance between the liquid and solid phases).
—Rates of pollutant transfer and loss when the impoundment is half-filled with solids were assumed to be typical of the surface impoundment both before and after it fills with sewage sludge.

3. Surface Disposal Risk Characterization

We found that the risks to human health from the surface disposal of sewage sludge to be extremely small. The incremental cancer risk to a highly exposed individual (i.e., ''high end'' risk) did not exceed 3.5 in ten million (3.5×10^{-7}) for either exposure pathway (USEPA, 1999a). Dioxins have extremely low volatility and would not be expected to offer significant exposure through inhalation. Also, dioxins do not dissolve readily in water. Even in the absence of a liner, combined with high porosity soil and a short distance to ground waters, only insignificant amounts of dioxins could ever reach the groundwater. For these reasons, we conclude that no action to regulate dioxins for sewage sludge surface disposal is necessary.

The surface disposal risk assessment supporting the proposal for no action did not explicitly consider cancer risks based on infant or childhood exposures. Based on the overall low cancer risk estimated for surface disposal of sewage sludge in that risk assessment which supports this final action, EPA has concluded that the cancer risk to infants and children due to exposure to dioxins from surface-disposed sewage sludge is not expected to be significant.

The surface disposal risk assessment also did not explicitly consider ecological risks. Surface disposal units are sited, designed, operated, and maintained to contain and isolate sewage sludge in order to minimize or eliminate exposure to humans and other organisms. The human health risk assessment that was performed for surface disposal units identified only two relevant exposure pathways for receptor populations: volatilization of dioxins to the atmosphere and leaching to groundwater. The summed exposures and subsequent incremental cancer risk estimated for dioxins from these two pathways to the modeled highly exposed human populations were very low (i.e., 3.5×10^{-7}). As already noted, dioxins have low volatility which results in insignificant volatilization. Dioxins also are extremely hydrophobic (i.e., do not readily dissolve in water), which likewise results in minimal leaching to groundwater and subsequent transport to surface waters to impact aquatic organisms. Based on the properties of dioxins and the design and operational characteristics of the disposal units, only an insignificant quantity of dioxins could move to the surrounding media to expose humans and other species. In addition dioxins exhibit similar mechanisms of toxicity across vertebrate species, including humans (USEPA 2000a). Therefore, while ecological impacts could not be predicted, we assumed that the results of the sewage sludge risk assessments that protect humans are also generally protective for ecological species.

In sum, EPA concluded that existing regulations are adequate to protect public health and the environment from the reasonably anticipated adverse effects of dioxins in sewage sludge that is surface-disposed.

C. Description of Incineration Risk Assessment

We used four steps to estimate risks from firing sewage sludge in sewage sludge incinerators (USEPA, 2000b). First, we estimated the rate at which pollutants are emitted from incinerator stacks. Next, we estimated the movement of pollutants in air near incinerators, including estimates of how much pollutant plumes overlap. We then overlaid maps of expected ground-level concentrations of pollutants and human populations. Finally, we determined the extent and nature of resulting health risks of human exposure to emitted dioxins.

The last step was accomplished by performing a multi-pathway risk assessment for exposure to dioxins that result from the firing of sewage sludge in a sewage sludge incinerator. The risk assessment estimated hypothetical average and high end risks to the highly-exposed sub-populations of farmers and home gardeners. We evaluated the risk to the hypothetical highly-exposed individual who is exposed by both a direct route (*e.g.*, inhalation) and indirect routes (*e.g.,* eating contaminated food). In addition, we conducted a probabilistic analysis to estimate the range of risks for home gardeners and farmers impacted by the modeled facilities and to quantify the uncertainty associated with these estimates.

In response to peer review comments, EPA corrected an emission rate for one sewage sludge incinerator and recalculated risks. We also combined the risk assessment and the risk characterization into a single document (USEPA, 2000b). Finally, we clarified the discussion and explanation of the multi-pathway exposure and risk model that was used in this risk assessment.

We considered multiple hearth units without afterburners to be the worst case technology for sewage sludge incineration and likely the highest emitters of dioxins and coplanar PCBs. The analysis focused on the six highest emitting incinerators for dioxins/dibenzofurans and coplanar PCBs from an initial screening of 135 incinerators so as to provide a high end to a bounding estimate of the risk from sewage sludge incineration.

