

WORKING GROUP ON ACTION TO CONTROL CHEMICALS

WATCH/MIN/2008/3

Meeting date: 23rd/24th October 2008**Open Gov. Status:** Fully open**Type of paper:** Final**Paper File ref:****Exemptions:****WORKING GROUP ON ACTION TO CONTROL CHEMICALS**Minutes of the 14th meeting of the Working Group on Action to Control Chemicals held on 23rd and 24th October 2008, Crowne Plaza Hotel, NEC, Birmingham Bootle**Members Present**

Steve Fairhurst (Chair)
 Steve Bailey
 Robin Chapman
 Rosemarie Hutchinson
 Len Levy
 Steve Binks
 Martie van Tongeren
 Ching Aw
 Alastair Hay
 Tony Fletcher (day 1)
 Len Levy
 David Farrar
 Julian Peto (ad hoc member – day 1)
 Robin Howie (ad hoc member – day 1)
 Hilary Cowie (ad hoc member – day 1)

Observers

Francis Pollitt (day 1)
 Suchita Nadkarni (day 2)

Apologies

Steve Williams
 Tony Fletcher (day 2)

Invited speakers

Peter Hatto (day 2)
 Rob Aitken (day 2)

HSE Officials Present

Nicola Gregg (Secretariat)
 Anna Rowbotham (Secretariat)
 Rob Turner
 Andy Darnton
 Garry Burdett
 Dil Sen
 John Unwin
 John Cocker
 Helen Ratcliffe
 Jackie Germain
 Delphine Bard
 Brian Fullam
 Christine Northage
 John McAlinden
 Bronwen Ley
 Peter Ellwood
 Sam Bradbrook

Day 1 : 23rd October**1 Introductions and apologies**

1.1 The Chairman welcomed everybody to the 14th meeting of the committee. He thanked in particular the three ad hoc members for their attendance. He also welcomed Dr. Francis Pollitt from the Health Protection Agency and Secretary to the Committee on Carcinogenicity.

2	Administrative issues
2.1	The Chairman asked for any declarations of interest related to the items on the agenda. Robin Chapman, Steve Bailey, Steve Binks, Marti van Tongeren, Len Levy and Alastair Hay all expressed interests in nanomaterials. David Farrar expressed an interest in welding fumes.
2.2	WATCH secretary Nicola Gregg reminded WATCH members to send in their 07/08 declarations.
2.3	Dates for next meeting The secretary reminded members that the 15 th WATCH meeting would be held on 24 th February 2009, at HSE, Rose Court, London
2.4	Adoption of agenda WATCH members agreed to adopt the proposed agenda (WATCH/Agenda/2008/2).
3	Minutes of 13th meeting
3.1	Members had commented by correspondence on the draft minutes of the 13 th meeting. As a result a few small editorial changes needed to be made to the version available at the meeting (WATCH/Min/2008/1). Members agreed that the Secretariat would make these changes and then the minutes would be deemed to be finalised.
3.2	Matters arising/Secretary's report The Secretary informed WATCH that minuted actions from the 13 th meeting in respect of 6.26 and 8.9 had been addressed. No further suggestions had been received in respect of point 7.12.
4	Asbestos: The risks of mesothelioma and lung cancer in relation to relatively low-level exposures to different forms of asbestos - what statements can reliably be made about risk at different exposure levels? (Day 1)
4.1	The Chairman introduced the item by reminding members about the progress that had been made on this topic to date. Following the June WATCH meeting, members were asked to comment by consultation on a paper prepared by Andy Darnton (HSE, Statistics Branch): <i>The risks of mesothelioma and lung cancer in relation to relatively low-level exposures to different forms of asbestos : What statements can reliably be made about risk at different exposure levels</i> (Annex 1). Several members had provided comments. The Chairman noted that there seemed to be a reasonable commonality in the views expressed in the consultation with respect to the acceptability of different risk statements presented in the paper. As a result of the comments raised in the consultation, a number of issues warranted further exploration. The Chairman informed members that the primary aim of further discussion on this item was to consider the extent to which the committee, as a whole, could make statements about the risks posed by low level exposures to asbestos based on the available evidence. The Chairman informed WATCH that specific comments about the methodology used in the Hodgson and Darnton (H&D) model ¹ and its validity for informing statements on risk had been raised again by a member during the consultation (Annex 2, p12-15). Given that the reliability of the model was a crucial issue, he asked members to focus discussions on this topic first. He invited Andy Darnton to give a presentation to WATCH, produced in response to the WATCH member's specific comments.

4.2

Presentation on methodological aspects of the Hodgson and Darnton model

Andy Darnton gave a presentation to WATCH addressing four methodological issues highlighted by the member in the comments in Annex 2. He said that the aim of the presentation was to show that whilst the issues raised were important, adjustments to take them into account were not expected to make a big impact on the validity of the H&D model.

1. Comparison of studies with different follow up periods

The first question considered was: ***Is the absolute potency of amphiboles and relative potency of chrysotile underestimated in the H&D analysis because of studies with substantially incomplete follow-up?*** This question relates to a fundamental aspect of the H&D approach: since mesothelioma risk rises steeply with time, and since the different cohorts in the analysis have been observed for different times, does the metric adopted for mesothelioma risk adequately allow for these differences between cohorts? In their analysis, Berman and Crump^{2,3} took a different approach to that taken by H&D. Berman and Crump fitted their mesothelioma model separately to data within individual cohorts, which allowed the time since first exposure to be taken into account. In contrast, in the H&D analysis, models were fitted to cohort-level summary measures of risk and exposure.

Andy Darnton presented a graph showing how the quantities in the H&D metric for mesothelioma risk would be expected to vary with time since first exposure. The graph showed (1) cumulative expected mortality from all causes of death, and (2) cumulative predicted mesothelioma mortality, each plotted against years since first exposure for a hypothetical cohort of 100,000 men who had been exposed to asbestos at the age of 30, for 5 years. Cumulative expected all cause mortality was calculated from overall male mortality rates typical of the 1970s and predicted mesothelioma mortality was calculated using the HEI/Peto model for mesothelioma risk in relation to time since first exposure (which is also the model used by Berman and Crump). A third line on the graph gave the ratio of the cumulative predicted mesothelioma mortality to the cumulative expected all cause mortality (e.g. plot 2/ plot 1) which is the metric for mesothelioma risk in the H&D analysis. Up to 20 years after first exposure to asbestos, the risk of mesothelioma was low. Twenty years after first exposure, the risk of mesothelioma started to rise rapidly with time. The ratio of plot 2/ plot 1 increases rapidly from 0 to 1 between approximately 15 and 30 years after first exposure to asbestos in the hypothetical cohort. Although some degree of variation is seen beyond 30 years follow-up – e.g. between 35 and 60 years after first exposure the ratio of plot 2/plot 1 is > 1 and falls below 1 after a very long follow-up of 60 years – the ratio is broadly constant. This suggests that for the follow-up periods typical of cohorts in the analysis, the mesothelioma metric should not vary dramatically with follow-up time.

In addition to the theoretical analysis of the effects of follow-up period on the predicted risks of mesothelioma, Andy Darnton informed WATCH that some cohort data had also been examined. He showed a slide giving the expected all cause mortality, mesothelioma deaths and these expressed as a percentage of all cause mortality (%XS) for 5 different cohorts for which data for different follow-up periods were available (Wittenoom; Wittenoom environs; Quebec; Libby and US insulators). For longer follow-up periods the mesothelioma %XS was increased in all but one of the cohorts (Wittenoom).

However, increases were particularly marked only in the case of the Quebec cohort (an almost 4-fold increase) and Libby (almost 2-fold).

The effects of follow-up period were also explored in a cohort of Nottingham gas mask workers⁴. This cohort mainly included women who were exposed to crocidolite during the manufacture of gas masks in WW2. This cohort is of particular interest in relation to how mesothelioma risk varies with time since exposures to asbestos were accrued over relatively short periods of time and the cohort now has almost complete follow-up. He pointed out that this cohort had not been included in the original H&D analysis because an average exposure could not be determined for this group. Andy Darnton showed a graph plotting the cumulative expected all cause mortality, the cumulative observed mesothelioma mortality, and the percentage excess mortality against time since first exposure to asbestos (in years) for this cohort of workers. The percentage excess mortality for the cohort was found to increase rapidly, 15 years after first exposure, reaching a peak of around 10%, 30 years after first exposure to asbestos. After 30 years since first exposures the excess mortality was found to decline with increasing time. Thus, for this particular cohort, the ratio of mesothelioma to all cause mortality is higher for moderately long follow-up (about 30-40 years) than very long follow-up (50-60 years).

Andy Darnton summarised the comparison of studies with different follow-on periods by highlighting that, at least in principle, the metric adopted in the H&D analysis for mesothelioma risk should adequately account for differences in follow-up period. From the limited empirical evidence from cohorts, he pointed out that the Quebec cohort, for which the varying follow-on periods were found to influence the predicted risk of mesothelioma the most, was known to be a particularly problematic dataset due to issues in the study associated with potential exposure to tremolite asbestos. Furthermore, the Nottingham cohort suggests some attenuation in risk with very long follow up times and so, if true, although estimates of mesothelioma risk from studies with shorter follow-up may underestimate the peak risk following exposure, they should still be reasonable estimates of the overall risk. In conclusion, the data presented give some degree of confidence that the mesothelioma metric will broadly account for different follow up periods.

2. Competing risks

Andy Darnton informed WATCH that the second methodological question to be considered is: ***Does the H&D analysis underestimate the risks due to mesothelioma and lung cancer because of high mortality in cohorts for “competing risks”?*** In other words, when considering the risks of mesothelioma or lung cancer in cohorts that have been exposed to high levels of asbestos, does mortality in the cohort due to other diseases associated with the exposure – but which tend to occur sooner – prevent the full extent of the mesothelioma risk being expressed? He provided a hypothetical example to illustrate this issue, based on a cohort of 10,000 men aged 30 who had been heavily exposed to asbestos for 5 years and followed up for 50 years to the age of 80. In the example, two different scenarios about the overall rate of mortality in the hypothetical cohort were considered:

- (i) The overall mortality rate for the cohort was broadly in line with national mortality rates for men for the mid 1970s.
- (ii) The cohort has high mortality from all causes of death such that death

rates in the cohort are X times as high as national rates throughout the follow-up period (i.e. the all-cause 'standard mortality ratio' $SMR = X$).

Andy Darnton pointed out that although interest is primarily in the effect of other specific diseases associated with asbestos rather than the effect of an overall increased mortality from all causes, which could be for other reasons, for the purposes of the illustration the effect on the observed mesothelioma risk would be broadly the same. He presented a graph comparing three different metrics with years since first exposure for these two scenarios: (1) person-years remaining (2) predicted all cause deaths (based on 1970s death rates) and (3) predicted mesothelioma deaths (based on the HEI/Peto model). When values of 1,2,3 and 4 were assumed for the SMR (i.e. the death rate in the hypothetical cohort was 1,2, 3 and 4 times higher than the national mortality rate) the ratio of mesothelioma deaths to expected deaths in the cohort was found to be 0.217; 0.206; 0.196; 0.184 respectively. This suggests that even with cohorts with extremely high mortality from other causes of death (such as those with an all cause SMR of 4), reductions in the measured mesothelioma risk (expressed as a percentage of all cause mortality) are fairly modest.

3. Life expectancy

Andy Darnton informed WATCH that the third methodological issue to be considered is: ***Are the lifetime risks presented in the H&D analysis underestimates of the risks for those exposed today because of increased life expectancy?*** He gave members an overview of how lifetime risks are calculated from the derived risk model. In the H&D analysis, the metric for mesothelioma risk (P_M) gives a measure of the observed mesothelioma deaths as a proportion of total expected all cause mortality as calculated from national deaths rates relevant to the time periods over which the cohorts were observed. Thus these mesothelioma risks relate, essentially, to patterns of mortality in the past. In the H&D analysis the mortality rates from the mid 1970s rates were taken to be broadly typical of average all cause mortality that would have been used to calculate expected numbers in the cohorts. Using this approach, estimates of lifetime risks for mesothelioma could be derived for populations for which this pattern of mortality is still relevant. The 1970s average male mortality patterns showed that 70% of those aged 30 would die between the ages of 40-80 years (e.g. the age during which H&D assumed all mesotheliomas would occur if asbestos exposure was accrued over 5 years from age 30). Thus the relevant expected all cause mortality for 100,000 men aged 30 during the period in which they are at risk from mesothelioma is 70,000, and the lifetime risks per 100,000 is thus just $70,000 \times P_M$.

