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## WATCH COMMITTEE

### Comparison between the dose-response relationship for the respiratory effects of respirable coalmine dust with similar relevant data available for other poorly soluble dusts of limited cytotoxicity

#### Issue

1. From the available data, how does the effect on the respiratory tract of other respirable, poorly soluble dusts of limited cytotoxicity compare with the dose-response relationship established for coalmine dust?

#### Timing Considerations

2. No particular timing considerations.

#### Recommendation

3. WATCH is invited to consider this paper and to express what it considers to be the most reliable scientific position on the action points in paragraph 26; this could then be used by HSE in conjunction with ACTS, to decide on an appropriate future course of action.

#### Background

4. At the February 2007 meeting of WATCH, the committee considered an item (WATCH/2007/1) concerning the dose-response relationships for the effect on the respiratory tract of respirable, poorly soluble dusts of limited cytotoxicity. Much of the emphasis in the paper was on coalmine dust and on research and analysis conducted by the Institute of Occupational Medicine (IOM). In the follow-up period after the February meeting, HSE and WATCH agreed on the best means by which the WATCH conclusions on the dose-response relationship for coalmine dust should be presented to ACTS. This information was then presented to ACTS at its meeting in May 2007. The outcome of the ACTS meeting was reported to WATCH at the June 2007 WATCH meeting – see WATCH/MIN/2007/2, item 8.

5. At the June WATCH meeting the Chairman drew attention to aspects of the conclusions reached by WATCH in February that had not yet been progressed further. HSE undertook to develop its analysis of such matters and report to WATCH in November. That is the purpose of this paper.

6. The conclusions from the February 2007 WATCH meeting pertinent to this paper are that WATCH recommended (**bold text**):

- characterising the best dose-response position that can be extracted from the data on the effects on the respiratory tract of exposure to coal mine dust; **and then to make the most defensible statements justified by the data for the other dusts included in the IOM analysis;**
- consideration of some work to **better guide duty holders as to what category of dust they might be dealing with** and hence, if specific guidance or control standards for that dust were not available, **which benchmark or reference would need to be adhered to;**

7. It has been stated previously by IOM and HSE that the data available on coalmine dust came from the largest and most comprehensive study available of any cohort of workers exposed to a dust of these characteristics (respirable, poorly soluble, limited cytotoxicity). The data are based on an extremely detailed exposure assessment that could probably never be rivalled in any other study. The IOM report presented some data and analysis for the respiratory effects of a small number of other dusts– heavy clay, polyvinyl chloride (PVC) dust and talc – whilst acknowledging that these data were substantially less robust than the data for coalmine dust.

8. HSE has now attempted to extend the IOM analysis by referring to assessments made in previous HSE/WATCH documents of some other dusts that can be regarded as in the category of “poorly soluble, limited cytotoxicity” – carbon black, kaolin, cement dust and pulverised fuel ash (PFA).

### Argument

9. In relation to the dose-response relationship for the lung effects of respirable coalmine dust, it was agreed by WATCH that the *mean* loss in FEV<sub>1</sub> (beyond that due to ageing) after a working lifetime following exposure to 4 mg.m<sup>-3</sup> respirable coalmine dust for 40 years would be 178 ml. Around this mean there would be a distribution of response, such that in 37% of the workforce the loss in FEV<sub>1</sub> would be 627 ml and in 17% the loss would be 993 ml.

10. **Comparison of coalmine dust with carbon black:** In HSE’s opinion, carbon black provides the next most comprehensive, relevant dataset to coalmine dust. WATCH undertook a detailed consideration of carbon black in 2002 (WATCH/12/2002 and WATCH/17/2002). It was concluded that there were relatively good quality data from large-scale American and European multi-centre studies of carbon black manufacturing workers that allowed a dose-response relationship for the effects on FEV<sub>1</sub> to be discerned.

11. Statistical projections of the most reliable data from the European multi-centre study indicated that 40 years of exposure to 1, 2, and 3.5 mg.m<sup>-3</sup> *inhalable* carbon black (8-hr TWA) would lead to deficits in FEV<sub>1</sub> of 48, 96 and 169 ml in non-smoking males respectively. A direct comparison with the data on coalmine dust is difficult because the exposure metric for carbon black refers to *inhalable* rather than *respirable* dust. The authors of the study claimed that measures of inhalable dust were highly correlated with those for respirable dust, such that inhalable dust values could be regarded as a valid

proxy for respirable dust; however, a general ratio between the two was not given.

