

predictor of the asbestos potency in this production population.

The Henderson and Enterline study. OSHA calculated the value of K_L based on the mortality experience of 1075 retirees from an asbestos products manufacturing plant [Ex. 84-48] by computing the slope of the dose-response relationship from the linear regression ($K_L = 0.0066$). Henderson and Enterline had presented exposure data in terms of total dust measured in millions of particles per cubic foot, and hence a factor was needed to convert from particles to fiber count. OSHA employed the value 1.4 f/ml/mppcf, based on the work of Hammad in cement plants, which gives a best estimate of K_L of 0.0047.

Crump has pointed to what he believes to be "considerable uncertainty in the methods used by OSHA to convert from particles to fibers" [Ex. 237A, p. 14]. Citing the CHAP [Ex. 84-256], he recommends that a conversion factor of 2 should have been employed, giving a K_L of 0.0033. He also notes that "Enterline himself employed a conversion factor of 3.0 [Enterline 1981] [Ex. 84-127]" [Ex. 237A, p. 15]. However, when Dr. Enterline testified before the Ontario Royal Commission in June of 1981, he expressed considerable doubt about the conversion factor of 3, noting "I don't know how anybody comes up with a number like that anyhow" [Ex. 85-2, p. 53]. Enterline also noted that the conversion factor depended on the operation and that "I think, in asbestos cement, maybe that's [3's] the wrong number" [Ex. 85-2, p. 53]. In addition, in the same footnote [Ex. 84-127] cited by Dr. Crump, Dr. Enterline noted that the British Advisory Committee on Asbestos used conversion factors of 1, 2, and 5 f/cc/mppcf and that "the most conservative estimate of response at low doses in terms of protecting the public would result from assuming a low conversion factor" [p. 42]. Whereas CHAP employed a slightly higher conversion factor, it also noted that—

... since follow-up of this group began at age 65, it is essentially a study of a survivor population and as such may have underestimated the maximum relative risk actually experienced by the entire cohort. If this peak relative risk provides the best basis for predicting the long-term experience of individuals exposed at lower levels, then the fitted slope should be increased perhaps by a factor of 2.0 [Ex. 84-256, II-102].

CHAP made such an adjustment in its estimate of the slope, to account for these biases (Ex. 84-256, II-100). Therefore, given the fact that CHAP recommends a value of K_L considerably higher than that put forth by OSHA in the November and April proposals and

since Dr. Crump has suggested a value somewhat lower, OSHA believes that its estimate of 0.0047 for K_L represents a reasonable median estimate of the potency factor for lung cancer in this study population. As noted in Ex. 84-392, however, "A study of a retiree cohort with these characteristics would understate mortality by as much as 62% relative to the maximum observable risk" [p. 30]. Thus accounting for this possible underestimation, and with regard to the variation in possible conversion factors, the range of uncertainty around this value may extend from 0.0022 to 0.0108.

The Finkelstein Study. Finkelstein established a cohort of 241 production and maintenance employees from records of an Ontario asbestos cement factory. OSHA computed a K_L for this cohort based on an average cumulative 18-years exposure of 112.5 f-y/ml for the production workers alone. This group had an SMR of 850, based on 17 observed lung cancer deaths versus 2 expected. These data produced a summary K_L of 0.067 (Ex. 84-392, p. 33). OSHA noted some uncertainties in this estimate, particularly because the two lowest exposure categories show risk increasing steeply with exposure, whereas the highest exposure category showed a cancer rate lower than that of the lowest exposure group. OSHA speculated in the proposal that this inconsistency may be due to the small number of deaths in each category.

Several participants raised the question of the suitability of using this value of K_L in the overall estimate of K_L . In particular, Dr. Crump pointed to the lack of a dose-response relationship for lung cancer in this cohort, quoting the CHAP conclusion that "no sensible dose-response for lung cancer can be inferred from these results" [Ex. 237A, p. 28]. CHAP noted that:

... possible explanations for these results are incorrect exposure estimates and/or very high competing risks for the heavily exposed persons [Ex. 84-256, p. II-111].

It should be noted that CHAP included Finkelstein's study among those categorized in the Level 1 Exposure category, that is, having job histories and industrial hygiene measurements made at the relevant exposure site. Using the entire cohort (both production and maintenance workers), CHAP computed an SMR of 600 (20 observed versus 3.3 expected). Noting reservations about the exposure levels, CHAP gave a K_L of 0.048 of this cohort [(6.08-1)/(105)].

Given the same reservations as expressed by CHAP, OSHA believes 0.048 to be a valid expression of the

potency of exposure to asbestos in this population of asbestos-cement workers, and has lowered its original estimate of K_L to reflect some reservations about the data.

The Dement et al. Study. OSHA calculated a lung cancer potency factor from the study of Dement and his colleagues, who investigated the mortality experience of 768 workers in a chrysotile textile products manufacturing plant. Data from impinger measurements of total dust in terms of mppcf were available since 1930 for exposures in a textile plant using chrysotile [Dement et al., 1982, Ex. 84-35]. Using a factor of 3 to convert from mppcf to f/ml (also used by CHAP), OSHA computed K_L as the slope of the weighted regression of excess SMR on the midpoint of dust levels in f-y/ml. As noted in the November proposal, this produced a value of K_L of 0.042. Participants in the hearing argued that this K_L was overestimated because Dement and his colleagues had overestimated the SMR's by using an inappropriate control group for the calculation of the expected. As OSHA explained in its preliminary risk assessment, Dement et al. employed U.S. national death rates rather than local county rates for computing expected values. The authors noted that:

The choice of an appropriate comparison population for mortality analyses is difficult and arguments could be made for using rates for a set of counties contiguous to the county in which the plant was located. However, there are serious limitations to this approach which were considered in this study and resulted in rejecting the use of local county rate. First, the county in which the plant was located is the site of a large shipyard industry with peak employment of approx. 29,000 persons in 1943 [Blot et al. 1978]. Employees for this industry were largely drawn from the local population. Many of these workers are thought to have been exposed to asbestos during ship construction and repair. In an ecological study Blot et al. (1978) demonstrated an association between county lung cancer rates and shipyard employment. In a more refined case-control study, Blot et al. (1979) demonstrated a summary odds ratio of 1.6 for shipyard employment and lung cancer after adjusting for smoking, other occupations, age, race, and county of residence. These data suggest that lung cancer death rates in the area in which the plant was located are likely to be elevated by local shipyard employment.

A second factor to be considered in choosing local rates for comparison is the effect that the plant being studied might have had on local lung cancer death rates. Because of a lack of an employment record system prior to about 1930, it is difficult to estimate the exact number of persons ever employed at this plant; however, this is likely to exceed 10,000 prior to 1965. Thus [sic] could have a