Andy Darnton pointed out that it might seem intuitive that in order to use the derived mesothelioma risk to predict lifetimes risks for a population with today's mortality patterns, more recent mortality rates should be used in the above calculation. However, this will actually underestimate the lifetime risk because there will be fewer deaths in the 'at risk' period (age 40-80) due to increased survival to ages 80+. He thus raised the question: ***How should we adjust for increased life expectancy?*** One approach could involve adjusting the expected all cause mortality to take account of additional person-years (e.g. survivors in the 40-80 age group). For 1000 survivors to the age of 30 the 1970s average life-table predicts 30970 person-years at risk between age 40 and 80. Using the 2002-2004 life-table for Great Britain

	<p>(GB) gives an estimated 33630 person-years, some 8.5% more. Thus, a crude adjustment for increased life expectancy would be to multiply the lifetime risk estimates derived in the H&D paper by about 8.5%.</p> <p>4. Mesothelioma risk at very long follow up times</p> <p>Andy Darnton informed WATCH that the fourth methodological issue associated with the H&D study was how very long follow up periods affected the prediction of mesothelioma risk. Although the Peto / Health Effects Institute-Asbestos Research model (also adopted by Berman and Crump) predicts that mesothelioma risk continues to increase rapidly with time since exposure, there is some evidence from various cohorts that this is not the case. However, it was difficult to precisely determine the effects of very long follow on periods because only small numbers of individuals survive to very long follow-up times. In terms of relevance to the H&D analysis, the key question is: <i>Is the assumption that all the mesothelioma risk is expressed by age 80 a reasonable way of approximating lifetime risk?</i> If mesothelioma risk does continue to increase with time then this would imply that risks due to exposure in childhood could be substantially higher than risks due to exposures at, for example, age 20. Andy Darnton discussed the effects time since first exposure using examples from the Wittenoom, Paterson, Quebec, and Nottingham cohorts. Though the results are generally not statistically significant, there is a suggestion from all but the Quebec cohort that the risk does eventually start to decline. Data from the GB asbestos workers study is also consistent with such a decline.</p>
4.3	<p>General discussion on methodological aspects of H&D model</p> <p>The Chairman thanked Andy Darnton for the presentation and opened the item for general discussion.</p> <p>A WATCH member commented on the issue of life expectancy. As life expectancy increases, more people would be expected to live longer, reaching the age of 60 or 70. Hence, as the absolute number of individuals reaching 60 years increases, the absolute number of mesothelioma cases would also be expected to increase. Increasing life expectancy could therefore be expected to increase the risk of mesothelioma much more substantially. Rather than simply multiplying the predicted risk by the proportional increase in person-years at age 40-80 (i.e. 8.5%) account should be taken of the fact that the additional person-years are subject to a risk that increases with approximately the third power of time, and so this would lead to a larger adjustment factor.</p>
4.4	<p>A WATCH member pointed out that the two cohorts in the Quebec study could be looked at separately since data in respect of these was available. This might enable more insights to be gained into exposures to crocidolite.</p>
4.5	<p>A WATCH member commented that in the comparative analysis discussed by Andrew Darnton, the pattern and duration of exposure associated with these hypothetical scenarios had not been discussed. It was important to consider how exposures vary over time. The Chairman pointed out that for most of the asbestos worker cohort studies, exposure periods tended to be short (e.g. a few years) whereas the follow-on periods were much longer. The concern with asbestos exposure stemmed from the fact that mesothelioma was known to be a disease with a long latency period. To some extent therefore it did not matter what pattern of exposure had occurred over the duration of the exposure period; what mattered was that</p>

	exposure had occurred and disease could potentially manifest, given a sufficiently long latency (follow-on) period.
4.6	Garry Burdett added further insights into the H&D analysis. He informed members that the H&D model indicated that the relative mesothelioma rates for crocidolite and amosite were 500 times and 100 times higher respectively than the rate for chrysotile. If considering mesothelioma only as a health outcome, these differences in fibre potency are important. He pointed out that there had been much debate over whether chrysotile causes mesothelioma. Exposures in the cohorts regarded as 'key' in terms of understanding the risk of mesothelioma (e.g. Wittenoom) occurred primarily to amphibole asbestos. Exposures were to be relatively short, with the average exposure being 0.4 months.
4.7	Andy Darnton referred members to two slides to illustrate the relationship between latency period and mesothelioma risk. He presented a graph for the Wittenoom cohort, as analysed by Berman and Crump, showing the relationship between mesothelioma deaths versus the number of years since last exposure. Although cases of mesothelioma increase steadily with time since last exposure, the risk appears to tail-off at for the highest latencies observed. There was, however, a large confidence interval around these data points, which makes it hard to be sure that this effect is real. In a second slide, he showed a graph of the relationship between excess mortality observed for 100,000 workers in the GB asbestos workers database versus the number of years since first exposure and the 95 % confidence interval. The percentage excess mortality was found to increase, peaking at 45 yrs since last exposure and then decline with increasing time since last exposure.
4.8	A WATCH member queried the observation that excess mortality appears to tail-off with increasing time since first exposure. He referred to the fact that national mesothelioma mortality rates are still increasing in the oldest age groups and suggested that observations about the risk at very long follow-up times in cohorts that were based on small numbers may not be reliable. He expected the GB asbestos workers database to include workers who may have received high exposures at times in the past when asbestos was more widely used and therefore expected the excess mortality to increase. He suggested that the GB asbestos workers database could be used to gain further insights into the risk profile for the UK, if considered in conjunction with national UK mortality data. Andy Darnton commented that exposure data for workers included in the GB asbestos workers database was expected to be varied and, therefore difficult to characterise.
4.9	<p>Validity of H&D model as the basis for informing estimates of the risk of mesothelioma presented in Annex 1</p> <p>The Chairman asked WATCH to consider the extent to which the H&D model for mesothelioma could be regarded as valid for amosite for the different points down the exposure scale as suggested in the Annex 1 to the item (e.g. 0.1, 1 and 10 f/ml.yrs). He noted that in their written comments in Annex 2, several members considered the model to be valid for some of the exposure scenarios presented in Annex 1 but not for others. He asked to what extent the committee had confidence in making predictions about risks posed by low level exposures to amosite, using values read from predictions of risk derived using the H&D model as shown in the graphs in Annex 1.</p> <p>In inviting members to consider this, the Chairman further elaborated on the aims of the discussion and the associated issues. In seeking to draw a</p>

	<p>conclusion from the written comments provided by members to the paper (Annex 1) sent out during the consultation exercise, he noted that diverse views had been received. Some members were satisfied that absolute risks estimates for certain exposure scenarios could be made based on the H&D relationships as presented in the paper. Other members had commented that there were exposure scenarios for which risk estimates could not be established from the H&D relationship with confidence. The Chairman asked the committee to focus on the task of discussing these issues with a view to reaching a consensus view on which exposure scenarios risk estimates could confidently be derived on the basis of the H&D model and whether these could be regarded as absolute risk predictions. He acknowledged that there were many issues to consider in this respect, such as the inherent uncertainty associated with exposure estimates in the cohorts included in the analysis (discussed at length at the November 2007 WATCH meeting) and the effects on the model prediction of incorporating different life expectancies and follow-up periods. This given, he asked WATCH to consider what scope there was for modifying the risk estimates derived using the H&D relationship to account for these factors.</p>
4.10	<p>A WATCH member asked to what extent altering the risk estimates, for example by a factor of 3 or 4 to account for some of the uncertainties discussed, would alter the answers to the questions posed in the consultation. These adjustments would not alter his view on the approaches the committee had taken to address this topic: the important issues related to the topic had been captured.</p>
4.11	<p>A WATCH member commented that most of the issues in relation to the measuring mesothelioma mortality tended to result in the underestimation of the absolute numbers rather than an overestimation. Based on this observation, some reassurances are provided that the H&D model does not overestimate risk and therefore there is greater confidence that the model can be used to make acceptable risk predictions.</p> <p>The Chairman pointed out that there were substantial uncertainties in the exposure estimates derived for many of the cohorts included in the H&D analysis that typically suggest an underestimation of cumulative exposures. This in turn would lead to an overestimation of the risk per unit exposure rather than an underestimation. The member replied that the H&D model was likely to underestimate mesothelioma risks by a factor of 2-3, and so the risk per unit exposure would be essentially balanced out any over-estimation because of errors in the exposure data. He stressed that, in accepting that the H&D model underestimates risk, there is scope for accepting this model as a valid tool for predicting risks that is unlikely to over-estimate them.</p>
4.12	<p>A WATCH member considered that effects due to life expectancy could readily be accounted for when estimating risks. The life expectancy for the UK population is known for the past and the present and could be used to make reliable adjustments to the risk estimates. Adjusting risk estimates to account for different follow-on periods was also relatively straightforward and could be done robustly. He emphasised however that there were fundamental uncertainties relating to how exposures to asbestos have been characterised in cohort studies with respect to fibres size & length, pattern and duration and to risk predictions that are derived on the basis of extrapolations beyond observed data ranges.</p>
4.13	<p>A WATCH member asked for further clarification on the basis for 'non' or 'sub' linearity observed in the dose-response relationship for mesothelioma</p>

	<p>risk. He asked whether this was routed in how cumulative exposures were determined; the 'dose' component of the relationship.</p> <p>Andy Darnton commented that observations of data in the H&D analysis suggested that for pleural mesotheliomas, that tend to dominate at lower exposures to asbestos, the dose response relationship appears to be non-linear. Hence, when extrapolating beyond the observed data, the non-linear model tends to overestimate the relative mesothelioma risk with decreasing levels of exposure when compared with the risks predicted for the same exposures using a linear model. There is currently no obvious approach for further investigating whether the non-linearity of the dose-response relationship for pleural mesotheliomas is plausible. Nevertheless, the issue of whether extrapolating from linear and non-linear dose response relationships under or overestimates the risks, is an important one.</p>
4.14	<p>The Chairman pointed out that whilst the issue of sub-linearity or nonlinearity is crucial when extrapolating outside the observed range, this was not an issue when considering the range of the observed data. He asked WATCH members to focus initially on the observed data range.</p>
4.15	<p>With reference to Annex 1, a WATCH member considered the absolute risk estimates to be questionable and requested clarification of what other members had considered to be 'acceptable' in terms of predicting absolute risk using the H&D model. The Chairman referred to an example of comments received from a member on p17 of Annex 2 who, after giving consideration to the analysis presented in Annex 1, agreed with the draft position statement in point 6.ii of the cover paper: <i>reliable absolute predictions about risks associated with low-level exposure to asbestos cannot be made using the H&D dose-response model, but it can be used to make predictions about the level of risk of one situation relative to another.</i> This indicated that members supported the expression of an absolute numerical risk estimate for some situations but not others.</p>
4.16	<p>Garry Burdett asked to what extent the predictions of the risk of mesothelioma were influenced by data from cohorts that had been exposed to crocidolite. Andy Darnton replied that data from the Wittenoom cohort, involving exposures to crocidolite asbestos, make an important contribution. Adding to this, Gary Burdett informed WATCH that a couple of studies on the Wittenoom cohort had been published since the H&D analysis that indicated that the asbestos fibre burden of the lungs of workers decreased with time since exposure, with a half-life of around 7 years for crocidolite. These studies also suggested that the rate of mesothelioma may decrease with time since first exposure. He agreed that studies of the Wittenoom cohort were highly pertinent to understanding of the risk of mesothelioma.</p> <p>Andy Darnton replied that he was aware that earlier predictions of mesotheliomas arising in Wittenoom cohort had been revised downwards based on a prediction model that now accounts for lung clearance. In relation to the more recent studies of lung burden in workers from the Wittenoom cohort, a WATCH member pointed out many cases of asbestosis had been observed in the group; a condition in which asbestosis fibres could sequester in the area of fibrosis. This could account for the much higher half-life having been observed for fibres in workers' lungs (e.g. 7 years) than observed in laboratory studies (e.g. 1.5-2 years). The clearance of fibres from the lungs of workers had not been taken into account in these studies. The WATCH member expressed reservations about the methodologies used in these studies and hence, their overall usefulness. Another WATCH</p>