12. Bearing this in mind, for the purposes of a rough comparison with coalmine dust, it might be assumed that about 50% of the inhalable dust fraction of carbon black was respirable. Hence, using simple linear extrapolations, a working lifetime of exposure to  $4 \text{ mg.m}^{-3}$  respirable carbon black would be predicted to lead to a mean loss in FEV1 of 386 ml. This compares with a mean loss of 178 ml for workers exposed to the same dose of respirable coalmine dust (see Table 1B).

13. In comparing the data on coalmine dust with that for carbon black, it should be noted that the projections for respirable carbon black require considerable extrapolation beyond the observed range of data. At the time of the last phase of the carbon black study the arithmetic mean of *inhalable* dust exposure across all plants was only  $0.57 \text{ mg.m}^{-3}$ , which introduces considerable uncertainty when extrapolating to  $4 \text{ mg.m}^{-3}$  for the *respirable* fraction.

14. The studies on carbon black indicated exposure-related increases in the reporting of respiratory symptoms. However, the authors of the European multi-centre study expressed concern about inconsistencies in the way the symptoms data were collected in the different factories in the study, so that any general comparison with the coal mine dust data would be fraught with uncertainty.

15. **Comparison of coalmine dust with kaolin:** An HSE Criteria Document (EH65/13) reflecting a WATCH-agreed position was published in 1994. Based on a large-scale cross-sectional study of English china clay workers, it was predicted that 40 years of exposure to  $2 \text{ mg.m}^{-3}$  respirable kaolin dust would lead to a mean decrement in FEV<sub>1</sub> at age 60 of approximately 220 ml. By extrapolation it was also predicted that a 40-year exposure to  $4 \text{ mg.m}^{-3}$  respirable kaolin dust would lead to a mean decrement in FEV1 of 440 ml; this compares to a mean 178 ml loss for coal mine dust (see Table 1B). [Note: kaolin exposure levels adjusted from those stated in EH65/13 to reflect current sampling methods for respirable dust].

16. **IOM comparison of coalmine dust with other dusts:** The IOM report included a brief comparison of the respiratory effects of coalmine dust with a number of other dusts - heavy clay, PVC dust, and talc. To facilitate direct comparisons between studies, lung function effects were expressed in terms of standardised units of FEV1. A standardised unit is equal to the difference between the observed and predicted FEV1, divided by the standard deviation for FEV1. Similarly, exposure units were standardised in terms of units of cumulative exposure (100 units =  $100 \text{ mg.years.m}^{-3}$ , equivalent to 40 years exposure to  $2.5 \text{ mg.m}^{-3}$ ).

17. For each 100 units of dust exposure, the mean decrements in FEV1 in standardised units were 0.19 for coalmine dust, 0.26 units for talc and 0.66 units in PVC workers. Note that in the case of PVC dust there were concerns expressed in the IOM report about the possible underestimation of exposure,

which might well unjustifiably exaggerate the apparent difference in response between PVC dust and the other two dusts.

18. To put these values in context, 0.19 standardised units of FEV1 for a man of height 1.75 metres would equate to an eventual average loss in FEV1 of about 100 ml (see Table 1A). Table 1B shows the equivalent average loss of FEV1 following cumulative exposure to 160mg.m<sup>-3</sup>.years (4 mg.m<sup>-3</sup> over 40 years) of coalmine, talc and PVC dust.

19. In the heavy clay study, there were no measurements of lung function. However, relative risks of reporting symptoms were judged to be very similar for coalminers and heavy clay workers.

**Table 1A Comparison of predicted FEV1 losses from cumulative exposure to 100 mg.m<sup>-3</sup>.years respirable dust**

Cumulative exposure to 100 mg.m <sup>-3</sup> .years (equivalent to 2.5 mg.m <sup>-3</sup> for 40 years)	Loss in standardised units of FEV1	Equivalent loss of FEV1 (ml/sec) for a man of height 1.75 m
Coalmine dust	0.19	100
Talc	0.26	136
PVC	0.66	350
Carbon black		241
Kaolin		264

**Table 1B Comparison of predicted FEV1 losses from cumulative exposure to 160 mg.m<sup>-3</sup>.years respirable dust**

Cumulative exposure to 160 mg.m <sup>-3</sup> .years (equivalent to 4 mg.m <sup>-3</sup> for 40 years)	Equivalent loss of FEV1 (ml/sec) for a man of height 1.75 m
Coalmine dust	178
Talc	240
PVC	608
Carbon black	386
Kaolin	440

20. **Other possible comparisons pursued by HSE – (i) cement dust:** WATCH members might recall a relatively recent HSE update of the data on Portland cement (WATCH/2005/3). No reliable conclusions concerning quantitative dose-response relationships could be drawn for cement dust mainly due to imprecision in the exposure data. Hence, this dust will not be discussed further here.

