

significant impact of local lung cancer death rates, assuming an overall lung cancer SMR of 200 or more for these workers.

The effects of shipyard and asbestos plant employment make the use of local death rates inappropriate for this study [Ex. 84-35, p. 879-880].

In addition, state (South Carolina) mortality rates from lung cancer were similar to those of the United States. Moreover, "[A]vailable smoking data for this cohort suggest that the observed lung cancer and nonmalignant mortality excess among white males cannot be explained by cigarette smoking independent of asbestos exposure" [Ex. 84-37, p. 430].

Although Crump pointed to the arguments raised by Acheson and Gardner [Ex. 84-243] that local rates should have been preferred, OSHA found these arguments unconvincing. Crump recommended a K_L of 0.023, approximately half the value of K_L calculated by OSHA. Crump noted that:

... Not only does this modification provide a better fit to the Dement *et al.* data, the estimated background rate agrees closely with the 75% excess of local lung cancer rates over national rates (See Figure 3 of Acheson and Gardner, 1983 [Ex. 84-243]). The lower estimate of $K_L = 0.023$ also reduces the discrepancy between this and other studies which show a much smaller K_L .

OSHA believes that a reduction of the K_L to 0.023 is inconsistent with the available data: First, Dement *et al.* noted that:

... even if rates for contiguous counties had been used ... the expected lung cancer rates for white males would have been increased by only approx. 15%, not nearly sufficient for the observed excess lung cancer risk [Ex. 84-35, p. 880].

Moreover, as Dement pointed out in 1982:

... rates for contiguous counties for black males were approximately 45 percent below U.S. rates; thus, the overall excess, among blacks is underestimated by the present study, although the numbers were small [Ex. 84-229, p. 179].

Thus, to some extent, these overall estimates may be underestimated. Hence, OSHA concludes that its original estimate of K_L for this study, 0.042, is valid and reasonable, and thus has adopted it for the final rule.

C. *Calculation of the Overall K_L* . OSHA's best estimates of K_L for the proposed rule, and the final determination of K_L for each study are given in Table 2, along with a range of uncertainty. The ranges listed are the result of estimates of exposure uncertainties (usually a factor of two), methodological uncertainties that led to alternate evaluations of risk or exposure, or, in some cases, statistical

uncertainties associated with small numbers. In addition to some controversy over the individual K_L 's, there was widespread disagreement as to which studies should ultimately be included in the determination of an overall K_L for lung cancer.

TABLE 2.—ESTIMATES OF K_L FROM PROPOSED RULE AND FINAL DETERMINATION

	Propo-	Final	Range
	posal		
Henderson & Enterline.....	0.0047	0.0047	(.0022-0.011)
Weill <i>et al.</i>	0.0033	0.0033	(0.0016-0.0086)
Finkelstein.....	0.067	0.048	(0.033-0.12)
Peto.....	0.0076	0.0076	(0.0009-0.023)
Dement <i>et al.</i>	0.042	0.042	(0.23-0.21)
Berry and Newhouse.....	0.0206	0.0096	(0-0.0008)
Seidman <i>et al.</i>	0.068	0.045	(.023-.06)
Selkoff <i>et al.</i>	0.020	0.020	(0.008-0.03)
Arithmetic Mean.....	0.027	0.019	
Geometric Mean.....	0.0113	0.01	
Median.....	0.0138	0.0138	

In its preliminary assessment, OSHA used the eight non-mining-and-milling studies to derive an overall estimate of K_L of 0.01. As noted in the November proposal:

Considering the industrial processes other than mining and milling, OSHA believes 0.01 to be a reasonable estimate of K_L . It is the geometric mean and median of the K_L 's derived from studies of asbestos manufacturing and insulation application processes. The geometric mean had the advantage of minimizing the influence of outlying values and a K_L of 0.01 is approximately within one order of magnitude of all the estimates of K_L . In sum, the K_L of 0.01 is a best estimate which contains appropriate recognition of studies with higher and lower values of K_L . It should be noted however, that the uncertainties around this estimate of K_L are such that an appropriate estimate of K_L could lie between 0.003 and 0.03 [48 FR 51125].

The distinct nature of mining-milling data (and hence, the estimate of K_L from these data) has been considered earlier. There is some evidence that risks in the asbestos mining-milling operations are lower than other industrial operations due to differences in fiber size. This differential was discussed by Nicholson [Ex. 303A]. Thus, in determining the best overall value for K_L for the final rule, the data from mining and milling processes were not considered.

OSHA still believes it to be valid to employ the same eight studies it used to derive the estimates for the November and April proposals. As discussed earlier, OSHA modified some of the values of K_L for the final rule. Based upon these revised values, OSHA has determined that the best estimate of K_L is 0.01; the same value derived for the proposals. The values given under the final estimate column in Table 2 have an arithmetic mean of 0.019 and a geometric mean of 0.01. OSHA believes

it has chosen reasonable estimates for the individual K_L 's and has been responsive to the comments made by participants in the hearing. In some cases, OSHA has lowered its original value of the estimate of K_L in light of these comments or the addition of new data indicating such a change was warranted. The end result is that these small changes in individual values have little effect on the overall K_L value. This is most likely due to the Agency's choice of a reasonable K_L for the proposal.

Some scientists have suggested that some asbestos processes such as asbestos textile manufacturing, may pose a greater hazard than other processes. As noted earlier, while mining and milling appear to pose a lesser carcinogenic hazard than manufacturing processes, when OSHA compared the potency factors for lung cancer (K_L) among different studies of different processes, no consistent pattern of differential lung cancer risk by process emerged. Therefore, again, the choice of a midpoint unit risk for all industrial processes is a reasonable and justified choice.

In sum, the K_L of 0.01 is a best estimate which contains appropriate recognition of studies with higher and lower values of K_L . It should be noted, however, that the uncertainties around this estimate of K_L are such that an appropriate estimate of K_L could lie between 0.003 and 0.3.

As discussed earlier, Crump believed that both the Seidman *et al.* and Selkoff *et al.* studies should have been excluded from the calculation of K_L . Along with the other adjustments discussed above, Crump estimated an overall K_L of 0.0085. As Dr. Crump noted in his testimony:

OSHA has developed what I would term an upper limit assessment of asbestos risk. In dealing with uncertainty, OSHA has, in a number of instances, made assumptions that tend to minimize the possibility of underestimating the risk. In addition, the uncertainties in some of their assumptions appear to be underestimated by OSHA. The three most significant assumptions in OSHA's risk assessment that lead to upper limit estimates of risk are the assumptions of: (1) a linear dose-response relationship; (2) the same potency for all forms of asbestos; and (3) attribution of the lung cancer component of risk caused by smoking to the overall risk of asbestos [Ex. 237A, p. 4-5].

However, in addition to Dr. Crump's recommendations, several commenters noted a number of different ways for incorporating the available data into an overall estimate of risk. For example, in his written testimony, Dr. Marvin Schneiderman, who served as a member of CHAP and who was one of the reviewers of OSHA's November