	member pointed out that observations from the study of crocidolite workers were not relevant to the general population.
4.17	<p>Consideration of risk the estimates presented in Annex 1 for Case 1: mesothelioma risk in relation to cumulative exposure to amosite at 10f/ml.yr</p> <p>The Chairman commended Andy Darnton in respect of the amount of work that had been carried out in the preparation of Annex 1. This given, he requested that members avoided generating any suggestions for further analytical work for HSE, but focused instead on the perspectives on risks associated with low level exposures to different types of asbestos fibre presented in Annex 1. He directed members to Case 1: mesothelioma in relation to amosite exposure (pages 6-7) and asked them to focus on risks potentially associated with cumulative exposures accrued over 5 years from age 30 of 10 f/ml.yr. From Figure 1, it could be seen that cumulative exposures to amosite fibres at 10 f/ml.yr correspond to lifetime mesothelioma risks of 565/100,000 and 700/100,000 as predicted by the H&D “best” model and the H&D linear model respectively. He asked members to consider this scenario exclusively; if members did not feel confident in supporting absolute risk estimates for this scenario, they would be unlikely to support absolute risk estimates for other scenarios. He reminded members that the WATCH Secretariat had captured the balance of opinion across six members on this point expressed during the consultation on Annex 1 by correspondence. This indicated that there were a spread of views that ranged from support for endorsing absolute numbers, through to concern about the reliability of the risk estimates and suggestions that they should only be used to make predictions about the level of risk of one scenario relative to another. He asked WATCH to discuss this point with the aim of deriving a consensus view on the level of confidence in absolute risk estimates.</p>
4.18	<p>A WATCH member asked why the committee was seeking to endorse the concept of absolute or relative estimates of the risks of disease associated with exposure to asbestos, based on the considerations of perspectives presented in Annex 1. He suggested that an alternative approach could be adopted where the analysis of risks conducted by Andy Darnton was published in a peer-reviewed journal, thus inviting broader comment across the scientific community. Another WATCH member agreed that publication of the analysis and wider peer review would be worthwhile but added that it was also important that WATCH gave consideration to making statements about levels of confidence in different risk estimates.</p>
4.19	<p>The Chairman clarified that the primary function of WATCH, as a government advisory body, was to provide advice to HSE on scientific issues related to chemical risks. Regulatory agencies frequently have to address issues on risk – and may be asked to question a stance on risk issue taken or predicted by other government departments or advisory groups. In asking WATCH to address this issue, HSE is seeking advice on what risk estimates could be confidently endorsed and what risk estimates could not be confidently endorsed. Using Table 1, Case 1 on page 8 on Annex 1 as an example, the Chairman informed members that the scenarios in Annex 1 were intended to represent the type of exposure situation likely to be encountered in life that corresponded to the exposure and risk estimates presented graphically in Figures 1a and b. He emphasised that the intention had been to convey what potentially could be the risks for current real life situations. Andy Darnton provided WATCH with further insights into how the</p>

	values of 0.1, 1 and 10 f/ml.yr in Annex 1 were chosen to reflect credible current exposures by showing members a number of slides of typical exposures that could be expected to be associated with different current occupational scenarios (e.g. maintenance workers removing insulation).
4.20	Dil Sen (HSE, Senior Medical Advisor) agreed that exposures at 0.1, 1 and 10 f/ml.yr are likely to reflect current real life scenarios where exposures to low-level asbestos fibres are a concern. He provided an example of a scenario in which workers who had fitted computer cables through the roof space of a school building had inadvertently drilled through materials containing asbestos. Concerns had also emerged when schoolchildren and teachers had re-entered the building after the work had been carried out to find visible dust present.
4.21	A WATCH member commented that exposures to fibres between 1-5 f/ml.yr were commonly encountered by workers stripping out material containing asbestos on a daily basis. He considered that the scenarios presented in Annex 1 did therefore reflect real life scenarios likely to be encountered today.
4.22	<p>A WATCH member asked for further insights into the types of jobs that these scenarios would apply to. He asked, for example, what level of exposure would an individual likely to receive when removing artex-coated ceilings or piping from domestic premises or installing cables.</p> <p>Garry Burdett replied that the extent of exposure, considered in terms of a 'simple equation' would vary as a function of the mechanical force with which asbestos containing material is disturbed and the duration over which this force is applied. Airborne exposure levels in the range 1 –10 f/ml could readily occur when handling, breaking up or ripping out materials that had been sprayed with asbestos. However, this is the maximum level of exposures that these types of activities are expected to give rise to. Much higher exposures were expected to occur when materials containing asbestos are disturbed using power tools. He added that having reliable risk estimates for different exposure scenarios was an important issue from HSE's perspective when making risk management decisions. For example, the HSE is required to regulate certain types of activities involving the removal of asbestos by issuing licenses; the removal of materials containing asbestos insulating board requires a license, whereas the removal of chrysotile containing textured coating, previously a licensed process, no longer requires a licensed contractor. Decisions on whether tasks should be licensed or not are informed by the consideration of the associated risks and reliance on numerical risk estimates are necessary. As another example, as part of the duty to manage asbestos (Control of Asbestos Regulations 2006) the UK government proposes to invest around 4.5 billion pounds over 30 years to reduce the burden of disease caused by exposure to asbestos based on a number of different initiatives. Quantified risk estimates were used in the development of this regulation to inform regulatory impact assessments on the value for money of risk control measures in terms of the number of lives saved.</p>
4.23	A WATCH member pointed out that tasks that generated low airborne levels of asbestos fibres (e.g. removal of artex ceilings), would only give rise to these levels transiently. Sustained exposures at these low levels was very unlikely to occur, hence the exposure could be regarded as short-term.
4.24	A WATCH member commented that one of the fundamental problems with the risk estimates is that they were derived from epidemiological studies of

	<p>industrial worker cohorts and not general workers cohorts reflecting exposure scenarios likely to be encountered today. Observations of mesothelioma cases indicate that there are around 100 cases of this disease amongst general workers for every one case reported in the industrial cohort studies. Good exposure data for individuals who work in environments where asbestos exposure is not controlled (e.g. carpenters, plumbers, and maintenance workers) is lacking. Some of these workers will have used power tools on asbestos containing materials. Given these tasks, the lifetime risk of mesothelioma for these workers is expected to be very substantial high at around 10% and 20% for plumbers and carpenters respectively.</p>
4.25	<p>The Chairman asked WATCH if the substantial risk estimates predicted for plumbers and carpenters were hypothetically superimposed on the H&D dose-response curve, would the committee consider that the cumulative exposure that corresponded to this level of risk realistically reflected the cumulative exposure to amosite that these workers would have in fact been exposed to? If the committee deemed this not to be the case, did it consider that some critical aspects have been overlooked in respect of the attempt that has been made to characterise the dose-response relationship for mesothelioma associated with exposure to amosite?</p>
4.26	<p>A WATCH member commented that interpreting cumulative exposures expressed in f.ml/yr in the context of modern-day tasks was not straightforward. Although studies simulating the release of fibres for tasks such as sawing asbestos insulation board have suggested that airborne levels could reach 25f/ml, it is not clear how this data can be used to predict typical cumulative exposures in workers conducting tasks in reality. He did not therefore consider the cumulative exposure metric expressed in f.ml/yr to be a useful metric when attempting to understand the risks these workers faced. He added that cohort studies on amosite exposure were difficult to interpret and there was some conflicting evidence in respect of the risk of mesothelioma for exposed workers. For example, cases of mesothelioma were not found in studies of South African asbestos miners, despite the fact that they had been exposed to very high levels of amosite.</p>
4.27	<p>A WATCH member asked for clarification on the non-linear aspects of the dose-response relationship for the risk of mesothelioma; the reasoning behind these risks appearing disproportionately higher for lower exposures and the implication this had for risk estimation at the lower end of the exposure spectrum. Andy Darnton replied that evidence for a non-linear relationship between cumulative exposure to asbestos and risk of mesothelioma had emerged from observations from the study of different sites of mesothelioma (pleural and peritoneal). Non-linear models were therefore considered for mesothelioma in which risk was proportional to a power of cumulative exposure; and separate power function components were incorporated to reflect differences in pleural and peritoneal mesothelioma data. Based on the best fitting model, pleural mesothelioma risk is proportional to a power of cumulative exposures less than 1 whereas peritoneal mesothelioma risk is proportional to a power greater than 2. Pleural cases therefore dominate over peritoneal cases at low asbestos exposures, with peritoneal mesotheliomas becoming more important with increasing exposure levels. In the range of exposures relevant for asbestos worker cohorts, the overall dose-response relationship observed looks broadly linear. However if a non-linear dose-response relationship truly applies for pleural mesothelioma, a higher risk of disease would be predicted for lower exposures.</p>

	<p>The WATCH member commented that risk assessments are traditionally based on the assumption of a linear dose-response relationship. Unless there is strong evidence to the contrary, he suggested that the assumption of a linear dose-response relationship for the risk of mesothelioma from exposures to asbestos could help simplify the task of characterising and communicating this risk.</p>
4.28	<p>Background risk estimates</p> <p>Several WATCH members requested clarification of the derivation of the background risk estimate of 25/100,000 presented in Annex 1. To this end, a WATCH member presented a slide showing the cumulative mesothelioma death rates per 100,000 during the period 2002-4 for men versus women. This graph had been based on mesothelioma mortality data compiled across a large number of countries. It could be observed that the majority of death rates appear to lie close to a straight line that did not pass through zero but converged towards a risk of 25/100,000. He informed the committee that the point of convergence is suggestive of a background risk of mesothelioma at this level. He added that the data suggested that whilst mesothelioma death rates for women in Britain had increased, many observed cases could not be obviously linked to recognised asbestos exposures. The cause of these additional mesotheliomas above the background level is unknown but it is possible that some could be accounted for by environmental sources of exposure, such as low levels from released during building maintenance work. That some mesotheliomas occur spontaneously – and therefore contribute to a background level of mortality - is consistent with what is known about many other kinds of cancer.</p>
4.29	<p>A WATCH member asked to what extent exposure to asbestos could be ruled out for background cases of mesothelioma. The WATCH member replied that whilst exposure to asbestos could not be ruled out for these cases, there was also no evidence that mesothelioma cannot occur spontaneously. Knowledge of cancers that have been linked to exposure to other substances suggests that these cancers can also occur spontaneously. This may also be true for mesothelioma.</p>
4.30	<p>The Chairman pointed out that this was not of concern in the consideration of absolute risk associated with cumulative exposures of 1 and 10 f/ml.yr, representative exposure scenarios discussed in Table 1, since in Figure 1b, these exposures intercepted the H&D “best” line above the background risk estimate line.</p>
4.31	<p>Expression of risks in absolute versus relative terms.</p> <p>A WATCH member expressed being uncomfortable with the idea that WATCH had been requested, in the document to consider the potential risks posed by different exposures to asbestos in ‘relative’ or ‘absolute’ terms. Whilst he accepted the H&D model to be valid, estimates of absolute risk derived from the relationship would be rendered invalid if different numbers were inferred from information on actual cases of mesothelioma mortality.</p>
4.32	<p>Another WATCH member also expressed being uncomfortable with the questions posed in Annex 1 in relation to considering absolute and relative risks for three different exposure scenarios. In his opinion, the question should not consider risks as relative or absolute, but should address instead the underlying issue of the degree of confidence that can be placed in the numbers derived from the analysis. He suggested that the issue might be better approached by considering precise or imprecise estimates of risk.</p>

4.33	A WATCH member offered definitions of relative risk versus absolute risk. In his view, relative risk referred to differences in the risk of one type of asbestos fibres relative another. He understood this term to relate to different fibre potency in terms of inducing disease. Absolute risk, on the other hand, referred to the risk posed by different concentrations of each different type of fibre.
4.34	Another WATCH member indicated that he was not comfortable with the wording of questions posed in Annex 1 and suggested that these could be more readily addressed if re-worded. In his view, the issue centred around the meaning of 'reliable absolute risk estimate'. He interpreted this as the level of uncertainty one could place in an absolute risk estimate. For example, when asked about the level of confidence in the absolute risk estimate of 565/100,000 predicted by the H&D "best" model for cumulative exposures at 10f/ml.year, he would not be confident that an absolute risk estimate of 700/100,000 was not also equally valid. However, he had greater confidence in the statement that the risk was <1000/100,000 for this level of cumulative exposure.
4.35	Another WATCH member understood the term 'relative' to be used when describing how the risks associated with one situation relate to that of another. For example: 'the risk for scenario 1 is 1/10 th of that for scenario 2'. Whilst agreed relative risk expressions are useful when making risk management decisions, they are not useful for indicating the risks for individuals. Absolute risk estimates are required in this case rather than relative estimates.
4.36	The Chairman informed WATCH that the analysis presented in Annex 1 had merely been an attempt by the team at HSE to offer different possible positions for the committee's consideration, which could potentially be adopted or dismissed. The aim of the task had been to stimulate thinking. He noted, however, that several members had expressed that they did not like the way in which the questions in Annex 1 had been framed. Acknowledging this, he asked members to consider other ways in which questions related to the risks posed by low level exposures to asbestos could be framed so that position statements could be more readily derived. He emphasised that the ultimate goal of the session was for the committee to derive position statements and the route by which this was achieved is entirely the choice of the committee.
4.37	<p>Framing questions to derive position statements</p> <p>Taking the discussion forward from point 4.35, the Chairman asked WATCH to focus on framing conclusions to this item and invited members to put forward tentative positions. To this end, he asked WATCH to consider, in the first instance deriving a position, using a preferred approach, with respect to mesothelioma risks associated with amosite, at the high end of the exposure range; 10 f/ml.yr.</p>
4.38	A WATCH member suggested that the issue could be 'framed' by drawing further insights into real life scenarios where exposures to low levels of asbestos could occur. Although certain scenarios were already known about (e.g. use of drawing pins in asbestos insulation board in school buildings, drilling materials containing asbestos, wiring cables in lofts etc), no reliable exposure estimates were available for these scenarios. He suggested that if Annex 1 was prepared for publication, it would be helpful to include some insights into real life low level exposure scenarios in order to contextualise the analysis and more clearly define the issues. In doing this, he considered

