

suitable basis of meta-analysis. There is little information with which to assess factors recognized by epidemiologists as key to meta-analysis, for example sources of bias or confounding in the individual studies and comparability of exposures and worker characteristics across studies, and to verify certain conditions required for comparability of SMRs across these studies (see *e.g. Modern Epidemiology*, Rothman and Greenland, p. 655). In addition, the inclusion criteria and length of follow-up differ across the three studies. Finally, each of the studies is extremely small. Even if it were appropriate to calculate a 'summary' SMR based on them, the precision of this SMR would not be much improved compared to those of the original studies.

In their written testimony, DCC suggested that OSHA should aggregate the data from the Davies, Cooper, and Kano studies in order to determine whether there is a discrepancy between the results of these three studies, taken together, and OSHA's preliminary risk assessment (Ex. 38-201-1, pp. 13-14). DCC performed a calculation to compare OSHA's risk model with the observed

lung cancer in the three cohorts. DCC stated that:

OSHA estimates a chromate worker's risk of dying from lung cancer due to occupational exposure as about one chance in four \* \* \* [Assuming that there were about] 200 workers in the Kano study, the total in the three studies would be 600. A calculation of one quarter would be 150 deaths. To compensate for a working life of less than OSHA's 45 years [an assumption of 20 years] provides \* \* \* a refined estimate of about 70 deaths. An observed number less than this could be due either to exposures already in practice averaging much less than the current PEL of 52, or to lead chromate having much less potential (if any) for carcinogenicity than other chromates. In any event the actual incidence of death from lung cancer would appear to be no more than one tenth of OSHA's best estimate (Ex. 38-201-1, pp. 15-16).

The method suggested by DCC is not an appropriate way to assess the carcinogenicity of lead chromate, to identify a discrepancy between the pigment cohort results and OSHA's risk estimates, or to determine an exposure limit for lead chromate. Among other problems, DCC's calculation does not make a valid comparison between

OSHA's risk estimates and the results of the Davies, Cooper, and Kano studies. OSHA's 'best estimate' of lung cancer risk for any given Cr(VI)-exposed population depends strongly on factors including exposure levels, exposure duration, population age, and length of follow-up. The 'one in four' prediction cited by DCC applies to one specific risk scenario (lifetime risk from 45 years of occupational exposure at the previous PEL of 52 µg/m³). OSHA's best estimate of risk would be lower for a population with lower exposures (as noted by DCC), shorter duration of exposure, or less than a lifetime of follow-up. Without adequate information to adjust for each of these factors, a valid comparison cannot be drawn between OSHA's risk predictions and the results of the lead chromate cohort studies.

The importance of accounting for cohort age and follow-up time may be illustrated using information provided in the Cooper *et al.* study. As shown in Table V-11 below, approximately three-fourths of the Cooper *et al.* Plant 1 cohort members were less than 60 years old at the end of follow-up.

**Table V-11: Followup of Workers in Cooper et al. (Plant 1)**

year of birth	number of workers	age at end of followup*	percent of cohort
1950 - 1954	8	25 - 29	3.3%
1945 - 1949	18	30 - 34	7.3%
1940 - 1944	19	35 - 39	7.7%
1935 - 1939	19	40 - 44	7.7%
1930 - 1934	29	45 - 49	11.8%
1925 - 1929	53	50 - 54	21.5%
1920 - 1924	36	55 - 59	14.6%
1915 - 1919	33	60 - 64	13.4%
1910 - 1914	17	65 - 69	6.9%
1905 - 1909	8	70 - 74	3.3%
1900 - 1904	5	75 - 79	2.0%
1895 - 1899	1	80 - 84	0.4%

\* age of follow-up based on birthyear, assuming survival and follow-up to 1979;

actual follow-up will be shorter for 14 deceased workers and 9 lost to follow-up

For a population of 600 with approximately the same distribution of follow-up time as described in the Cooper *et al.* publication (*e.g.*, 0.4% of workers are followed to age 84, 2% to age 79, etc.), OSHA's risk model predicts about 3-15 excess lung cancers (making the DCC assumption that workers are exposed for 20 years at 52 µg/m³), rather than the 70 deaths calculated by the DCC. If the workers

were typically exposed for less than 20 years or at levels lower than 52 µg/m³, OSHA's model would predict still lower risk. A precise comparison between OSHA's risk model and the observed lung cancer risk in the Davies, Cooper and Kano cohorts is not possible without demographic, work history and exposure information on the lead chromate workers. (In particular, note that year 2000 background lung cancer

rates were used in the calculation above, as it was not feasible to reconstruct appropriate reference rates without work history information on the cohorts.) However, this exercise illustrates that DCC's assertion of a large discrepancy between OSHA's risk model and the available data on workers exposed exclusively to lead chromate is not well-founded. To make a valid comparison between the OSHA risk