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ADVISORY COMMITTEE ON TOXIC SUBSTANCES

CONSIDERATION BY WATCH OF POORLY SOLUBLE DUSTS OF LIMITED CYTOTOXICITY

A Paper by Steve Fairhurst (WATCH Chairman)

Issue

1. A recommendation is sought from ACTS on what, if any further work on this topic should be done by WATCH.

Timing

2. No particular timing issues.

Recommendation

3. ACTS is asked to consider this paper and to respond to the request in paragraph 10.

Background

4. At the November 2006 meeting of WATCH, within a session focussing on "new and emerging issues", WATCH considered that a number of issues pertaining to what have historically been termed "nuisance dusts" needed to be examined. These issues were progressed by WATCH during 2007.

Argument

5. WATCH began its evaluation by considering the data available for coalmine dust. The outcome of the WATCH discussion of February 2007, followed by a clearance-by-correspondence exercise in March-April 2007, was seen by ACTS in May 2007 as part of a paper "Advice on priorities that the Health and Safety System should address during 2008-2011"; this is presented again here at Annex 1. Note that it was accepted that the term "nuisance dust" is inappropriate and not now used in HSE documentation; hence "poorly soluble dusts of limited cytotoxicity" has been used here as the descriptor of the type of dusty material with which this paper is concerned.

6. In November 2007 WATCH then considered other dusts of this type for which there is a reasonable body of relevant data on the dose-response relationship between inhalation exposure and the consequences for respiratory function. The outcome of this WATCH discussion is given in Annex 2. Two important general points are that:

- for each of the dusts examined, a significant effect on FEV_1 with exposure to 4 $mg.m^{-3}$ respirable dust is apparent; and
- notwithstanding some variability, the scale of reduction in FEV_1 under such conditions is of the same general order as that for coalmine dust. These findings reinforce the conclusion that a range of dusts of the "poorly soluble, limited cytotoxicity" type are predicted to produce reductions in FEV_1 on long-term exposure to 4 $mg.m^{-3}$ respirable dust.

7. WATCH generated a number of ideas for additional work that might be undertaken to develop further the scientific and technical understanding of this regulatory issue – see bullet points in Annex 2. However, WATCH considered that at this point a steer was required from ACTS on any further course of action.

Link to HSE Strategy

8. This work relates primarily to HSE's statutory responsibilities within COSHH; the implications of this work will also be considered in the context of the Disease Reduction Programme (DRP) project on Respiratory Disease.

Consultation

9. There has been no consultation on this paper beyond the previous discussions at WATCH.

Action

10. ACTS is asked to reflect on the outcomes of the WATCH considerations summarised in Annexes 1 and 2 and to recommend what, if any further work should be done on this topic by WATCH.

Contact

ACTS Secretariat

Annex 1 (seen previously by ACTS in May 2007)

Note: what are presented below as "draft" conclusions were subsequently confirmed as final by WATCH.

The potential long-term respiratory effects and current regulatory position surrounding the inhalation of "low toxicity/low solubility" dusts in general

A view from WATCH

1. At the November 2006 meeting of WATCH, within a session focussing on "new and emerging issues", WATCH considered that a number of issues pertaining to what have historically been termed "nuisance dusts" needed to be examined. These issues were progressed as an agenda item at the February 2007 meeting of WATCH. For this agenda item, HSE provided a paper summarising a study in British coalminers conducted by the Institute of Occupational Medicine (IOM). This study was selected because it represents the most comprehensive and large-scale study available on the respiratory effects of dust. An IOM position paper was also presented to WATCH that compared coalmine dust to a small number of other dusts; the authors of this paper considered that coalmine dust could be used as a benchmark for other "low toxicity" dusts.

2. The draft conclusions of WATCH from the February 2007 meeting are:

i. with some qualifiers (presentationally, a little more could be done to clarify the health effects of exposure to the dusts studied; and only a limited number of dusts had been included in the IOM research), the IOM research, particularly that related to the effects of coalmine dust, represented a thorough, robust analysis and WATCH agreed with the IOM/HSE assessment of the findings;

ii. it recommended characterising the best dose-response position that can be extracted from the data on the effects on the respiratory tract of exposure to coalmine dust ; and then to make the most defensible statements justified by the data for the other dusts included in the IOM analysis;

iii. the dose-response data indicated that the effect on the respiratory tract of exposure to coalmine dust, within the exposure range studied, occurred as a continuum, with no clear threshold appearing;

iv. the term 'nuisance dust' was not being used in HSE documentation; WATCH recommended that any generic term used in the future should be a fall-back term that clarifies its exclusion of specified entities (e.g. 'dust not otherwise characterised', which would exclude, for example, 'chalk dust');

v. it recommended 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;

vi. it recommended reconsideration of the wording of some of the statements in the COSHH ACOP and in EH40 in the context of the discussion that had taken place;

vii. that the next ACTS meeting (in May 2007), at which there will be consideration of priorities for future years of the Disease Reduction Programme, would be a suitable

destination for the distillation of the dose-response curve for coalmine dust and for any associated observations and recommendations from WATCH, in relation to the issue of exposure to, and control of, dusts in general.