	<p>that it would be acceptable to assume a linear dose-response relationship for the risk of mesothelioma. A prospective publication could also include a discussion on what can be inferred from the asbestos cohort data. For example, on one hand exposures to asbestos received during one working day in Wittenoom could, to some extent be regarded as 'harmless; whilst on the other hand exposures received over 3 months of work could be regarded as appreciable. A key question would be: can the risks associated with 3 months of work at the site be reliably quantified? Beyond this the reality is that little is known about the risks that are associated with tasks that may be pertinent to the issue today. He emphasised that it was important to clearly convey in any prospective publication on the subject that there is a lack of knowledge for current exposure scenarios and, given this uncertainty, explain the assumptions and rationale that had been used to quantify the potential risks for these scenarios.</p>
4.39	<p>A WATCH member agreed that insights were needed into the potential risks associated with different tasks where exposures to low levels of asbestos may occur in order that appropriate advice on risk management measures could be given, for examples as part of 'Asbestos Essentials'. In his opinion, the discussion was to some extent focusing too much on the detail of the science; over-analysing what is essentially the best available data, rather than reaching a consensus view that acknowledges the limitations of the available data. He suggested that risk estimates would be considered in terms of being 'useful' risk estimates rather than 'absolute' or 'relative' risk estimates.</p>
4.40	<p>The Chairman drew WATCH's attention to the graph in Figure 1b (page 7, Annex 1). This suggested that the lifetime risk of mesothelioma due to exposures to amosite asbestos at 10 f/ml.yr lay between 250/100,000 and 1000/100,000 when derived using the H&D "min" and "max" models respectively. The lifetime risk of mesothelioma derived using the H&D "best" model was 565/100,000. The "max" risk estimate was approximately twice the "best" estimate, whereas the "best" estimate was approximately twice the "min" estimate. On this basis, the Chairman asked if WATCH was willing to accept the idea that the H&D model provided an estimate of the risk of mesothelioma associated with exposures to amosite, to within a factor of 2.</p>
4.41	<p>A WATCH member challenged the validity of placing confidence intervals around estimates of risk that had essentially been derived for studies of asbestos worker cohorts from which reliable exposure estimates had not been obtained. In view of this concern, the Chairman suggested to WATCH that the idea that no risk estimates could reliably be taken from the H&D prediction of the dose-response relationship could indeed be a valid outcome to the discussion and a position that the committee could opt to adopt.</p>
4.42	<p>Gary Burdett gave further insights to the committee on the Tyler and Patterson amosite workers cohorts. The National Institute of Occupational Safety and Health (NIOSH) had carried out four separate investigations of the Tyler plant. The plant had used the same machinery though out its life that had been originally obtained from the Patterson site when this closed and was essentially at the end of its life. Knowledge about the limited effectiveness of this machinery essentially informed the estimate of exposure that the site; it was known that exposures could not be reduced below 2f/ml. He clarified that, other than the South African amosite miners, the Patterson and Tyler cohorts were the only other cohorts involving amosite exposures included in the H&D analysis. These were therefore the only cohorts that informed the dose-response relationship for the risk of mesothelioma for</p>

	exposures to amosite predicted by the H&D model.
4.43	A WATCH member considered the systematic review of available data and derivation of a dose-response relationship had been an appropriate approach to take. He regarded that there was less uncertainty for risk estimates derived using the observed data range than for estimates that had been derived by extrapolation for lower exposure levels. He acknowledged that this approach did not provide a satisfactory indication of absolute risks. The member felt comfortable with accepting that this approach provided the best estimate of risks associated with low level exposures to asbestos, within perhaps a 2-fold uncertainty margin around the middle of the range of estimates but a 50 or 100-fold uncertainty margin for estimates at the lower end of the range. He considered the characterisation of uncertainty to be an appropriate aspect of risk prediction but pointed out that this practise was not widely applied and good methods for defining the acceptability of different levels of uncertainty were not available. He recommended that a more detailed scrutiny of uncertainties associated with the H&D model be carried out.
4.44	A WATCH member commented that if people are given advice to avoid doing certain activities or tasks that may give rise to exposures to asbestos, they need to be informed why these should be avoided and be provided with some idea of what the potential risks associated with the tasks are. An appropriate model or modelling tool, if one was available could potentially be useful in this respect, for example by predicting risks for individuals of different ages carrying out specific tasks in terms of low, medium or high risk. For example, if such a tool was available based on the H&D model, ages of exposed individuals could be entered into model in order to derive age-specific risk estimates. Documents on the tolerability of risk (e.g. HSE R2P2 framework) could then be examined to determine whether the level of risk determined for these individuals was acceptable or not. There is currently no good model available upon which such predictions could be made. However situations where exposures incidents have occurred and individuals are naturally concerned occur in reality and several cases have recently been highlighted in the press. The member considered that it was inappropriate to respond to these situations with comments or statements that indicated that the risks to human health associated with the exposures that the individuals may have encountered were not known. In his view the need to progress the issue towards some quantification of the risks, given current concerns over low level exposures to asbestos, was imminent. If an attempt to quantify the risks is not made in light of current knowledge, future generations will still be facing the same problems.
4.45	The Chairman noted that a number of valid comments had been made during the discussion, but reminded members that the ultimate aim of WATCH's deliberations on this item was to reach a conclusion. He emphasised again that a request from the committee for HSE to conduct further analysis at this stage, would present difficulties with respect to resource availability etc, given the resources that had already been utilised in the preparation of the analysis in Annex 1 and work that had been carried out in respect of addressing this item at previous WATCH meetings.
4.46	A WATCH member concurred with other members who had expressed reservations about the acceptance and reliability of absolute risk estimates. The reality was that limited data from two similar cohorts had essentially been used to inform the derivation of the relationship between the risk of mesothelioma and exposure to amosite asbestos. This given, he considered

	<p>that the risk estimates derived should be regarded as estimates of 'limited reliability' since they were informed by limited data. He expressed reservations about using risk estimates of limited reliability to reflect the risks for a broad range of scenarios because this was unlikely to be realistic. In his view, the available information suggests there is a consistent relationship between exposure to amosite and mesothelioma that suggests that there is problem that needs to be addressed; but that does not allow reliable quantification of the potential risks. The WATCH member commented that he was willing to accept a conclusion to the item that reflected the consideration of risk estimates in this basis. In his view such a conclusion could provide a sound basis for further actions.</p>
4.47	<p>The Chairman asked the WATCH member to clarify against which exposure scenarios these 'limited reliability' risk estimates could be made. The member replied that there were two situations where risk estimates of 'limited reliability' could be applied: the retrospective analysis of the risks of mesothelioma in people with past exposures to asbestos and the analysis of current exposures and how these can be prevented. Whilst addressing the first scenario was problematic, recent initiatives on asbestos taken by HSE aligned with the goal of addressing the second situation.</p>
4.48	<p>The Chairman invited Helen Ratcliffe (HSE Policy Group – asbestos policy) to inform WATCH about initiatives on asbestos that HSE had recently implemented. Helen Radcliffe informed the committee that HSE has established a national awareness-raising campaign on asbestos that included a number of separate initiatives running over 6 weeks. This included securing slots on radio stations most likely to be listened to by plumbers, carpenters and other workers and adverts in 'red top' newspapers. The aim of this initiative was to educate people more about the risks posed by working with materials containing asbestos. The initiative included a 'call to action', directing individuals to call the HSE information telephone line to obtain further information. Wider direct mail-shot activities were also planned, following a pilot scheme that was carried out in the North West of England in the early part of 2008.</p>
4.49	<p>A WATCH member agreed that awareness raising initiatives were very important but pointed out that individuals are still likely to ask the question: 'What is my risk'. In order to answer this question some quantification of risk is required, hence the task of exploring and deriving statements on how these risks should be best expressed is still a pertinent one for WATCH.</p>
4.50	<p>The Chairman brought WATCH back to Case 1: mesothelioma in relation to amosite exposure (page 6, Annex 1) in which three exposure scenarios were presented; 0.1, 1 and 10 f/ml.yr. He asked members whether they considered the scenario involving exposures at 10 f/ml.yr proposed in the paper to be higher than any contemporary asbestos exposure scenarios and therefore unrepresentative of exposures that were likely to be experienced today. A WATCH member disagreed; in his experience people without protection could easily encounter exposures as high as 10 f/ml.yr.</p>
4.51	<p>The Chairman asked WATCH whether having discussed the limitations of the data, deficiencies in the exposure analysis and issues of uncertainty; members considered that whilst the H&D model could not be relied upon to inform specific risk estimates, the underlying analysis enabled the identification of :</p> <p>(i) Situations for which the level of risk is substantially above the background level and for which action should be taken and/or</p>

	<p>(ii) Situations for which the level of risk cannot be distinguished from the background level of risk and are therefore of much less concern.</p> <p>Chairman suggested that the next logical step would be to identify specific, current real-life exposures scenarios that could be assigned to these categories. This could be achieved by considering available exposure data for different scenarios and where this was 'positioned' on the H&D model. On this basis scenarios could be assigned to either category (i) or (ii).</p>
4.52	<p>A WATCH member commented that the suggestion in the Chairman's proposal that background exposure could be used as a 'threshold' for concern and action were inconsistent with requirements in the management of occupational risks to reduce exposure to hazardous agents as far as reasonably practicable. He added that the risks associated with background exposures to asbestos have not been characterised or reliably quantified. Although attempts to address this have been made, it is not possible to determine with any degree of certainty what background risks are due to. Background levels are generally regarded as insignificant. However, past experience has shown that disregarding risks posed by substances that are potentially hazardous to health because these were perceived to be insignificant resulted in a failure to prevent adverse health outcomes. Background risks associated with asbestos should not be considered as insignificant, but should instead be regarded as of lower priority than the risks associated with more apparent exposures to asbestos.</p>
4.53	<p>Consideration of risk estimates in the context of the HSE R2P2 framework</p> <p>The Chairman referred WATCH to the 5th section of comments (pages 17-18, Annex 2) in which risk estimates for asbestos exposures were discussed in the context of the HSE R2P2 framework. He invited comments from members on how this reflected their views.</p>
4.54	<p>Rob Turner (HSE, Corporate Specialist Division) clarified that when risks are deemed to be 'acceptable' in the context of the R2P2 framework this did not imply that the risks should be ignored and no exposure control measured adopted. Exposure control measures should still be considered. When exposure levels are around the background level, but obvious additional control measures are available these should, in good practice, be applied provided this is financially viable. Disproportionate amounts of effort and costs should not however be applied to the task of forcing levels that are around the background level down further.</p>
4.55	<p>The Chairman reminded members that the in depth consideration of policy, risk management issues and the associated cost was beyond the remit of the committee and the focus should primarily be on addressing the science and how this is most appropriately use to inform regulatory decision-making.</p>
4.56	<p>A WATCH member queried the statement on page 18 of Annex 2 : '<i>an individual risk of death of 1/1000 per annum might represent the upper limit of tolerability for any substantial category of workers</i>'. In his view, this limit seemed high. Rob Turner explained that the concept in R2P2 had been to reflect the tolerability of risks as a band or continuum with an upper limit of tolerability at one extreme and a lower limit of tolerability at the other. The intention is that risk estimates are considered in the context of the bands in the R2P2 framework and different risk management actions are prompted by the outcomes. Risks management decisions are generally more difficult for</p>

	risk estimates that emerge on the boundaries of the tolerability band.
4.57	<p>A WATCH member informed that committee that he had given thorough consideration to the analysis presented in Annex 1 and how this could be usefully applied to the derivation of risk estimates. He had reached the conclusion that, in Figure 1b, risk estimates that emerged in the upper right-hand portion of the graph could be regarded as “unacceptable” whereas risk estimates below the background line of 25/100,000 could be regarded as “broadly tolerable”. He did not, however, wholly understand the significance of the background line or the basis for sub-linearity associated with low exposure levels.</p> <p>The Chairman advised members not to become too concerned with the idea the graphs are intended to portray a presentation of risk that was implicitly reliable and upon which actions should be taken. He re-emphasised that the aim of the discussion was for the committee to derive a position statement.</p>
4.58	A WATCH member noted that whilst the committee had broadly discussed cumulative exposures at 10 f/ml.yr, at the top end of the range representing contemporary scenarios, equal consideration had not yet been given to cumulative exposures of 0.1 f/ml.yr at the bottom end of the range. He suggested that if the committee could agree positions at both ends of the representative range, this would essentially cover the range where there is a level of concern and constitute progress, given that more detailed consideration of different risks between this range was particularly challenging.
4.59	A WATCH member considered that the committee was seeking a high degree of precision in order to make judgements on an issue for which there were little reliable data. He reminded members that the committee had several times in the past faced the task of appraising poor data sets for topics it had addressed, but had been able to derive sensible conclusions about the associated risks. He asked why the derivation of a conclusion for this particular issue was proving to be more challenging. In his view, he considered that HSE had thoroughly analysed the best available data and informed the committee well in this respect. He suggested that WATCH should therefore express a consensus view in which the H&D model was deemed to be valid and acceptable and adopt position statements on risk estimates for low-level exposures to asbestos using the HSE R2P2 framework approach.
4.60	Garry Burdett expressed the view that the H&D model is sufficiently robust and is useful for deriving risk estimates. Once derived, the question is: what can usefully be done with these estimates? He agreed with the suggestion raised in a member’s comments in Annex 2, that the risk estimates could be considered in the context of the HSE R2P2 framework based on three risk categories. He informed WATCH that ‘control banding’ approaches were used in some industrial sectors (e.g. the pharmaceutical sector). If the risk estimates derived using the H&D model in Annex 1 are considered in the context of a 6 or 9 box control banding model, then he did not expect any more than one box of the model to be potentially wrong at any one time, irrespective of the errors associated with the risk estimates. Presenting the risk estimates outcomes from the H&D analysis into a control banding context could provide a useful tool for communicating the risks.
4.61	Because of time pressure on the remainder of the agenda, the Chairman brought the discussion on Day 1 to a close. Noting that members had

