

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  $6 \times 10^{-5}$  at the 95th exposure percentile and  $6 \times 10^{-6}$  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  $2 \times 10^{-4}$  using the 1985 Q1\* of  $1.56 \times 10^{-4}$  (pg TEQ/kg-d)<sup>-1</sup>. 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  $2 \times 10^{-5}$  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,