

microscopy for the counting of fibers longer than five micrometers, have been utilized in Great Britain and the United States only since 1964 [Ayer et al., 1985, Ex. 84-253] and have been standardized in the United States only since 1972 [Leidel], 1979, Ex. 84-82] and even later in Great Britain. In any case, sampling has occurred only in a few of the worksites studied, and then only occasionally. In addition, variability in work activities and in sampling circumstances add considerable uncertainty to knowledge of dose.

Some of the epidemiologic studies, including those by Dement et al. [Ex. 84-35], Liddell et al. [Ex. 84-59] and Henderson and Enterline [Ex. 84-48], include measured air concentrations at the exposure site and used job histories of the study population to estimate exposure. In these cases the dose-response curve was calculated by estimating total asbestos exposure (in mppcf-years or in fiber-years/cc) according to the time that an individual spent at a job with a measured exposure. A conversion factor for converting from mppcf to f/cc was employed on a study-by-study basis, depending on the data available. Other epidemiological studies, for example those by Selikoff et al. [Ex. 84-90] and Seidman et al. [Ex. 84-87], did not have direct industrial hygiene measurements for the studied worker population. For these studies, exposure estimates were derived from industrial hygiene surveys of similar work operations and processes for which industrial hygiene data were available.

OSHA has evaluated these differences and has dealt with their implications on a study-by-study basis. Uncertainties associated with these measurements constitute much of the range of variability surrounding the K_L 's. Taken as a whole, the asbestos studies contain data of unusually high quality, which has enabled OSHA to make the risk estimates with a high degree of confidence.

There was considerable discussion during the rulemaking about the individual K_L 's for many of the studies that went into the estimation of the overall lung cancer risk, particularly the inclusion/exclusion of several of the studies in this calculation. The discussion below deals first with the comments on and adjustments to individual K_L 's and then discusses the impact of their inclusion in the overall estimate of lung cancer risk.

The Selikoff et al. and Seidman et al. Studies. Several participants in the hearing criticized OSHA for including the results from the Selikoff et al., 1979 [Ex. 84-87] and Seidman et al., 1979 [Ex.

84-90] studies in the calculation of K_L . The major objection to the use of these studies was the lack of concurrent exposure information on the cohorts. For example, Dr. Crump noted that:

The CPSC (1983) Panel placed these two studies in a separate category because of the weakness of the exposure estimates. The Seidman et al. study also involved brief exposures (less than four years) exclusively, which makes it less suitable than other studies for estimating the effect of long term exposures [Ex. 237A, p. 26].

Dr. Weill also expressed reservations about including the Selikoff et al. and Seidman et al. studies in the overall estimation of risk [Tr. 6/19, p. 184].

Though it is true that CHAP did characterize the Selikoff et al. and Seidman et al. studies as having "Level 2 exposure data" (no job histories or industrial hygiene measurements available for the cohort, exposure estimate made from best available sources), CHAP still computed K_L for these two studies with the information available. And, during cross-examination, Dr. Nicholson, a member of CHAP, indicated that CHAP did not weigh the K_L values from these two studies differently from those in other studies when deriving estimates of the final potency [Tr. 6/19, p. 148]. Dr. Weill emphatically stated that inclusion of the studies in the risk analysis was "not a fatal flaw" [Tr. 6/19, p. 184].

OSHA offered a full description of the exposure data used in these two studies in Exhibit 84-392. Since that time, however, new and more complete information on exposures for the Seidman et al. cohort have come to light which strengthen the case for including the results of the K_L calculation in the overall estimates of risk. This new information is discussed below.

Although no new evidence has been brought forward on the Selikoff et al. study of insulation workers, OSHA still believes it is appropriate to include the K_L from this study in determining the overall level of risk. It is the largest of all the studies (17,800 workers) and also reports the largest number of lung cancer deaths (652) and deaths from mesothelioma (180). Excluding this study would mean excluding 45% of all the asbestos-related lung cancer deaths and 84% of all the mesothelioma deaths from the overall analysis. OSHA believes it would be a serious error to eliminate such a large portion of the available data, when appropriate estimates of the exposure levels of these workers are available.

OSHA calculated the K_L from the Selikoff et al. data based on average values (for duration of exposure, level of exposure and time since onset of

exposure) derived from several sources. Although the use of average data and overall (average) levels of risk may not be as desirable as risks broken down by cumulative exposure, nevertheless, the estimates of K_L from these data are nevertheless valid and reasonable. OSHA predicted a K_L of 0.02 for the cohort, with an uncertainly band of (0.008 to 0.30). The value 0.02 is only twice the best estimate of an overall K_L of 0.01 and falls well within the range of overall uncertainty given for the overall K_L , that is, 0.003 to 0.03. Thus, OSHA has not adjusted the original value of K_L computed for this cohort.

The Seidman et al. Update. During the course of the hearing, the testimony of several witnesses strengthened OSHA's confidence in using results from the Seidman et al. study of 820 insulation manufacturing workers. As discussed in Exhibit 84-392, while no data exist on air concentrations at the time the Paterson factory operated, data do exist on air concentrations in two plants that manufactured the same products with similar fiber and machinery. One of these plants, in Tyler, Texas, opened in 1954 and operated until 1971. The other, in Port Allegheny, Pennsylvania, opened in 1964 and closed in 1972. Similar efforts to control dust in these newer plants were apparently made as were made in the Paterson, New Jersey plant. During 1967, 1970, and 1971, asbestos fiber concentrations in these plants were measured by the U.S. Public Health Service and were published by NIOSH [Ex. 2-12].

Participants in the rulemaking criticized the assumption that these exposure data were representative of the exposure conditions in the Paterson plant. Dr. Crump expressed his concern over the use of these data. He stated:

OSHA thus derived exposure estimates from measurements made 21 to 31 years later in the other plants in Texas and Pennsylvania. The reasonableness of these estimates is open to question. It is certainly plausible that the exposure measurements in these plants made after the dangers associated with asbestos became known were less, and perhaps far less than exposures experienced 21-31 years earlier under wartime conditions [Ex. 237A, p. 13].

Dr. Morton Corn, former Assistant Secretary for OSHA, who appeared at OSHA's hearing on behalf of the Building and Construction Trades Department was hired by the companies who owned the plants to recommend and install control measures in the two plants in the late 1960's. At the hearings he was asked to comment on the reasonableness of using data from Tyler, Texas and Port Allegheny to estimate