	<p>deliberated on this topic for several consecutive WATCH meetings, he proposed that it was time for the committee to articulate its position. To this end, the Chairman proposed scheduling an additional session on Day 2 of the meeting in order to try to derive an agreed position statement. In preparation for this extra session, he requested that WATCH members individually give to the secretariat their suggestions for the wording of a statement with which they could agree. He proposed that the WATCH secretariat would then construct a draft conclusion for further consideration at the Day 2 session. He acknowledged that several members need to leave at the end of day 1 and he thanked them for any draft text that they might be able to leave with the secretariat.</p>
4.62	<p>Deriving a position statement on the risks of mesothelioma and lung cancer in relation to relatively low-level exposure to different forms of asbestos (Day 2)</p> <p>The Chairman thanked WATCH members who had come together the previous evening to work on a draft position statement. He invited the secretariat to display this draft to the committee as a whole for further consideration.</p>
4.63	<p>WATCH members discussed further the wording of the draft conclusion and introduced some changes. Given that several members were absent at this point, a provisional text was agreed as suitable for post-meeting circulation among all members, with an invitation to submit further comments to the secretariat.</p>
4.64	<p>Subsequent to the meeting members were consulted by correspondence, up to 14 November. At that point, members signified their agreement with the following text as the best representation of the committee's collective view:</p> <p>WATCH decided that the H&D2000* model is a good reflection of the available data and can be used to estimate lifetime risk of mesothelioma and lung cancer from exposure to asbestos in some circumstances. However, WATCH also advised that the model may be less reliable when extrapolating beyond the exposure ranges for which there are epidemiological data, due to uncertainties in the dose-response relationship at lower levels.</p> <p>In addition to such uncertainties, the predictions from the model are subject to a number of other uncertainties in the original epidemiological data available including:</p> <ul style="list-style-type: none"> - exposure assessment, caused by the absence of reliable contemporaneous measurements and by differences in assessment methods between studies - cancer diagnosis, such as completeness of identifying mesotheliomas in the past - potential confounding factors, such as absence of control for smoking in some studies of lung cancer <p>The H&D2000 model can be used to produce estimated lifetime (to age 80) risks of asbestos-related lung cancer and mesothelioma (the two tumour types combined) per 100,000 individuals, for a 5-year duration of exposure to different concentrations of the various forms of asbestos, from age 30, for example:</p>

fibres/ml.yr	Crocidolite best (min-max)**	Amosite best (min-max)**	Chrysotile best (min-max)**
10	5600 (3200–8400)	2300 (960–4000)	56 (23–340)
1	750 (250-1600)	180 (35-570)	6 (1-45)
0.1	120 (24-360)	21 (2-100)	1 (0.1-7)

**Best estimate from the H&D 2000 best-slope model with maximum and minimum estimates based on the range of predictions consistent with the H&D2000 high-slope and low-slope models. All models give cumulative risk up to age 80.

These numbers should not be taken to be reliable absolute risk values.

However, WATCH concluded that the model is sufficiently robust to be used to differentiate the relative magnitudes of risk for the different fibre types in different exposure ranges and thereby distinguish between different operations in a manner that is amenable to a control-banding approach.

WATCH recommended that further work be done to develop such a control-banding approach for tasks involving remaining asbestos. Such an approach would emphasise proportionality, requiring action that is commensurate with the risk.

WATCH recommends that at a subsequent meeting it should seek to progress the ideas in the three paragraphs immediately above.

(1) Hodgson J and Darnton A (2000). Quantitative risks of mesothelioma and lung cancer in relation to asbestos exposure. *Annals of Occupational Hygiene*, **44**; 565-602.

(2) Berman W and Crump B (2008) Update of Potency Factors for Asbestos-Related Lung Cancer and Mesothelioma. *Critical Reviews in Toxicology* 38(S1): 1-47.

(3) Berman W and Crump B (2008) A Meta-Analysis of Asbestos-Related Cancer Risk That Addresses Fiber Size and Mineral Type. *Critical Reviews in Toxicology* 38(S1): 49-73.

(4) McDonald JC, Harris JM, Berry G (2006) Sixty years on: the price of assembling military gas masks in 1940. *Occupational and Environmental Medicine* 63:852-855.

5 Welding Fume and Chronic Obstructive Pulmonary Disease (COPD)

5.1 The Chairman opened the item by explaining the background. At a workshop in 2004 to discuss work-related chronic obstructive pulmonary disease (COPD), in the context of the Disease Reduction Programme, HSE had identified exposure to welding fume as a situation that required further consideration. An HSE project on welding fume was subsequently started in 2005 with the aim of improving good practice in target industries and thereby reducing the risk of COPD. In 2007, HSE was challenged to provide evidence that there was an established link between welding fume and COPD. [Details of HSE's subsequent action are given under "Argument", page 2 of the cover paper to the item]. The position then adopted by HSE was described to ACTS in November 2007 in the following terms: *'The Secretary to ACTS noted there was no evidence to link COPD to welding'*.

	<p>ACTS expressed surprise at this position and asked HSE to engage WATCH in exploring the basis and evidence for this statement.</p> <p>HSE had committed to providing to WATCH at its October 2008 meeting an explanation of the rationale for the statement made to ACTS. The Chairman welcomed Jackie Germain (HSE, Policy Group) who had been involved in HSE's work on welding fume. He asked members to consider the explanation offered in the cover paper and to form an opinion on its appropriateness, to be conveyed to ACTS. He opened the item for general discussion.</p>
5.2	<p>A WATCH member requested clarification on HSE's position on welding fume and COPD. The Chairman referred members to the statement in paragraph 10 of the cover paper: '<i>HSE remained concerned about the risk of COPD and other lung diseases in welders given the known toxicity of a number of fumes that can arise from this work</i>'. Jackie Germain described HSE's position as being that whilst there is some evidence to link welding fume with COPD there is insufficient evidence to establish a causal link to a significant amount of this disease. The Chairman suggested that this position could also be found in the cover paper, but then realised this was not the case and apologised for his error.</p>
5.3	<p>Dil Sen informed WATCH that smoking was a confounding factor in several studies of welders and could be one of the reasons why evidence for a causal link between welding and COPD cannot be firmly established.</p>
5.4	<p>A WATCH member observed that, in a review of the prescribed causes of COPD deemed to merit compensation, the Industrial Injuries Advisory Council (IIAC) had not established evidence that welders have a 2-fold or greater increased risk of developing disabling loss of lung function; on these grounds IIAC concluded that welding fume did not meet its criteria for prescription. Another WATCH member noted that according to IIAC one study had reported what appeared to be clear evidence of a link between COPD and welding, but a follow-up to the study had not clarified the situation. In his opinion, scrutiny of primary papers by WATCH would be needed in order to explore properly the evidence for a link between COPD and welding.</p>
5.5	<p>Rob Turner informed WATCH that the HSE project had been based on the view that welding fume is a possible cause of COPD, but the epidemiological evidence for this had been challenged. HSE is still interested in exploring possible links between exposure to welding fumes and respiratory disease, and the need to secure better control of exposure to welding fume, but would need to do so in the context of a wider range of potential respiratory ill-health outcomes, rather than a specific link to COPD.</p>
5.6	<p>A WATCH member asked from where the challenge to the link between COPD and welding had come? Rob Turner replied that the TUC had commented to HSE that the evidence base is poor, suggesting that more work was needed. The welding industry had challenged HSE on the evidence for a causal link, and HSE statements pertaining to there being an established causal link were subsequently withdrawn.</p>
5.7	<p>The Chairman asked WATCH whether it agreed with HSE's position as presented in the cover paper and portrayed verbally at this meeting? Several members commented that in their opinion there was insufficient information presented in the cover paper upon which to form an opinion. The Chairman acknowledged that a clear, succinct statement of HSE's position</p>

	was absent from the cover paper. In view of the members' comments he considered that the issue could not be progressed further at this meeting. A WATCH member reiterated his view that exploration of primary papers was needed to consider this issue further.
5.8	The Chairman thanked members for their comments and brought the item to a close. He agreed with members that an appropriate conclusion was that in the circumstances the committee could not reach a conclusion on this item. He proposed that the item be revisited at the next WATCH meeting.
6	Futures (Horizon Scanning) workshop
6.1	The Chairman opened the session by informing WATCH that the aim of this "futures" (horizon-scanning) session was for WATCH to try a different approach to fulfilling its horizon-scanning responsibility (as a government scientific advisory committee). HSE's Futures Team, based at HSL, would lead the session, presenting an outline of its work. The overall approach would then be tested by WATCH examining a question relevant to its future work, that being the possible effects of the REACH legislation on the UK chemical industry during the next ten years. The Chairman welcomed Peter Ellwood and colleagues from the HSL Futures Team. He handed over to Peter Ellwood to give a general introduction to the session.
6.2	Introductory presentation Peter Ellwood gave a presentation to WATCH covering the HSE horizon-scanning system and its key findings to date, HSE's Scenarios for the Future of Health and Safety in 2017 (Annex 2 to the item), and an explanation of the exercises that WATCH would carry out.
6.3	Following the presentation attendees were divided into three groups, each facilitated by a member of the HSL Futures Team, to work through the exercises
6.4	Exercises : Predetermined Elements and Critical Uncertainties First Exercise Given the number of participants, it was decided that only three of the four HSE scenarios in Annex 2 would be used. WATCH members and other attendees were dispersed into three groups, each of which worked on one of the HSE scenarios. Participants were asked to break into twos or threes and to consider issues that would affect the impact of REACH on the UK chemical industry. They were then asked to place their issues on either side of a line dividing 'High Impact' and 'Low Impact' issues. Then as a group they were asked to separate these into 'Likely to Occur' and 'Less Likely to Occur'. Second Exercise In this exercise, members and other attendees considered the 'High Impact/Likely to Occur' issues. They were asked to assess each issue against the following headings: (i) Description (ii) Impact (iii) Indicators (iv) Effect on the work programme of WATCH (v) The appropriate response from WATCH and others

	<p>Third Exercise</p> <p>In this exercise, WATCH members and other attendees were asked as a group to consider how REACH might turn out in their given scenario.</p> <p>The outputs from all three exercises were captured.</p>
6.5	<p>Evaluation</p> <p>The purpose of the session was to examine the views of WATCH on this being an appropriate approach to follow in fulfilling its horizon-scanning responsibility. Participants were asked to complete an evaluation form at the end of the session. Of the 17 participants, 11 forms were completed. One rated the event as Excellent, five rated it good and four, fair. Individual comments were generally positive, with participants welcoming the open-minded approach of those attending and the opportunity to network on such considerations, away from the normal working environment.</p> <p>The WATCH secretariat now needs to consider the role that this approach should play in future horizon-scanning sessions at WATCH.</p>
	Day 2 : 24th October
7	Introductions and apologies (Day 2)
7.1	The Chairman welcomed everyone to the second day of the 14 th meeting. Apologies for Day 2 of the meeting were received from Tony Fletcher and Steve Williams.
8	SCOEL Activities
8.1	<p>The Chairman invited the relevant WATCH members to give an update on the activities of the EU DG Employment Scientific Committee on Occupational Exposure Limits (SCOEL).</p> <p>WATCH was reminded that SCOEL was established in 1990 by the European Commission. Its primary role is the recommendation of what it considers to be appropriate values for occupational exposure limits that could be introduced in the EU (primarily as Indicative Occupational Exposure Limit Values, IOELVs, under the EU Chemical Agents Directive). SCOEL is increasingly required to consider also the recommendation of biological limits. Currently there are twenty-one serving members on SCOEL.</p> <p>The work programme of SCOEL derives from proposals from EU Member States (MS) and representative industry and worker bodies. The availability of suitable detailed substance assessment documents (“criteria documents”) is an issue, as is the preparation of summarising documents (eg SCOEL summaries). Recently several summary documents have been prepared for SCOEL by the Institute of Occupational Medicine, IOM (Edinburgh), but in the main it is SCOEL members themselves that are expected to lead on the production of “SCOEL Summary Documents”. One of the challenges facing SCOEL is the volume of work members are required to do. Up to twenty substances can appear on the agenda for a meeting. The review of criteria documents, and the preparation and review of SCOEL Summary Documents is a substantial undertaking for SCOEL members and a huge challenge to the available resources.</p>

