

as a reasonable estimate of occupational relative risk for further analysis.

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However, in the absence of a cancer unit risk, the EPA Diesel HAD sought to provide additional insight into the possible ranges of risk that might be present in the population. Such insights, while not confident or definitive, nevertheless contribute to an understanding of the possible public health significance of the lung cancer hazard. The possible risk range analysis was developed by comparing a typical environmental exposure level to a selected range of occupational exposure levels and then proportionally scaling the occupationally observed risks according to the exposure ratio's to obtain an estimate of the possible environmental risk. If the occupational and environmental exposures are similar, the environmental risk would approach the risk seen in the occupational studies whereas a much higher occupational exposure indicates that the environmental risk is lower than the occupational risk. A comparison of environmental and occupational exposures showed that for certain occupations the exposures are similar to environmental exposures while, for others, they differ by a factor of about 200 or more.

The first step in this process is to note that the occupational relative risk of 1.4, or a 40 percent from increased risk compared to the typical 5 percent lung cancer risk in the U.S. population, translates to an increased risk of 2 percent (or 10<sup>-2</sup>) for these diesel

exhaust exposed workers. The Diesel HAD derived a typical nationwide average environmental exposure level of 0.8 ug/m<sup>3</sup> for diesel PM from highway sources for 1996. Diesel PM is a surrogate for diesel exhaust and, as mentioned above, has been classified as a carcinogen by some agencies.

This estimate was based on national exposure modeling; the derivation of this exposure is discussed in detail in the EPA Diesel HAD. The possible risk range in the environment was estimated by taking the relative risks in the occupational setting, EPA selected 1.4 and converting this to absolute risk of 2% and then ratioing this risk by differences in the occupational vs environmental exposures of interest. A number of calculations are needed to accomplish this, and these can be seen in the EPA Diesel HAD. The outcome was that environmental risks from diesel exhaust exposure could range from a low of 10<sup>-4</sup> to 10<sup>-5</sup> or be as high as 10<sup>-3</sup> this being a reflection of the range of occupational exposures that could be associated with the relative and absolute risk levels observed in the occupational studies.

While these risk estimates are exploratory and not intended to provide a definitive characterization of cancer risk, they are useful in gauging the possible range of risk based on reasonable judgement. It is important to note that the possible risks could also be higher or lower and a zero risk cannot be ruled out. Some individuals in the population may have a high tolerance to exposure from diesel exhaust and low cancer susceptibility. Also, one cannot rule out the possibility of a threshold of exposure below which there is no cancer risk, although evidence has not been seen or substantiated on this point.

Also, as discussed in the Diesel HAD, there is a relatively small difference between some occupational settings where increased lung cancer risk is reported and ambient environmental exposures. The potential for small exposure differences underscores the appropriateness of the extrapolation from occupational risk to ambient environmental exposure levels is reasonable and appropriate.

EPA also recently completed an assessment of air toxic emissions (the National-Scale Air Toxics Assessment or NATA) and their associated risk, and we concluded that diesel exhaust ranks with other substances that the national-scale assessment suggests pose the greatest relative risk.<sup>35</sup> This assessment

estimates average population inhalation exposures to diesel PM in 1996 for nonroad as well as on-road sources. These are the sum of ambient levels in various locations weighted by the amount of time people spend in each of the locations. This analysis shows a somewhat higher diesel exposure level than the 0.8 ug/m<sup>3</sup> used to develop the risk perspective in the Diesel HAD. The NATA levels are 1.4 ug/m<sup>3</sup> total with an on-road source contribution of 0.5 ug/m<sup>3</sup> to average nationwide exposure in 1996 and a nonroad source contribution of 0.9 ug/m<sup>3</sup>. The average urban exposure concentration was 1.6 ug/m<sup>3</sup> and the average rural concentration was 0.55 ug/m<sup>3</sup>. In five percent of urban census tracts across the United States, average concentrations were above 4.3 ug/m<sup>3</sup>. The Diesel HAD states that use of the NATA exposure number results instead of the 0.8 ug/m<sup>3</sup> results in a similar risk perspective.

In 2001, EPA completed a rulemaking on mobile source air toxics with a determination that diesel particulate matter and diesel exhaust organic gases be identified as a Mobile Source Air Toxic (MSAT).<sup>36</sup> This determination was based on a draft of the Diesel HAD on which the Clean Air Scientific Advisory Committee of the Science Advisory Board had reached closure. The purpose of the MSAT list is to provide a screening tool that identifies compounds emitted from motor vehicles or their fuels for which further evaluation of emissions controls is appropriate.

In summary, even though EPA does not have a specific carcinogenic potency with which to accurately estimate the carcinogenic impact of diesel PM, the likely hazard to humans at environmental exposure levels leads us to conclude that diesel exhaust emissions of PM and organic gases should be reduced from nonroad engines in order to protect public health.

#### ii. Other Health Effects of Diesel Exhaust

The acute and chronic exposure-related effects of diesel exhaust emissions are also of concern to the Agency. The Diesel HAD established an inhalation Reference Concentration (RfC) specifically based on animal studies of diesel exhaust. An RfC is defined by EPA as "an estimate of a continuous inhalation exposure to the human population, including sensitive subgroups, with uncertainty spanning

<sup>35</sup> U.S. EPA (2002). National-Scale Air Toxics Assessment. This material is available electronically at <http://www.epa.gov/ttn/atw/nata/>.

<sup>36</sup> U.S. EPA (2001). Control of Emissions of Hazardous Air Pollutants from Mobile Sources; Final Rule. 66 FR 17230-17273 (March 29, 2001).