1. Overview of Risk Assessment Methodology for Incineration

The assessment considered 15 exposure pathways. We evaluated those pathways expected to result in the highest risk estimates for which data were available. We selected two exposure scenarios to represent highly-exposed sub-populations that reside near sewage sludge incinerators: (1) Beef and dairy farmers consuming home produced meat, dairy and crops and, at recreational fisher levels, fish caught near sewage sludge incinerators; and (2) home gardeners consuming home-grown produce grown near a sewage sludge incinerator as a portion of their diet. For both scenarios, we estimated average and high end exposures for children and adults at locations where they are expected to reside. We used a geographical information system to identify land uses and terrain around facilities, to identify watershed and water body parameters for estimating fish and drinking water ingestion risks, and to provide census information about farmers and residents exposed to incinerator emissions. We estimated the numbers of individuals exposed and the associated risks for six population age groups.

2. Key Assumptions for the Incineration Risk Assessment

Many important factors in estimating exposure vary from facility to facility. As a result, the highest emitting facility will not always produce the highest risk. We therefore selected the six highest emitting incinerators that also resulted in the highest potential inhalation exposures from the initial screening assessment of 135 incinerators. The variables that are important for exposure assessment and considered in the screen include, for example, distance to exposed population, activities of the exposed population, effective release height of pollutants, and meteorological conditions. We also considered emission rates, emission release characteristics, and actual populations near the facilities in the initial screening assessment.

To address high end risk, plausible ranges of values for key exposure and model variables were modeled using Monte Carlo procedures. This analysis estimated the range of possible risk values and their probability of occurring. The variables considered for the Monte Carlo modeling were identified by sensitivity analyses. The variables were exposure duration, beef and dairy consumption, beef and dairy biotransfer factors, air to plant transfer, dry sludge throughput, adult inhalation rate, and fraction of time an adult is indoors and outdoors.

The large number of exposure values used in the risk assessment are shown in appendix B of the Technical Support Document for incineration (USEPA, 2000b). Unless otherwise noted in the Technical Support Document, the source of the exposure values used in the incineration risk assessment is the EPA Exposure Factors Handbook (USEPA, 1997). The following is a summary of a few key values:

- Adult body weight is 71.8 kilograms (kg).
- Body weight of a 3–5 year old is 17.5 kg.
- Exposure duration for the farmer is 17.3 years.
- Exposure duration for the home gardener is 12 years.
- Adult inhalation rate is 13.3 cubic meters each day.
- Child 3–5 years old inhalation rate is 8.3 cubic meters each day.
- Child daily soil ingestion rate is 0.1 grams each day.
- Adult daily soil ingestion rate is 0.05 grams each day.
- Adult daily fish ingestion rate is 0.162 grams per kg. body weight per day.

For the farmer exposure pathway, we evaluated the inhalation of vapor and particle-bound pollutants released from the incinerator stack(s), soil ingestion, ingestion of homegrown fruits and vegetables, ingestion of home-produced beef and dairy products, ingestion of drinking water from nearby surface water bodies, and ingestion of fish at recreational fisher levels from those water bodies. The home gardener pathway included inhalation of vapor and particle-bound pollutants, soil ingestion, ingestion of homegrown fruits and vegetables, and ingestion of drinking water from surface water bodies. For infants in both home gardener and farm families, breast milk ingestion from an exposed mother also is included. Dermal exposure to soil and water, and consumption of other animal products were not quantified since exposures from these pathways are expected to be significantly less than the pathways evaluated.

Cancer risks due to infant and childhood exposures were calculated as a part of the multi-pathway sewage sludge incineration risk assessment. Risks were estimated for infants and children aged: less than one year, 1–2 years, 3–5 years, 6–11 years, and 12–17 years for both the home gardener and the farmer/recreational fisher exposure scenarios. The infant age group also included exposure via breast milk ingestion. In all scenarios modeled for infants and children, the estimated lifetime cancer risks were similar to those modeled for adults, and were less than or equal to 1×10^{-6}.