	<p>Although unpublished material may sometimes be forwarded to SCOEL during the consultation, SCOEL can only consider material that has been published or can be made publicly available.</p> <p>Draft SCOEL Summary Documents prepared by SCOEL are sent out for a 6-month public consultation period. Comments are often received from the UK (via HSE), other member state regulatory authorities, industry and individuals. Following the consultation, the draft criteria documents are reconsidered and, if it is judged to be necessary, amended to take account of comments received. Contributors of comments receive acknowledgments.</p> <p>In giving the update it was suggested that, given the problem of the large workload that SCOEL has, a system where national governments were more involved in drafting criteria documents that the committee could in turn review would be very helpful. He emphasised that SCOEL was very under-resourced and was heavily dependent on the contributions of its twenty-one individual members. Members often received papers shortly before the meetings, leaving little time for thorough consideration. The system currently had many limitations and was largely driven forward by the commitment of key individuals. Political pressure may be needed to bring about improvements.</p> <p>The Chairman thanked the WATCH members giving this update and opened the item for general discussion.</p>
8.2	<p>A WATCH member asked what connections there were between the SCOEL proposals for IOELVs and the control standards developed within REACH. Under REACH, a “derived no-effect level” (DNEL) will emerge for a substance during the Registration process, and it could be that this might differ from the IOELV proposal. Christine Northage (HSE, REACH Exposure and Risk Management) informed WATCH that the technical guidance document for REACH states that where a well-founded, recently established OEL is available for a substance, this could be used as the DNEL value under REACH. A WATCH member observed that in general one might expect DNEL values to be lower than OEL values, because the approach set out to deriving DNELs employs relatively large uncertainty factors.</p>
8.3	<p>The Chairman pointed out that under REACH the onus to derive DNELs lies with companies undertaking Registration. Therefore it would be for industry to bring to SCOEL’s attention any apparent mismatches between DNEL and IOELV proposals. There is currently no mechanism in place for REACH regulatory authorities to become involved in the establishment of DNELs, nor is there a process by which regulatory agencies could systematically consider DNEL values. A WATCH member expressed concern that, in the absence of a mechanism for checking DNELs against OELs, a ‘free for all’ scenario could arise in which industry could propose DNELs that were in disagreement with OEL values.</p>
8.4	<p>Another WATCH member commented that it was important to recognise the difference between the approaches for deriving DNELs and IOELVs. The DNEL is essentially a tool to assist with risk characterisation for REACH and as such, is a simple process designed to people to readily understand and apply. Setting official regulatory occupational exposure limits for industrial chemicals is an important activity that regulatory agencies are required to carry out. A different set of considerations apply to the setting of a regulatory</p>

	limit.
8.5	A WATCH member commented that clarification was needed on the links between DNELs derived for REACH and occupational exposure limits recommended by SCOEL. For example, if a DNEL is derived by industry for a substance registered under REACH, would it not be appropriate that SCOEL should not be asked to recommend an IOELV for that substance? The DNEL could be regarded as the appropriate indicator of the degree of control required.
8.6	A WATCH/SCOEL member commented that these issues had not been discussed at SCOEL. SCOEL has a limited technical brief and the appropriateness of the work of the committee taking into account such issues needs to be addressed at a higher lever in the EC.
8.7	A WATCH member considered it important to think beyond the numerical values of occupational exposure limits. A DNEL value is designed to provide an indication that exposure at this level is unlikely to pose a risk to human health; this level should be used to inform on the implementation of exposure control measures. Nevertheless, the value of a DNEL could have an impact on companies and their ability to be competitive. DNELs that are conservative will require the introduction of more stringent exposure control measures that could have financial implications for a company. This could impact on the competitiveness of that company. Hence the issue was broader than that of comparing numbers.
8.8	A member asked whether there might be an opportunity in the future for WATCH to explore this issue further. For example, would it be feasible to identify some case study substances for which the derivations of the DNEL and IOELV could be examined and the outcomes compared? This should be borne in mind as potential future work for WATCH.
8.9	There was a brief discussion on the role of SCOEL in relation to carcinogens. A WATCH member informed the committee that although IOELVs could, in theory, be set for some carcinogens (primarily those considered to operate by a non-genotoxic mechanism), in general the consideration of established carcinogens had been 'parked' by SCOEL. Often a reliable "health-based" exposure limit cannot be derived and thus it is unclear how best to address these substances within the remit of SCOEL. The EC has given some consideration the process for setting exposure limits for carcinogens based on the consideration of a level of exposure that would not cause an increase in risk of 1/100,000, as derived using a linear extrapolation model for the dose-response relationship. He pointed out that such an approach was not accepted in regulatory work in the UK.
8.10	A WATCH member informed the committee of the role and activities of another EU committee, that responsible for recommending criteria for establishing occupational diseases. This committee operates in a similar manner to SCOEL. The committee has several UK members. Resources were also an issue.
8.11	The Chairman brought general discussion on this topic to a close and thanked members for their contributions. He commented that several important issues had been raised, although these cannot be resolved by WATCH. Nevertheless, it was important for all concerned to consider the potential routes by which these issues can be taken forward.

9	Lead : Current Regulatory Position
9.1	<p>The Chairman opened this item by reminding WATCH that concerns had been raised at ACTS in May 2008 that studies in the published literature suggested that adverse health effects might be associated with exposures to lead at levels below the current UK regulatory standards. ACTS had asked if there was a need to conduct an updated review of the toxicological profile of lead and lead compounds, leading to a reconsideration of appropriate risk management standards in the UK occupational context. The Chairman referred members to paragraph 19 of the cover paper to the item (WATCH/2008/9), asked them to consider if:</p> <ul style="list-style-type: none"> (i) the toxicological and occupational exposure profiles available to HSE and WATCH for lead and lead compounds are up-to-date and reasonably clear; and/or (ii) it is not so much the scientific/technical data and their interpretation that requires revisiting; the key issue is deciding what regulatory action should be taken, based on the available information and understandings. <p>The Chairman opened the item for general discussion.</p>
9.2	<p>A WATCH member commented that the package of papers for this item was very helpful, particularly Annex 1 that gave an overview from the Existing Substances Regulation (ESR) Risk Assessment Report on lead and lead compounds. In his view, concerns about neurological effects at blood lead levels of 40 µg/dl, together with data on reproductive health effects, suggested that the current action level of 50 µg/dl for workers other than young persons and women may be too high and a lower level, more in line with the current scientific evidence may be more appropriate.</p>
9.3	<p>Another WATCH member noted that there seemed to be evidence that there might be an association between blood lead levels of 10 µg/dl and increased cardiac and stroke mortality. He asked whether there was any evidence to suggest that workers occupationally exposed to lead, at much higher levels, also had increased risk of cardiac and stroke mortality? Such data may inform insights into the dose-response relationship for blood lead levels and cardiovascular disease. He asked whether the register of lead workers might provide data that could be used in such an investigation? Dil Sen replied that whilst blood lead levels in individual workers could be deduced from regulatory monitoring schemes, it was not possible to trace individual workers in these schemes who may have been examined by clinicians or general practitioners in order to deduce rates of mortality or morbidity and the associated causes. Cardiac and stroke mortality rates in the lead workers covered by monitoring schemes were therefore not known. However, another WATCH member commented that many epidemiological studies of lead workers had been carried out. Although these have examined primarily cancer mortality, examinations of 'all cause' mortality, including cardiovascular mortality would also have been observed. He did not recall that any epidemiological study has reported an increase in cardiovascular mortality associated with exposures to lead.</p>
9.4	<p>A WATCH member referred the committee to Annex 1: "General Aspects" from the EU ESR Risk Assessment Report, RAR (p691) that cited text from a review on lead by the International Programme on Chemical Safety (IPCS), in 1995 <i>"In retrospective occupational mortality studies, where blood lead levels were higher than those that currently characterise most</i></p>

	<i>occupational settings, no consistent relationship between blood lead and cardiovascular disease has been observed”.</i>
9.5	Another WATCH commented, based on his experience of the lead industry in the past. Historically, workers were typically exposed to lead giving blood levels up to 80 µg/dl. In the past, data relating to such situations had been examined to explore possible correlations between lead exposure and cardiovascular disease; no association was found.
9.6	A WATCH member commented that for lead there is an abundance of data; subtle physiological effects have been linked to exposure levels lower than current occupational exposure guidelines. This raised questions about the level of protection and caution that should be incorporated into control levels for lead. Traditionally, such standards have been based on clinical effects, but it might be that more subtle effects should also be taken into account in the derivation of limits. The industry-commissioned review of lead considered under ESR provides a more updated view than that considered by SCOEL, but also has a different level of caution built into its risk assessment than that of the SCOEL assessment. Further debate is needed on the level of protection and confidence that should be applied when setting control standards, particularly as we are about to enter the era of DNELs established under REACH.
9.7	A WATCH member observed that the biological limit value for lead recommended by SCOEL is 30 µg/dl blood for men and women; this could be compared to the biological limit values for lead in blood in the UK, at paragraph 6 of the cover paper. The WATCH member asked whether the biological limit recommended for lead by SCOEL had been adopted by the EU? Christine Northage replied that the SCOEL secretariat had indicated that the recommendation by SCOEL for a biological limit value was currently on hold within the EU process, and no immediate action was foreseen.
9.8	Another WATCH member commented that although biological limit values are recommended by SCOEL, it was unclear how any biological limits ultimately established in the EU should be interpreted in practical terms. He considered that such biological limits would be more informative if presented in the context of biological monitoring and exposure control. A WATCH member pointed out that SCOEL did not have a mandate for risk management and it was essentially the responsibility of the EC and member states to decide how biological limit values should be integrated into risk management measures. Christine Northage pointed out that an EU biological limit for lead would have a special status, as under the Chemical Agents Directive, it would be legally binding.
9.9	In relation to the different UK action levels for blood lead for adults and adolescents, a WATCH member asked whether the differences in uptake rates for adults and the young were the basis for the differences in these limit values? Dil Sen replied that blood circulation is more dynamic in the young, leading to the potential for greater lead uptake. A WATCH member added that calcium levels were influenced by blood lead levels and this was an important consideration for the young, for whom the skeletal system was still developing. Dil Sen added that lead induces effects on the central nervous system and the young are more vulnerable since their nervous systems are still developing.
9.10	A WATCH member observed that the consideration of exposure to lead via drinking water seemed to be missing from the ESR RAR for lead. Christine

	Northage referred to the exposure assessment in the ESR document and confirmed that exposure from this source had been considered.
9.11	The Chairman reminded members of point (i) of paragraph 19 of the cover paper. He asked members if they agreed that HSE and WATCH now had an up-to-date position on the toxicological and exposure profile of lead and lead compounds? WATCH members affirmed that HSE and WATCH had an up-to-date view on the toxicological profile of lead. One WATCH member expressed a reservation in the relation to the completeness of the exposure profile. The Chairman then asked for the opinion of WATCH in relation to the current UK regulatory position on lead (point ii)?
9.12	A WATCH member suggested that WATCH should now forward the package of papers, together with its conclusion, to ACTS such that ACTS can consider whether or not a revision of the UK biological limit for lead is appropriate. In his view, the UK biological limit for lead should be based on the consideration of no-adverse-effects-levels from toxicological evidence, the approach that is generally used to assess the health risk posed by chemical substances. If such an approach was adopted for lead, it is likely that the outcome would be a reduction in the limit.
9.13	The Chairman asked WATCH if it considered that it is appropriate for HSE to re-visit the UK regulatory limits for lead? WATCH members signified their agreement, although one member commented that consideration should be given to what priority this topic deserved. A key issue is what level of caution should be applied in setting standards for a well-characterised substance; appropriate steering is needed in this respect.
9.14	A WATCH member asked whether lead was included in the HSE initiative on cancer under the Disease Reduction Programme? He referred to the analysis being undertaken by Lesley Rushton's group at Imperial College, London, one aspect of which is looking at stomach cancer and the evidence for it being associated with occupational exposure to some substances. The WATCH member pointed out that if it was that case that lead was included in the study, the results might provide further justification for re-visiting the regulatory position on lead. The Chairman did not have the information to hand to say whether or not lead was included in this study.
9.15	A WATCH member observed that SCOEL had proposed a single atmospheric limit value for lead and a single biological limit value for lead in blood, whilst in the UK different levels have been established for men, women and young people. He considered that the basis for these differences should be explored further, particularly in respect of differing susceptibilities across different age and gender groups. Another member pointed out that there were other stakeholders who were likely to be interested in the issue of lead and vulnerable groups (e.g. the UK Health Protection Agency), and suggested that WATCH advocated consultation with these bodies.
9.16	The Chairman brought discussion to a close, thanking WATCH members for their comments. In respect of point (i) of the cover paper, he confirmed with WATCH its view that the toxicological and occupational exposure profiles available to HSE and WATCH for lead and lead compounds are up-to-date and reasonably clear. In respect of point (ii) of the cover paper, the Chairman noted that on the basis of the toxicological evidence presented in the package of papers to the item, WATCH had recommended that the UK standard for

