

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