3. Incineration Risk Characterization

We found that average and high-end risks were about the same for farmers and home gardeners. However, estimated risks were higher for receptors closer to the facility than farther away in both groups. The most significant pathway for the farmer was ingestion of home-grown beef and dairy products and was ingestion of home-grown produce for the home gardener. At locations where farmers and home gardeners are likely to reside near the six assessed facilities, potential risks ranged from 1×10^{-8} to 1×10^{-6} for farmers, and from 4×10^{-8} to 1×10^{-6} for gardeners. For infants of farmers, the highest estimated risks for the breast milk ingestion pathway were 2×10^{-8}, and were 5×10^{-8} for infants of home gardeners. These risks are at or below the Agency's acceptable risk range of 1×10^{-6} to 1×10^{-4}. Furthermore, based on census data, an extremely small numbers of farmers are predicted to be exposed to risk levels near the upper end of the predicted range. The risk assessment estimates that the average and high-end risks for highly exposed sub-populations in the proximity of the six largest dioxin emitters are at or below the range of acceptable risks.

Additionally, the concentration of dioxins in sewage sludge fed into sewage sludge incinerators does not influence the amounts of dioxins being emitted from the incinerator. The key factors influencing the amount of dioxins being emitted are the combustion conditions in the incinerator, incinerator design, and the efficiency and operational conditions of any air pollution control devices used on the incinerator. The Agency's Dioxin Source Inventory (USEPA, 2001a) estimated that total dioxins (chlorinated dioxins and chlorinated dibenzofurans only) being emitted from all of the Nation's sewage sludge incinerators was approximately 14.8 g. TEQ per year in 1995, a very minor fraction of the total North American dioxin inventory, which was 3255 g. TEQ per year as of 1995. The amount of dioxins emitted from sewage sludge incinerators is expected to be further reduced as the self-implementing means to meet the requirement for all sewage sludge incinerators to comply with either 100 parts per million (ppm) total hydrocarbons (THC) or 100 ppm carbon dioxide (CO) in their emissions are implemented. 40 CFR 503.45, 64 FR 42552, 42560 (Aug. 4, 1999).

We reviewed plans for any future changes for the six multiple hearth incinerators used in our risk assessment to determine if any significant reductions in emissions of dioxin and dioxin-like compounds might be expected in the future. The operators of three of the six incineration facilities indicated that no changes that might reduce emissions were planned in the foreseeable future. These facilities are currently meeting the total hydrocarbon emission limitation of 100 ppm.

One facility started up a new fluidized bed incinerator in June 2000, replacing two existing multiple hearth incinerators. One of the two existing multiple hearth incinerators will remain as a backup incinerator, with only occasional use. Testing of fluidized bed incinerators has demonstrated more complete destruction of organic compounds than in multiple hearth incinerators (USEPA, 1992). Another facility has shut down its incineration operation completely and is drying their sewage sludge instead.

The operator of the largest and highest emitting of the incineration facilities plans to start eliminating incineration of sewage sludge in their multiple hearth incinerators over the next three to four years. This facility plans to use a new high temperature process to convert sludge to a glass-like aggregate. An initial evaluation indicates that the aggregate process is cost-effective. The facility operator expects to submit a permit application within the next year to build the first aggregate unit. If this initial unit is successful, the operator will submit another permit application to build additional units to replace the entire multiple hearth incineration facility. However, if the new aggregate process does not prove feasible, then this facility will continue to use the existing multiple hearth incinerators. The facility operator also may consider building fluidized bed incinerators to start replacing the aging multiple hearth incinerators.

EPA promulgated amendments to the incineration subpart of the Part 503 standards on August 4, 1999 (64 FR 42551–42573). These amendments included a provision making all sewage sludge incineration requirements self-implementing. All incinerator owners/operators must now continuously monitor for either THC or CO emissions and operate their incinerators to limit either THC or CO emissions to 100 ppm or less (40 CFR 503.40, 503.44, 503.45 (a)). We will continue to inspect the operations and records of these incinerators to assure attainment of the THC or CO limits.

The exposure and risk assessments performed for dioxins from sewage sludge incinerators estimated very low exposure and subsequent incremental cancer risk (i.e., 1×10^{-6}) to the modeled highly exposed human population. This small incremental dioxin exposure from incineration of sewage sludge predicts that contamination of surrounding environmental media such as soils, surface water, and sediments is also small. On this basis, we concluded that sewage sludge incineration also would not appreciably increase dioxin concentrations in surrounding environmental media. In addition, dioxins exhibit similar mechanisms of toxicity across vertebrate species, including humans (USEPA 2000a). For these reasons, we would not expect ecological species to suffer adverse effects due to dioxins from sewage sludge incineration.