3. In the context of ACTS considering potential priorities for future work under the Disease Reduction Programme, this Annex presents an HSE/WATCH attempt to provide a clear picture of the dose-response relationship for the effects on lung function of inhaled respirable coalmine dust – see WATCH conclusions (i), (ii), (iii) and (vii) above.

4. This dose-response relationship is shown as a bar chart (Figure 1). The data to the right of the vertical dotted line in the bar chart refer to results in non-smoking coalminers aged 60. The bar chart indicates three categories of lung function impairment that could result from a working lifetime of exposure to coalmine dust at respirable dust concentrations of 0 to 4 $mg.m^{-3}$. These three categories of lung function impairments are degrees of defined losses in FEV_1 (the amount of air that can be breathed out in 1 second); “mild” (a loss of 367 ml); “moderate” (627 ml); and “severe” (993 ml). These losses are over-and-above the normal age-related losses. To put these findings in context, the FEV_1 in adults normally decreases by 25-30 ml per year i.e. up to 1200 ml over 40 years. The “severe” category would be almost certainly consistent with a diagnosis of Chronic Obstructive Pulmonary Disease (COPD)[1], and those with this category of loss had a 3-fold increase in the frequency of reporting breathlessness. The “moderate” category is also likely to be consistent with a diagnosis of COPD.

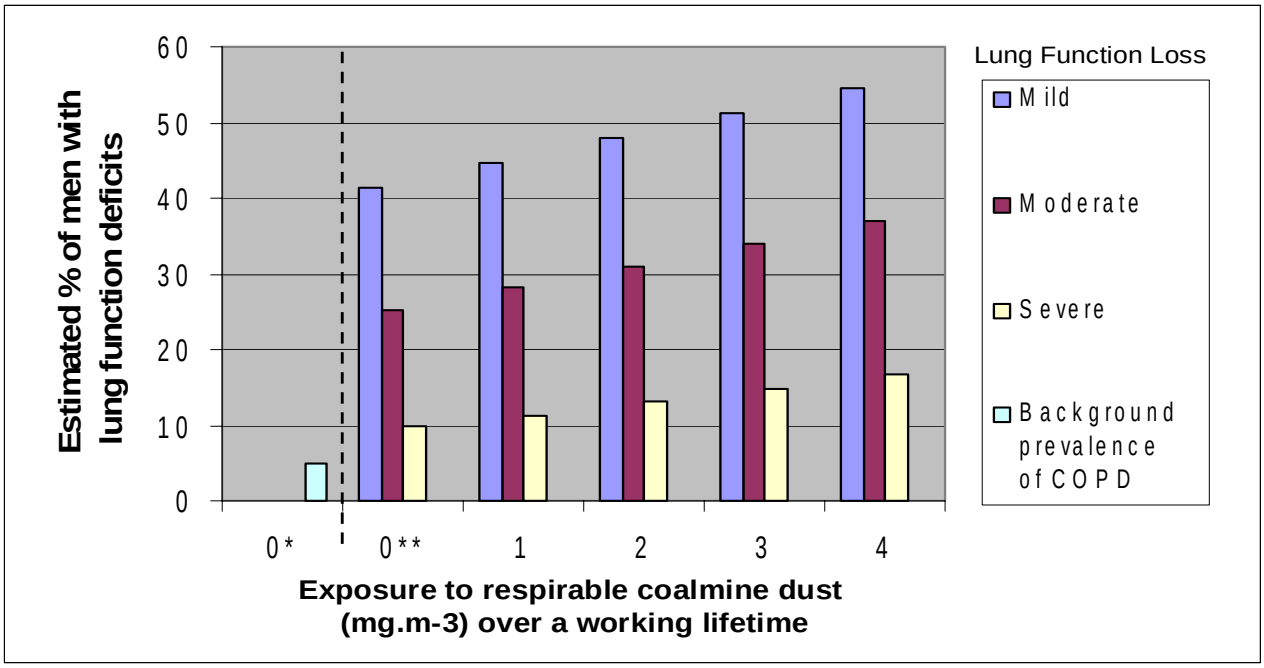
5. The bar chart shows that with increasing levels of coalmine dust exposure, there is a gradual increase in the percentage of workers with each of the three defined deficits in lung function, and no clear threshold is observable for the coalmine dust-related effect. The bar chart also indicates that even in the study reference group of workers in the same industry said to be “non-dust exposed”, 10% showed severe deficits in lung function consistent with COPD. These “unexposed” workers in the IOM study were surface workers at coalmines; it could be that these workers would have had some exposure to dust. In 2004 HSE undertook a review of the literature to identify the background prevalence of COPD in non-smoking, non-dust exposed males aged 60. It was difficult to specify a precise background prevalence of COPD in the population because of the different criteria used to diagnose COPD; however the 2004 HSE review concluded that an average background prevalence of COPD in never-smoking, non-dust exposed males aged 60 is likely to be about 5%. This 5% average has been included as a point of reference on the bar chart (Figure 1), to the left of the vertical dotted line.