	<p>lead should be revisited. In this context, members suggested that consideration should be given to:</p> <ul style="list-style-type: none"> (i) the relative priority that should be given to this issue along side other issues currently being addressed by ACTS (ii) the issue of relative susceptibility of different age and gender groups in the population (iii) options for consultation and collaboration with other stakeholder groups and government departments concerned with exposure to lead.
10	A Safe Guide to Handling and Disposal of Manufactured Nanomaterials
10.1	<p>The Chairman opened the item by clarifying that the aim of the session was to seek the committee's views on the published document: "Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials. PD 6699-2:2007", prepared by the British Standards Institute (BSI) Standards Committee NT/1 (Annex 1 to the item) and the possible endorsement of this document by HSE. He welcomed Peter Hatto (Chair of the UK National Committee on Nanotechnologies) and handed over to him to give an introduction to the background and purpose of the document.</p>
10.2	<p>Brian Fullam (Head of HSE's Nanotechnology Team) introduced the other attendees who were associated with the production of the document: Rob Aitken (Institute of Occupational Medicine, IOM) who had drafted the published document; Christine Northage (Exposure and Risk Management Team, HSE); Delpine Bard (Fibres Section, HSL) and Garry Burdett (Fibres Section, HSL). By way of an introduction, he informed WATCH that members of the team would give short presentations to set the scene for general discussion.</p>
10.3	<p>Introductory presentations</p> <p><i>Overview of carbon nanotubes</i></p> <p>Garry Burdett provided WATCH with a brief overview of carbon nanotubes (CNT). A broad range of CNT, with different characteristics, are currently being manufactured. CNT structures can be very difficult to characterise from samples taken in workplaces to determine occupational exposure. When examining samples of CNT, only particles of size greater than 200 nm can be seen using an optical microscope. CNT that are smaller than this can be visualised only using an electron microscope. He stressed that for some size ranges, heroic effort is needed to be able to count nanofibres and thereby assess exposure; it is not an easy task.</p> <p><i>Background and context to BSI PD 6699-2</i></p> <p>Peter Hatto discussed the background to BSI PD 6699-2. Many documents on nanomaterials have been published in recent years, ranging from guidance and recommended control standards to the recent publication by Poland <i>et al</i> (2008), familiar to WATCH, suggesting that CNT may show asbestos-like properties when introduced into the abdominal cavity of mice. Despite the general concern about the potential for nanomaterials to cause adverse health effects in humans, scientific data that clearly indicates the hazard(s) posed by these materials and the associated risk under specified exposure conditions remains sparse. As the manufacture and application of nanomaterials is becoming more widespread, Peter argued that there is a need for clear guidance on the appropriate handling and disposal of</p>

nanomaterials - even if a clear picture of the potential health risks is still lacking. Discussions on this theme had been held between BSI and stakeholders; this had led to the idea of developing a document to provide practical guidance to manufacturers who develop nanomaterials, and any workers involved in handling or disposing of these materials, on the identification and management of risks associated with manufactured nanomaterials. In response to this, BSI PD 6699-2 was prepared by the BSI Standards Committee NT/1 as one of a suite of guides in support of standardisation in the field of nanotechnology. The document was drafted by the Institute of Occupational Medicine (IOM) on behalf of the BSI committee and was widely consulted on during the drafting phase. Several organisations have endorsed the document. In response to comments received from consultees, at a late stage in the drafting process “benchmark exposure levels” for different types of nanomaterials were added to Part 8.3 of the document. This late addition was not appraised by the HSE representatives on the committee and HSE had now expressed some concern about the concept. Peter Hatto concluded by explaining that the BSI document is now available, free of charge, from the BSI website.

Approaches taken in drafting BSI PD 6699-2 and comments on benchmark exposure levels

Rob Aitken explained that the nanotechnology industry had, for some time, expressed concerns about identifying and managing the risks associated with manufactured nanomaterials, but beyond its awareness of their being potential problems, did not have clear strategies for dealing with them. This had been the key driver behind the document.

He said that whilst the document had been generally well received, some reservations had been expressed over the “benchmark exposure levels” included in the document. HSE had indicated that adherence to the benchmark exposure levels would in some cases imply a stringency of control that goes considerably further than the precautionary approach HSE advocates. HSE’s concern is that if the benchmark levels are applied, this would impose an approach to control of exposure that is not supported by current data on the toxicology of nanomaterials. HSE had added another concern, that being to question if control to these levels is achievable in practice.

Rob Aitken informed members that despite several hundred studies having been funded by governments around the world, there was still no clear, general picture of the hazard potential of manufactured nanomaterials, the typical exposures that might be encountered, or the resulting health risks. He reiterated that the primary purpose of the document is to set out a proactive risk assessment approach that encourages industry to consider what the issues might be and what control measures might be appropriate. One of the generic concepts in the document, intended to guide people in this respect, is that of assigning nanomaterials into “low”, “medium” and “high” exposure control categories. However, comments received from occupational hygienists and the industry during the final review stages of the document recommended that the document should include more detailed guidance on control of exposure. In response to this, benchmark exposure levels were suggested for four nanoparticle types, classified on the basis of their hazard potential (fibrous; carcinogenic, mutagenic, asthmagenic or toxic to reproduction [CMAR]; non-fibrous, non-CMAR insoluble; and non-fibrous, non-CMAR soluble nanomaterials). Rob said that these benchmark exposure levels are intended to be reasonably cautious and are based, in

	<p>each case, on the assumption that the hazard potential of the nanoparticle form is greater than the larger particle form of the same chemical entity. He acknowledged that although several attempts have already been made to test this assumption (e.g. the NIOSH programme on the toxicity of nanoparticulate titanium dioxide), controversy still remains.</p> <p>Drafting of BSI PD 6699-2 was informed by current regulatory standards; many parts of the guidance have been mapped against existing legislation and guidance for chemically similar but larger-sized entities.</p>
10.4	<p>The Chairman thanked Peter Hatto and Rob Aitken for their excellent introductions. He asked WATCH to consider the issues described in the cover paper and to :</p> <ul style="list-style-type: none"> (i) provide views on whether the benchmark exposure levels in Part 8.3 of BSI PD6699-2 have sufficient scientific basis (ii) provide views on the document as a whole (iii) decide whether it can recommend that HSE endorses this document <p>He pointed out to WATCH that the proposed benchmark exposure levels in Part 8.3 represented the considered judgement of individuals with substantial experience in the field of toxicology and occupational exposure control; but the consideration of the benchmark levels by WATCH would be the first formal appraisal of them by a government scientific advisory committee. He opened the item for general discussion.</p>
10.5	<p>A WATCH member suggested that a scientific expert on macrophages could be invited to a committee meeting to provide further insights into the interaction between nanomaterials and the respiratory system. A clear understanding of the biology of macrophages in the respiratory system and the potential effects of nanomaterials on different metrics related to respiratory function was needed. Without this fundamental knowledge, the member considered that it would be difficult to make valid deductions about exposure standards and ill-health concerns.</p>
10.6	<p>WATCH appraisal of BSI PD 6699-2 and 'Benchmark exposure levels'</p> <p>A WATCH member considered the document to be well-written and useful in terms of giving guidance, but expressed reservations about the benchmark exposure levels suggested in Part 8.3. In his view, there was a danger that the scientific basis for these levels would become the primary focus of interest in the document and the more important issue of providing practical advice that was clearly needed would be over-shadowed.</p>
10.7	<p>Another WATCH member offered a perspective on how risks associated with manufactured nanomaterials in the pharmaceutical sector were being managed. For several years the industry has been exploring what precautions should be taken and has had on-going dialogue with stakeholders on this issue. Although there is a consensus view that a precautionary approach to control is appropriate, there are also concerns that an over-precautionary approach could give rise to undue alarm and impede the realisation of the potential benefits of nanotechnologies. He considered that there were parallels here with the debate about genetically modified food. In his view, the BSI document provided some good, practical advice and the idea of applying a control banding approach was conceptually sound. However, he had concerns over a number of specific points – he considered that at some points the advice offered was over-precautionary, but in other places it was under-precautionary. He expressed</p>

	<p>concern that the document did not, to some extent, characterise the standards of control that the pharmaceutical industry was currently trying to achieve. For these reasons, he advised that HSE should not formally endorse the document.</p> <p>The Chairman asked the member to provide some examples of where he considered inappropriate advice had been given in the document. The WATCH member referred to the advice in the document that when controlling exposures it was adequate to adopt a default precautionary approach of using personal protective equipment (PPE); this is in contrast to current practice in exposure control and risk management, where the use of PPE is regarded as the last resort when all other options have been exhausted. In addition, he did not consider the benchmark exposure levels to be useful, as methods to reliably measure such low concentrations of nanomaterials in the workplace are not currently available.</p> <p>Another WATCH member asked the member if he could suggest ways in which the document could be improved? The member replied that in his opinion the document could be improved but this would involve a lot more work and input from others.</p> <p>Peter Hatto informed WATCH that the document was intended primarily for engineered nanomaterials being made by smaller companies, rather than for pharmaceuticals companies of global proportions. The WATCH member pointed out that this was not clear in the document and therefore the intended target audience for the guidance might not be appreciated.</p>
10.8	<p>Another WATCH member agreed that the document provided good occupational hygiene advice, but in its current form there was both under- and over-cautious exposure control advice. In respect of the benchmark exposure levels, he agreed with comments raised earlier that Part 8.3 would lead people to question the scientific basis for the levels. This was an unnecessary distraction from what should be the main focus of the document.</p>
10.9	<p>A WATCH member expressed the opinion that the document is useful and based on sound principles; and that the suggested benchmark exposure levels might be acceptable if it is stressed that the “limits” are pragmatic and not health-based standards. He agreed that suggesting appropriate exposure controls for nanomaterials was problematic since good measurement techniques were not available. He suggested that more activity to measure workplace exposures was needed. Overall, he did not have any concerns with the document and its potential use, as long as the suggested benchmark exposure levels were not used as exposure limits to which to adhere.</p>
10.10	<p>The Chairman requested further clarification on the intended purpose of the benchmark exposure levels. Rob Aitken replied that the document encouraged people to make measurements and the purpose of the benchmark levels was to provide a point of reference against which measurements could be compared. Nothing else had been published elsewhere that was helpful in this respect. He suggested that if measurements are above the benchmark exposure levels, the company involved should endeavour to put control measures in place to reduce exposure.</p>

10.11	A WATCH member pointed out employers have obligations under COSHH to monitor and control exposure. Whilst additional guidance that can help in this respect is good, this should not detract from the obligations under COSHH.
10.12	Christine Northage informed WATCH that HSE had received enquires from industry asking whether enforcement action could be taken on the basis of the benchmark exposure levels in PD 6699-2? She suggested that this emphasised how much of a focus of attention the numerical values of the benchmark exposure levels and how these are interpreted could become.
10.13	Peter Hatto reflected on the fact that WATCH members were not in favour of certain aspects of the document and had suggested that changes should be made. He informed WATCH that since its publication, the document had been down-loaded from the BSI website more than 1500 times. Although it was possible to introduce changes to the document now, he asked that careful thought is given to the changes that should be made. If changes were not required urgently, he informed WATCH that BSI PD 6699-2 was scheduled for review in two years time as part of the normal BSI review cycle. Brian Fullam added that in his view the document in its current form was unlikely to mislead employers to a detrimental extent; hence consideration could be given to revising the document in two years' time.
10.14	Health surveillance and exposure monitoring A WATCH member referred to text in section 9: "Health Surveillance" (page 16 of the BSI document), suggesting that health surveillance is not appropriate as no specific, measurable health effects have been associated uniquely with exposure to nanomaterials. Whilst acknowledging that health surveillance would not be possible, he suggested that it might be useful to compile a register of people currently known to be exposed to nanomaterials, for future reference. Peter Hatto replied that Defra has been attempting to gather this information on an informal basis, via a voluntary reporting scheme that finished in September 2008, but contributions to this scheme had been limited.
10.15	A WATCH member wondered if it was feasible for companies that followed the advice in the BSI document to achieve control to the suggested benchmark exposure levels. Rob Aitken asked the committee for its opinion on the value of collecting exposure information and for what it be should? A WATCH member replied that exposure data should be collected and could usefully indicate whether or not control measures were having the intended effect. If measured exposure data were found to exceed the levels intended, this should trigger the need to review the effectiveness of the control measures in place.
10.16	Brian Fullam provided WATCH with feedback from a recent OECD meeting on nanomaterials. At the OECD meeting the view was expressed that although exposure measurements should be made, adjustment of the data was necessary to account for the presence of nanoparticles from background sources background levels – in some circumstances environmental levels can be significant. An attempt should therefore be made to also measure background levels and subtract them from the workplace exposure measurements. Garry Burdett commented that the only reliable way to do this at present is to use electron microscopy in order to differentiate between background and workplace-specific nanoparticles in the collected sample.
10.17	The Chairman asked WATCH to clarify its view on the circumstances under