In making our final decision, we considered the results of the completed risk assessment for dioxins emissions from sewage sludge incinerators, the comments to our proposal not to set national standards for dioxin and dioxin-like compounds for sewage sludge incinerators, and the projected reductions of dioxin and dioxin-like compounds in emissions from sewage sludge incinerators. Based on the results summarized above, we conclude that no further regulatory action is needed to protect public health and the environment from adverse effects from dioxins in sewage sludge fired in a sewage sludge incinerator.

VII. Summary of Public Comments and EPA Responses

EPA received over 200 comments on the proposed amendments to the Standards for the Use and Disposal of Sewage Sludge. The majority of these comments concerned the proposed amendments to 40 CFR part 503, subpart B, land application of sewage sludge. EPA will address those comments when the Agency takes final action on the proposed amendments to subpart B of part 503. Today's final action concerns only the surface disposal and sewage sludge incinerator portions of part 503, found in subparts C and E. EPA's decision not to regulate dioxins in sewage sludge that is placed in a surface disposal unit is based in part on discrete portions of the risk assessment for land application. Regarding comments on the risk assessment, EPA is responding to those comments that relate directly to surface disposal as part of today's final action.

A. Major Comments Applicable to Both Surface Disposal and Incineration

We received relatively few comments on our proposal not to directly regulate dioxin and dioxin-like compounds in sewage sludge disposed in surface disposal and sewage sludge incineration facilities. The most prevalent comment that we received was overall support for the Agency's proposal not to further regulate dioxins for sewage sludge-only surface disposal units and incinerators. This group of commenters included a number of municipalities and treatment works associations, a sewage sludge processing company and a trade association. These commenters agreed that the risk to human health from dioxins in sewage sludge disposed in these types of facilities was very small and did not warrant setting limits. One municipality which supported the proposal not to further regulate surface disposal and incineration suggested that this decision be supported with a risk assessment similar to the risk assessment conducted for land application. This commenter apparently was unaware that comparable risk assessments which evaluated the appropriate exposure pathways for these management practices were conducted to support the Agency's proposal not to further regulate surface disposal and incineration.

A comment from a public policy institute stated that the decision not to regulate dioxins in sewage sludge disposed of by surface disposal and incineration is unacceptable because dioxin has been linked to health effects other than cancer. The commenter suggested that we evaluate other health effects, particularly reproductive and developmental toxicity. A comment from an environmental advocacy organization expressed a similar concern specifically about the incineration decision. We agree that other significant health effects may be associated with dioxin and dioxin-like compounds, but existing methodologies are not available to develop probabilistic estimates of human health non-cancer risks or to determine levels that would be without risk. Because the predicted cancer risk for dioxin is so low (i.e., 10^{-6} or less), we believe that existing regulations for surface disposal and sewage sludge incineration are adequate to protect public health from both cancer and non-cancer effects.

One State commenter asked if there is a connection between these actions not to regulate sewage sludge surface disposal and incinerators, and the effluent guidelines and standards for landfills at 40 CFR part 445. There is no connection intended or implied by the Agency.

B. Major Comments on Surface Disposal

One treatment authority stated that dioxin limits should be set for surface disposal sites which are operated similarly to land application sites (i.e., for cattle grazing and food crop production). We are aware of only two surface disposal sites which are operated in this manner. The current part 503 regulation addresses this situation: § 503.24(k) and (l) prohibit growing crops or grazing animals on active surface disposal sites ''unless the owner/operator * * * demonstrates to the permitting authority that through management practices public health and the environment are protected from any reasonably anticipated adverse effects of pollutants in sewage sludge * * *.''

A comment from an environmental advocacy group expressed concern that dioxins may become soluble and contaminate ground water when in the presence of solvents and surfactants, also found in sewage sludge. Data from the National Sewage Sludge Survey, which analyzed for more than 400 chemicals, indicate that the concentrations of solvents and surfactants in sewage sludge are relatively small (USEPA 1990). On this basis, we assumed that solubilization of dioxin and dioxin-like compounds by solvents and surfactants in sewage sludge would not be significant.