21. **Other possible comparisons pursued by HSE – (ii) pulverised fuel ash (PFA):** PFA was considered by WATCH in the early 1990s (EH65/2). There is a very limited dataset for this dust, with only one study providing quantitative exposure-response data and only for *inhalable* dust (Schilling et al 1988, copy attached as Annex 1). As can be seen from the paper, the results were suggestive of an exposure-related impairment in some lung

function parameters, but there did not appear to be any exposure-related effect on FEV1. Hence, a comparison with the FEV1 data on coalmine dust is not possible. In relation to respiratory symptoms, it is uncertain whether any meaningful comparisons with the data on *respirable* coalmine dust could be made, given the uncertainties surrounding the cumulative exposures to respirable PFA and the absence of a formal statistical analysis of the PFA data to take account of the effect of cigarette smoking. Hence overall little can be made of a comparison between PFA and coalmine dust.

22. **Additional considerations.** There are a number of general considerations that should be borne in mind when evaluating the available epidemiological data on the respiratory effects of dusts and in looking to make any comparisons between different dusts:-

- In many cases the data on these dusts derive from cross-sectional health surveys and the results are thereby subject to the healthy worker effect, ie it is possible that those with the poorest respiratory function might have left the industry.
- Quartz is a common contaminant in many mineral dusts, eg kaolin; the contribution to any overall effect made by the quartz component is unclear.
- Differences in particle size/specific surface area may be of relevance when comparing different workplace dusts. Carbon black contains particles in the nanometre size range, which in this respect sets it apart from the other dusts.
- When there appear to be inconsistencies between symptoms and lung function data this may lead to an over-emphasis on the spirometry data (regarded as being more “objective”). However, symptoms and lung function impairment are both of concern for occupational health, and may be caused by exposure to different size fractions of dust, such that an expectation of parallel dose-response data may not be appropriate. Symptoms of chronic bronchitis arise from changes in the bronchial airways, whereas FEV1 reductions arise from changes in the deeper lung in the smaller airways. An individual may have a reduced lung function but an absence of symptoms, and vice-versa. Symptoms may precede lung function impairment by some years. However, severe losses of FEV1 are likely to be accompanied by symptoms because the inhaled dust burden needed to cause severe losses in FEV1 is also likely to be sufficient to cause symptoms.
- Spirometry may be considered as a gold standard in terms of assessing changes in lung function. However spirometric data can be subject to bias in that not all workers may produce satisfactory spirometry. In the talc study, adequate spirometry were available for 83.7% of subjects and the remainder were not included in the statistical analysis; in the carbon black studies, 6% of workers were unable to complete the required respiratory manoeuvre.

### **Link to HSC Strategy**

23. The “emerging issue” for WATCH, that the regulatory positions surrounding exposure to dusts are of some concern, is a generic matter of relevance to HSE’s statutory COSHH-related work and to the Respiratory Disease Project of the Disease Reduction Programme.

### **Consultation**

24. No wider consultation beyond HSE on the content of this cover paper has been undertaken at this stage.

## **European Context**

25. There are no specific links to EU procedures or activities.

## **Action**

26. WATCH is asked to:-

i) Identify what conclusions can be drawn regarding how the dose-response data for the respiratory effects of respirable coal mine dust compare with the data for other poorly soluble dusts of limited cytotoxicity.

ii) Depending on the conclusions drawn, to give a view on the potential to use coal mine dust and/or other dusts as a benchmark(s) or reference point(s) for deciding on appropriate control standards for other poorly soluble dusts of limited cytotoxicity.

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## **Attachments**

Annex 1: Schilling et al (1988) *A survey into the respiratory effects of prolonged exposure to pulverised fuel ash*. Br J Ind Med **45**: 810-817