6. WATCH wishes to bring to the attention of ACTS the dose-response data for coalmine dust shown in Figure 1. As yet, no further work has been done in relation to how representative these data might be for a more generic group of dusts.

WATCH Secretariat
April 2007

[1] COPD is diagnosed on the basis of a reduction in $FEV_1 \geq 20\%$ of predicted, together with a reduction in the ratio of FEV_1/FVC to ≤ 0.7. For a man aged 60, height 170 cm, a normal FEV_1 would be 3.05 L and a 20% loss would be 610 ml.

Figure 1. Effect of coalmine dust on lung function in non-smoking males



•* General population (non-smoking males aged 60)
•** Surface coalminers (used as control in IOM study)

Data adapted from Cowie *et al* 2006 (Table 4) plus HSE review of background level of COPD

Annex 2

Minutes from WATCH meeting of November 2007

"WATCH had initially approached the issue of 'poorly soluble, limited cytotoxicity' dusts and the appropriate standard of control for exposure to dusts of this type by considering the data available on coalmine dust, given that this is the best dataset for a dust of this type. The dose-response relationship agreed by WATCH for the effects of respirable coalmine dust on lung function and the associated observations and recommendations from WATCH made at its February 2007 meeting were presented to ACTS at the May 2007 ACTS meeting. As a follow-on to this and discussions held at the June WATCH meeting, further analysis had been carried out to compare the dose-response relationship for the respirable effects of coalmine dust with similar relevant data available for other poorly soluble dusts of limited cytotoxicity (e.g. carbon black and kaolin). This analysis was considered by WATCH at its November 2007 meeting.

Such analysis indicated to WATCH that, for the different dusts examined, there was some variability in the data for the estimated reduction in FEV1 that would arise from exposure to 4 mg.m-3 of respirable dust; and there were a number of variable factors between the dusts (e.g. variable degrees of solubility within the "poorly soluble" general characteristic; distribution of particle size within the respirable range) that could influence their properties. **Nevertheless, two important general points are that for each of the dusts examined, a significant effect on FEV_1 with exposure to 4 $mg.m^{-3}$ respirable dust is apparent; and that notwithstanding some variability, the scale of reduction in FEV_1 under such conditions is of the same general order as that for coalmine dust. These findings reinforce the conclusion that a range of dusts of the "poorly soluble, limited cytotoxicity" type are predicted to produce reductions in FEV_1 on long-term exposure to 4 $mg.m^{-3}$ respirable dust.**

Several suggestions for potential further work were made by WATCH at its November meeting:

- Exploration of the effects of dust exposure on lung function parameters other than FEV_1, such as FVC, to gain a more comprehensive picture of the total range and degree of effects.
- Meta-analysis of the total data available from all of the individual studies, to further probe issues such as relative quality of data, consistency, uncertainty etc.
- Advocacy of experimental work aimed at producing a solubility test that would be a reliable indicator of the relative solubility of different dusts in the lung; this might be useful in assessing the degree to which the unknown toxicological properties of a dust with respect to the lung might correspond to the properties of the poorly soluble dusts studied here.
- Further development of benchmarking methods that might be used to find "best fit" approaches to connect a poorly soluble dust of limited cytotoxicity that has very limited data on it, with the dose-response data available for a more thoroughly studied dust with the most similar physicochemical characteristics.

WATCH agreed with this portrayal of the position and with the proposal that, via the WATCH chairman, a steer from ACTS was now needed to determine the future course of action.