C. Major Comments on Incineration

A comment from a public policy institute noted that we gave no explanation for our use of different assumptions for soil ingestion by children in risk assessments for incineration and land application to support our proposals (0.1 grams/day and 0.4 grams/day, respectively.) The apparent difference in the two values is attributable to the different approaches incorporated in the risk assessments for the land application and incineration proposals. The land application proposal was supported by a deterministic risk assessment for which single point values are assumed for various input parameters. The commenter is correct that the land application risk assessment for the proposal assumed 0.4 grams/day for soil ingestion by children. For incinerator risk assessment, we conducted a probabilistic analysis that uses distributions of values for exposure variables where a range of data is available, including soil ingestion by children. This distribution included low end values, mid-range values, and high end values. Soil ingestion by children at a rate 0.1 grams/day is the mean value and 0.4 grams/day is a high end value.

This commenter also stated that no additional dioxin exposure to humans should be allowed as a result of sewage sludge incineration. A comment from an environmental advocacy organization expressed a similar concern. We agree with the principle that additional exposure to dioxin should be minimized and are concentrating our resources on reducing the emissions from the sources which have the highest dioxin emissions in order to achieve this reduction. The total annual dioxins emitted from sewage sludge incinerators are very small in comparison to other sources (USEPA, 2001). Furthermore, based on the very low predicted risk, we are confident that no further regulatory action is necessary.

Another comment from the same public policy institute questioned EPA's finding that the estimated risks were higher for individuals close to a sewage sludge incinerator than those farther away since dioxins can travel more than 100 miles from their source. We agree that dioxins can travel for extended distances from the source, but disagree that the risks would be the same or higher for individuals farther away from the source. Our assessment estimated close-in risks as well as risks out to 30 miles. The assessment estimated risks at locations where individuals are likely to be found and calculated risks at sites of maximum exposure whether or not people are at these sites. The assessment looked at risk from inhalation as well as ingestion of food and water. In all cases the estimated risks were not significant (USEPA, 2000b).

Finally, this commenter expressed concern that if sewage sludge incinerators are upgraded as EPA is predicting, the ash from these incinerators will become even more toxic and hazardous to land apply. This concern appears to be based on the assumption that dioxins that are removed from the air emissions will be recycled in the fly and bottom ash from the incinerator. The upgrades for multiple hearth incinerators are designed to destroy dioxin-like compounds by increasing the temperature and time of exposure of emissions exiting from the multiple hearth incinerators. Fly ash collected by particulate collection systems have been exposed to the increased temperature and time conditions before their collection. Thus not only are the stack emissions of dioxin-like compounds greatly reduced, but any dioxin-like compounds contained in the fly ash is greatly reduced. In addition, the bottom ash from multiple hearth incinerators is not affected by the installation of air pollution equipment on the exit gas stream. In the situation where a multiple hearth incinerator is replaced with a fluidized bed incinerator, the net production of dioxin-like compounds in a fluidized bed combustion chamber has been demonstrated to be an order of magnitude less than that occurring in a multiple hearth incinerator. Thus the replacement of a multiple hearth incinerators with a fluidized bed incinerator will reduce the dioxin-like compounds in both the stack emissions and in the ash removed from the fluidized bed incinerator.

A public interest group contended that the incinerator risk assessment looks only at inhalation exposures. The commenter stated that the major issue with dioxin emissions from incinerators is not inhalation but deposition to the soil, crops, and water in the neighboring area. The commenter believes that without including data on increased generation and/or deposition of particulates due to sludge burning, the incineration risk analysis fails to adequately address the dangers posed to nearby residents from the combination of dietary impacts and inhalation factors. In response, the Agency notes that, as described above, the incineration risk assessment estimated risks from both direct inhalation and ingestion of substances impacted by deposition of incinerator emissions. The ingestion scenarios included ingestion of beef and dairy products, fish, and vegetables by children and adults, and soil ingestion by children.

A comment from an environmental advocacy group raised a number of concerns about deficiencies in the risk model EPA used in developing the proposal for incineration, including: protection of children and fetuses; use of deterministic methods instead of probabilistic methods; consideration of synergistic effects of pollutant exposures; consideration of ecological impacts; and background levels of human exposure to dioxins.

