the Dominion Colour Corporation (DCC) attributed the excess lung cancer risk observed in pigment worker studies to zinc chromate (Tr. 1707, 1747, Exs. 38–201–1, p. 13; 38–205, p. 90; 40–7, p. 92). For example, the CPMA stated that:

> When lead chromate and zinc chromate exposures occur simultaneously, there appears to be a significant cancer hazard. However, when lead chromate pigments alone are the source of chromium exposure, a significant carcinogenic response has never been found (Ex. 40–7, p. 92).

The latter statement refers to the Davies *et al.* (1984) study of British pigment workers, the Cooper *et al.* (1983) study of U.S. pigment workers, and the Kano *et al.* (1993) study of pigment workers in Japan, all of which calculated separate observed and expected lung cancer deaths for workers exposed exclusively to lead chromate (Ex. 38–205, p. 89). DCC and the Small Business Administration's Office of Advocacy similarly stated that the excess lung cancer risk observed among workers exposed to both zinc chromate and lead chromate cannot necessarily be attributed to lead chromate (Exs. 38–201–1, p. 13; 38–7, p. 4).

OSHA agrees with CPMA and DCC that the excess lung cancer observed in most pigment worker studies taken alone cannot be considered conclusive evidence that lead chromate is carcinogenic. Given that the workers were exposed to both zinc chromate and lead chromate, it is not possible to draw strong conclusions about the effects of either individual compound using only these studies. However, based on the overall weight of available evidence, OSHA believes that the excess lung cancer found in these studies is most likely attributable to lead chromate as well as zinc chromate exposure. Lead chromate was the primary source of Cr(VI) for several worker cohorts with excess lung cancer (*e.g.*, Davies *et al.* (1984), Factory A; Hayes *et al.* (1989); and Deschamps *et al.* (1995)) (Exs. 7–42; 7–46; 35–234), and as previously discussed, there is evidence from animal and mechanistic studies supporting the carcinogenicity of both zinc chromate and lead chromate. Considered in this context, the elevated risk of lung cancer observed in most chromate pigment workers is consistent with the Agency's determination that all Cr(VI) compounds—including lead chromate—should be regarded as carcinogenic.

Moreover, OSHA disagrees with the CPMA and DCC interpretation of the data on workers exposed exclusively to lead chromate. In the Preamble to the Proposed Rule, OSHA stated that ''[t]he number of lung cancer deaths [in the Davies, Cooper, and Kano studies] is too small to be meaningful'' with respect to the Agency's determination regarding the carcinogenicity of lead chromate (FR 69 at 59332). The CPMA subsequently argued that:

> [b]y this rationale, OSHA could never conclude that a compound such as lead chromate pigment exhibits no carcinogenic potential because there can never be enough lung cancer deaths to produce a ''meaningful'' result. This is an arbitrary and obviously biased assessment which creates an insurmountable barrier. Since the lead chromate pigments did not create an excess of lung cancer, there cannot be a significant enough mortality from lung cancer to be meaningful (Ex. 38–205, p. 90).

OSHA believes that these comments reflect a misunderstanding of the sense in which the Davies, Cooper, and Kano studies are too small to be meaningful, and also a misunderstanding of the Agency's position.

Contrary to CPMA's argument, a study with no excess in lung cancer mortality can provide evidence of a lack of carcinogenic effect if the confidence limits for the measurement of effect are close to the null value. In other words, the measured effect must be close to the null and the study must have a high level of precision. In the case of the Davies, Cooper, and Kano studies, the standardized mortality ratio (SMR) is the measurement of interest and the null value is an SMR of 1. Table V.10 below shows that the SMRs for these study populations are near or below 1; however, the 95% confidence intervals for the SMRs are quite wide, indicating that the estimated SMRs are imprecise. The Kano data, for example, are statistically consistent with a ''true'' SMR as low as 0.01 or as high as 2.62. The results of these studies are too imprecise to provide evidence for or against the hypothesis that lead chromate is carcinogenic.

Table V.10: Summary of Lead Chromate Cohort Studies

Study	Number of Workers	Person-Years of Observation	Oberved/Expected Lung Cancer Deaths	SMR (95% C.I.)
Davies (Plant C, high/med exposure)	180	3395	4/5.07	0.79 (0.20 - 2.00)
Davies (Plant C, low exposure)	34	813	3/1.38	2.17 (0.4-6.3)
Cooper (Plant 1)	246	4768	3/2.31	1.30 (0.27 - 3.81)
Kano (workers exposed only to Pb Cr(VI)	not reported	not reported	1/2.14	0.47 (0.01 - 2.62)

This lack of precision may be partly explained by the small size of the studies, as reflected in the low numbers of expected lung cancers. However, it is the issue of precision, and not the number of lung cancer deaths *per se*, that led OSHA to state in the preamble to the proposed rule that the Davies, Cooper, and Kano studies cannot serve as the basis of a meaningful analysis of lead chromate carcinogenicity (Exs. 7–42; 2–D–1; 7–118). In contrast, a study population that has confidence limits close to or below 1 would provide evidence to support the DCC claim that ''* * * if lead chromate pigments possess any carcinogenic potential at all, it must be extremely small'' (Ex. 38–201–1, p. 14) at the exposure levels experienced by that population. While this standard of evidence has not been met in the epidemiological literature for pigment workers exposed exclusively to lead chromate (*i.e.*, the Davies, Cooper, and Kano studies), it is hardly an ''insurmountable barrier'' that sets up an impossible standard of proof for those who contend that lead chromate is not carcinogenic.

Some comments suggested that the Davies, Cooper, and Kano studies should be combined to derive a summary risk measure for exposure to lead chromate (see *e.g.* Ex. 38–201–1, pp. 13–14). However, OSHA believes that these studies do not provide a