

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 sewage 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