

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)<sup>-1</sup>). The greater the numeric value of the cancer slope, the greater the carcinogenic potency of the substance. For example,  $1 \times 10^{-5}$  is greater than the numeric value  $1 \times 10^{-6}$ . 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  $1.56 \times 10^{-4}$  picograms toxic equivalence/kilogram body weight/day ((pg TEQ/kg-d)<sup>-1</sup>) (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  $2 \times 10^{-5}$ , 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 dairy 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 ( $1 \times 10^{-6}$ ) than the 95th percentile risk, which actually overestimates the predicted number of cancer cases for this population group. The estimate of