Cancer risks due to infant and childhood exposures were calculated as a part of the multi-pathway sewage sludge incineration risk assessment. Risks were estimated for infants and children aged: Less than one year, 1–2 years, 3–5 years, 6–11 years, and 12–17 years for both the home gardener and the farmer/recreational fisher exposure scenarios. The infant age group also included exposure via breast milk ingestion. In all scenarios modeled for infants and children, the estimated lifetime cancer risks were similar to those modeled for adults, and were less than or equal to 1×10^{-6}.

The incineration risk assessment was deterministic in approach. However, probabilistic methods and data distributions formed the second part of the risk assessment. This probabilistic component served as a sensitivity instrument and was used to select the most appropriate input values for the deterministic model runs. Finally, this risk assessment was subjected to external peer review. This review found that the risk assessment was scientifically sound.

At the present time, there is no method for evaluating synergistic health effects from exposure to pollutants with different mechanisms or modes of toxicity.

The exposure and risk assessments performed for dioxins from sewage sludge incinerators estimated very low exposure and subsequent incremental cancer risk (i.e., 1×10^{-6}) to the modeled highly exposed human population. This small incremental dioxin exposure from incineration of sewage sludge predicts that contamination of surrounding environmental media such as soils, surface water, and sediments is also small. On this basis, we concluded that sewage sludge incineration also would not appreciably increase dioxin concentrations in surrounding environmental media. In addition, dioxins exhibit similar mechanisms of toxicity across vertebrate species, including humans. For these reasons, we would not expect ecological species to suffer adverse effects due to dioxins from sewage sludge incineration.

Our decision was based on the incremental exposure to dioxins from incineration of sewage sludge, in line with Agency procedures for assessing cancer risks. However, EPA did consider background levels of exposure to dioxins in making this decision. We compared the incremental dioxin exposure from sewage sludge incineration to background dioxin exposure and concluded that no further regulatory action is needed to protect public health.

A treatment works association commenter agreed with the proposed decision not to regulate dioxin emissions from sewage sludge incinerators, but expressed concerns that the complex modeling used in the incineration risk assessments had not been adequately peer-reviewed, has largely not been verified, and has not been subjected to rigorous quality control measures. This commenter stated that most of the references for the modeling performed in the risk assessment have not themselves been peer-reviewed, and that adequate evaluation of such complex modeling requires a longer period than the 90 days allotted for public comments. We agree that the complex models were not individually peer-reviewed prior to proposal. However the entire incineration risk assessment using these models was peer-reviewed and appropriately revised prior to making our final determination. Furthermore, the verification to date shows that the models perform reasonably well for dioxins and furans (Lorber, *et. al.,* 2000). We are currently conducting a lengthy peer review and extensive model verification for an updated multi-pathway model (the Total Risk Integrated Methodology—TRIM) that will eventually replace the multi-pathway model used in the incinerator risk assessment. The models used in the risk assessment for sewage sludge incinerators are the best available at this time and adequate for purposes of this action. We also note that the comment period was originally 60 days, and EPA was requested to extend the comment period to allow for more time to review the technical support documents. EPA agreed and reopened the comment for an additional 30 days. 65 FR 1278 (March 2, 2000). Consistent with similar Agency actions, we believe that a 90 day comment period was reasonable for this action.

A State environmental agency commented that dioxin emissions from medical waste combustors and solid waste combustors should be further reduced since these are the main sources of air deposition compared to wastewater treatment plants. EPA has issued guidance and regulations for reduction of dioxin emissions from both municipal waste combustors and medical waste incinerators that have already resulted in drastic reductions of dioxin-like compounds. For municipal waste combustors, national emissions of dioxin-like compounds have been reduced from 4,170 g. TEQ per year in 1990 to 40.6 g. TEQ per year in 2000. Continued compliance with current regulations is expected to further reduce emissions to 12 g. TEQ per year by 2005 (USEPA, 1999b). For medical waste incinerators, emissions of dioxin-like compounds have been reduced from 600 g. TEQ per year in 1990 to 150 g. TEQ per year in 2000 and further reductions are expected to drop to 5–7 g. TEQ per year by 2002 (USEPA, 1996b).

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Administrator.

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