	<p>which it would be appropriate to measure exposure to nanoparticles? A WATCH member replied there were two main reasons for measuring exposure:</p> <ul style="list-style-type: none"> (i) Research: Good measurements for exposures to nanomaterials are not currently available. These are needed in order to develop appropriate exposure control measures. Many aspects of exposures to nanomaterials are not clear and further research is needed. The member considered that there is also currently insufficient knowledge to inform what levels of exposure can be deemed to be 'safe' and more research data are needed on this issue. (ii) Examining the effectiveness of control; and connecting the degree of control secured with the desired degree of health protection being sought. <p>Other WATCH members agreed with this view.</p>
10.18	<p>A WATCH member pointed out that employers currently had obligations under COSHH to monitor exposures and carry out health surveillance. In light of the problems employers were facing in respect of meeting these obligations for nanomaterials, he asked whether it would be useful for WATCH to provide some guidance on how these COSHH obligations can be met. If people were given advice on how to measure exposure using consistent criteria, the data so derived could be compiled into a database of useful and usable information.</p> <p>Garry Burdett emphasised the difficulties of measuring nanomaterials in reality. Reliable determination of the recommended benchmark exposure levels (in PD-6699-2) for single walled and even some multi-walled CNTs in the workplace is currently very difficult, if not virtually impossible, even when 'state-of-the-art' technology is used.</p>
10.19	<p>A WATCH member expressed surprise that a clearer understanding of the crucial issues surrounding nanomaterials is still lacking. In his view, although there is justification for adopting a general precautionary approach regarding the health risks from exposure to nanomaterials, where data are lacking, one must also consider aspects specific to a particular nanomaterial. For example, the concern that CNT might, under some circumstances, behave like asbestos fibres, needs to be balanced with an approach towards addressing the potential risks of nanomaterials that was not over-precautionary, and thereby unduly restrictive on the development, utilisation and acceptability of this technology. Industry needed to gather data on the nanomaterials they were manufacturing or using but it should be recognised there would be intellectual property or company confidentiality issues in respect of disclosure.</p>
10.20	<p>The Chairman thanked members for their comments and brought discussion on the item to a close. He reminded WATCH that the committee had considered a review of the toxicity of particles that are intentionally produced for use in nanotechnology applications, seen from an occupational health perspective, at the January 2005 WATCH meeting. Hopes had been expressed at the time that knowledge on the toxicity of nanomaterials would move forward rapidly in the coming years, but this has not been the case. There remained an incomplete understanding of the toxicological hazards of nanomaterials and the human health risk associated with different materials and exposure conditions.</p> <p>The Chairman confirmed with WATCH that its views were:</p>

	<p>(i) the BSI document is useful overall, but it had concerns about how up-to-date was some of the detail in the document. It should be made clear who is the intended target audience for the document (WATCH considered the document to be too generic and simplistic for more specialised sectors of the nanomaterials industry but more suitable for raising awareness and understanding in less-informed sectors).</p> <p>(ii) WATCH opposed the presence of ‘benchmark exposure levels’ in the document because their meaning and regulatory significance could be readily misinterpreted.</p> <p>(iii) WATCH advised HSE not to formally endorse BSI PD 6699-2 in its current form; but was in favour of participating in any opportunities for future development and revision of the document.</p> <p>In relation to the purpose of making measurements of occupational exposure to nanomaterials, WATCH considered that exposure measurements should be gathered with the purpose of:</p> <p>(a) considering different exposure control options and their effectiveness; and</p> <p>(b) collecting and storing pertinent exposure data that could be useful in the future, alongside the monitoring of occupational health.</p>
11	Azo dye penetrants – update
11.1	<p>The Chairman opened this item by referring to the previous consideration by WATCH in February 2008 of the potential cancer hazard and risk posed by the use of azo dye penetrants such as CI Solvent Red 164, a penetrant dye used in the detection of cracks in metal components (WATCH/2008/1). He invited John McAlinden (HSE, Chemicals Risk Management Unit) to provide the committee with a brief update on activities and developments since WATCH/2008/1.</p>
11.2	<p>Use of CI Solvent Red 164 – Brief update</p> <p>John McAlinden gave a short presentation to WATCH on the use of CI Solvent Red 164, updating members on developments since WATCH/2008/1 (he also distributed a short briefing report to members)</p> <p>WATCH/2008/1 issue</p> <p>John McAlinden reminded members that WATCH had reviewed the use of CI Solvent Red 164 as penetrant dye in the detection of cracks in metal components at the February meeting (WATCH/2008/1) and had reached the following conclusions:</p> <p>(i) WATCH had considered there to be a paucity of hazard and exposure data on CI Solvent Red 164 and proposed that the substance is treated as though it has carcinogenic potential, subject to the same exposure control approach as other suspect carcinogens.</p> <p>(ii) Exposure data, to inform on the degree to which current practices and associated exposures conform to these expectations were currently lacking. The need to gather exposure data was emphasised</p> <p>(iii) The issue required more attention from industry</p>

- (iv) Recommendations for a potential substitute could not be made as there was insufficient available information to recommend an alternative

Planned visits to UK sites to collect data

Since this review, he informed members that HSE had not become aware of any new hazard or airborne exposure data. HSE has visited five formulators reported in WATCH/2008/1 and all have agreed to submit workers' urine samples for analysis. Results of urine sample analysis were available for workers at two sites (see below) and were pending for two other sites. The fifth formulator company had ceased to trade.

Visits to user sites are scheduled to start during November 2008. Visits will be made to a range of sites where non-destructive testing using azo dye-containing liquid penetrants is carried out (e.g. founding, forging, welding and in-service inspection).

Risk management

HSE's Metals and Minerals Sector has published a sector information minute : SIM 03/2008/10 'The use of liquid dye penetrants containing the azo compounds CI Solvent Red 164 in the detection of flaws or cracks in metals components'. This document provides guidance for industry users and HSE and Local Authority inspectors on precautions to be taken when using a liquid dye penetrant containing CI Solvent Red 164.

HSE has made direct contact with Founding, Engineering and Non-Destructive Testing (NDT) user groups to make them aware of SIM 03/2008/10. The Foundry Industry Safety and Health Targets Initiative (SHIFT) has published a safety alert advising member companies of the issues covered by the WATCH review/position and SIM 03/2008/10.

A supplier/formulator initiative will be considered on completion of the HSE survey of exposure data.

Potential substitutes

No further information has been made available to HSE since WATCH 2008/1

Preliminary discussion of biological monitoring results.

John McAlinden referred members to a limited data set in Appendix 1 of the briefing report tabled, giving biological monitoring (BM) results from workers at two UK sites formulating liquid dye penetrants containing the azo compounds CI Solvent Red 164. The analysis concentrated on probing the production of the metabolites aniline and o-toluidine. Results were presented from two formulators visited:

- (i) Formulator A: aniline and o-toluidine levels measured in urine samples from 3 workers were found to be within the HSE reference background levels (for an unexposed population) of <10 µmol/mol creatinine and <5 µmol/mol creatinine for aniline and o-toluidine respectively.
- (ii) Formulator B: all results were 'non-detects' – the assay technique used would have detected levels of o-toluidine in urine samples at or near the background levels.

The very limited data set presented indicated that urinary levels of aniline and o-toluidine for the workers concerned were no higher than urinary levels

	of these two substances in the general population.
11.3	General discussion The Chairman thanked John McAlinden for giving an update to the committee. He asked members whether they had any questions.
11.4	A WATCH member considered that it was reassuring that biological monitoring had indicated no significant exposure to o-toluidine, in view of the recent decision by the International Agency for Research on Cancer (IARC) to upgrade o-toluidine from a Class 2a to Class 1 carcinogen within its classification system.
11.5	A WATCH member asked whether CI Solvent Red 164 had been pre-registered under REACH? John McAlinden replied that he was not aware of this. The Chairman added that he was not aware of an easy means by which this could be readily deduced. A WATCH member replied that a search tool was available on the European Chemicals Agency (ECHA) website by which pre-registered substances could be searched for using their CAS number.
11.6	A WATCH member asked whether the relevant companies had made any changes in the labelling or advice given in respect of handling CI Solvent Red 164 since WATCH had taken its position in February? John McAlinden replied that to the best of his knowledge there had not been any changes.
11.7	There being no further comments, the Chairman thanked members for their input and brought this information item to a close.
12	Date of next meeting
12.1	The Chairman thanked everybody for their contributions to the meeting. The Secretary reminded WATCH that the next meeting will be held on 24 February 2009 in HSE's Rose Court office, London. The meeting closed at 15.30

HSE Hot Topics

Social

- Demographics and Ageing
- Obesity
- Flexible working and employment patterns
- Complex and ambiguous occupational health issues

Technological

- Nanotechnology
 - o Molecular manufacturing
- Human Performance Enhancement
- Pervasive Computing
 - o Cyber security
 - o Terahertz technology
 - o Robots and artificial intelligence
 - o Future of keyboards
- Biotechnology
 - o Synthetic biology
 - o Genetic testing
- Rapid manufacturing

Environmental

- Climate Change
- Recycling
- Sustainability
- Effects of environmental and other legislation on H&S
- Emerging pests and diseases
- Energy
 - o Nuclear new build
 - o Clean coal
 - o Hydrogen economy
 - o Wind
 - o Wave
 - o Methane Gas Hydrates
 - o Solar
 - o Gas
 - o Carbon dioxide capture
 - o Compressed air energy storage
 - o Microgeneration/combined heat and power

Economic

- Globalisation

Political

- Public perception of new technologies

Summaries of the HSE Scenarios for the Future of Health and Safety in 2017

A Virtue of Necessity

This is a scenario in which people are happy to embrace new technology, but in an economy where they can't necessarily afford to. They buy things that will last, and there is an emphasis on the local economy, on community and on self-sufficiency. As UK competitiveness declined, many young people emigrated for work, so there is an increasingly aged population. There is great interest in well-being and work/life balance and people take responsibility for their own welfare and that of the environment.

In health and safety terms, we see fewer large companies and many more small enterprises whose workers have a wide range of working patterns and work environments. Home and work are increasingly blurred. Pervasive computing is used to monitor workers' health and stress levels and people look out for themselves because 'no-one else is going to do it'. We see exemplary health and safety practices, but also companies who fly under the regulatory radar to save costs. Many British companies have been bought by overseas owners who bring their own views of H&S with them.

The Digital Rose Garden

This is transformational scenario. Britain has harnessed the creativity of its diverse society. New businesses in biosciences, materials sciences and nanotechnology attract the best brains resulting in a brain gain. Offshoring is declining as increasing labour costs in emerging economies make it less attractive, so British graduates are staying at home.

In health and safety terms, there is no work/life boundary. Immersive computing means workers are 'always on' always available. Human performance enhancement technologies are readily adopted. There is an emphasis on local offices facilitated by communications technology but consistency of design makes for easier regulatory compliance, but in manufacturing the huge number of innovative production methods gives government agencies and health and safety personnel problems in deciding what the risks are.

Boom and Blame

In this scenario we see increasing privatisation, a free market, with Britain economically successful for the time being, but people worry about how stable that position is. Sustainability has taken a back seat to competitiveness and the environment has suffered. Offshoring of production to reduce costs continues and waste is being offshored to minimise disposal and remediation expenses. Companies routinely do genetic profiling of prospective employees and subcutaneous RFID sensors monitor health. Working hours are long and companies offer a range of performance enhancing drugs.

Tough Choices

In this doom and gloom scenario, a declining economy has driven the brightest and the best overseas and innovation has slowed as a result. Unemployment is high and social divides have amplified. Deregulation in Europe designed to jump-start the economy has resulted only in an increase in air, soil and water pollution. The black market is thriving.

Businesses are struggling and worn-out workplaces create health hazards and the potential for accidents. Accidents and a blame culture are leading to increased litigation. Stress and violence are rife. There is much under-reporting of health and safety failures.

