

Meeting date: 27 October 2010

Open Gov. Status: Fully open

Type of paper: Final

Paper File ref:

Exemptions:

WORKING GROUP ON ACTION TO CONTROL CHEMICALS	
Minutes of the 19th meeting of the Working Group on Action to Control Chemicals held on 27 October, at HSE, Mallard House, York	
<p>Members Present</p> <p>Steve Fairhurst (Chair) Robin Chapman Ching Aw Rosemarie Hutchinson Tony Fletcher Alastair Hay David Farrar Robin Howie (ad hoc member) Steve Bailey Steve Williams</p> <p>Observers</p> <p>George Kowalczyk (Health Protection Agency, HPA)</p> <p>Apologies</p> <p>Steve Binks Julian Peto (ad hoc member) Len Levy</p>	<p>HSE Officials Present</p> <p>Sarah Mallagh Garry Burdett Andy Darnton</p>

1	Introductions and apologies
1.1	The Chairman welcomed everyone to the 19 th meeting of the committee. Apologies were received from Steve Binks, Julian Peto and Len Levy. He explained that the WATCH Secretariat had also sent all material relating to this meeting to the two other ad hoc members who had been involved in the consideration of asbestos in previous meetings, but had received no response.
2	Administrative issues
2.1	The Chairman requested declarations of interest in the items on the agenda. David Farrar noted that he had interest to declare for the item on asbestos.
2.2	The Chairman said that by the end of the meeting he would appreciate members' views on York as a venue for holding future meetings; and on the usefulness of the web community for pre-meeting consideration of papers and the sharing of views.

3	Asbestos; statements about cancer risk under various conditions (fibre type, dose, commencement of exposure, exposure period and lifespan)
3.1	<p>The Chairman introduced the item by reminding members that he would begin by requesting each member's opinion on two matters:</p> <ul style="list-style-type: none"> - Based on previous considerations, the WATCH position of November 2008 and the Hodgson & Darnton (H&D) model, what could be said with confidence about the issues listed in paragraph 9 of the WATCH paper WATCH/2010/3? - Whether or not new studies published since 2008 raise any issues about the robustness of the H&D model and the conclusion of WATCH in 2008?
3.2	He repeated his assertion that it was necessary for WATCH to come to a definitive conclusion on these issues at, or immediately after, this meeting. He suggested that it would affect the credibility of WATCH if the committee was seen to be discussing issues continuously without a definitive outcome.
3.3	He referred to Annexes 2 and 3, produced by Andy Darnton (HSE) and a WATCH member respectively. He suggested that the numerical risk values calculated for various scenarios in these two Annexes were in general similar, with only some relatively minor differences. He believed the main issue was how much faith could be placed on the risk values presented?
3.4	He also referred to the additional paper produced by HSE, analysing the results of new studies published since 2008, and asked whether or not these new findings affect the robustness of the H&D model and thereby challenge the WATCH position of 2008?
3.5	The Chairman also reminded the committee that Len Levy had identified a recent paper by Dennis Paustenbach's group in the USA on the evaluation of bystander exposure to asbestos in occupational settings. The Chairman suggested that the paper was interesting but its findings were not crucial to the issues presented to WATCH.
3.6	He then turned to each WATCH member in turn for his/her opinion on the questions posed.
3.7	The first member stated that the main purpose and motivation for WATCH should be protecting worker health. In this context, he considered that the additional work done was of excellent quality, but with regard to protecting workers in the workplace, it did not contribute much more to what WATCH had already seen and considered,
3.8	He believed that in trying to address the questions posed in paragraph 9 of the main WATCH paper, one is moving beyond the region where one can state with confidence what will happen at certain exposure levels, particularly low level environmental exposure scenarios. He considered that the available data from historical worker cohort studies was not reliably representative of different situations such as those WATCH was being asked to consider; WATCH was in danger of moving into speculation.
3.9	He believed that work done over the years, for example on codes of practice, has improved the protection of workers potentially exposed to asbestos, but residual risk to workers still exists. He agreed with the Chairman's view that WATCH needed to come to a clear conclusion. Perhaps all one could say was that low levels of exposure to amphibole forms of asbestos in particular, incur a

	<p>residual risk of cancer; and that exposure should be controlled as stringently as possible in each situation.</p> <p>He suggested that it would be useful to know what levels of exposure to asbestos occur in buildings 2-3 years after the removal of asbestos?</p>
3.10	<p>The next member suggested that it was difficult to come to a firm answer on any of the questions posed at paragraph 9 of the main WATCH paper, due to the limitations of the available data. He believed that the main issue was how to consider what was a “safe” level in buildings for society at large and for workplaces, while remembering that the public should not be harmed because of work operations.</p>
3.11	<p>He thought that Annexes 2 and 3 presented interesting work. He expressed his concern about the reliability of extrapolations of risk to such low levels of exposure, but he was happy that the work gave an idea of the <i>scale</i> of the risk that might apply under different circumstances.</p>
3.12	<p>He expressed a concern that, in relation to chrysotile exposure, WATCH and regulatory authorities should not ignore the “high risk” chrysotile dose-response curve (derived mainly from studies in North and South Carolina, USA). He cautioned against making all chrysotile risk predictions based on the “low risk” chrysotile dose-response curve, given that the reasons for the difference between the “high” and “low” risk curves are not fully understood. There was an argument for being cautious in addressing chrysotile exposure scenarios, by making use of the “high risk” data..</p>
3.13	<p>Another WATCH member expressed his agreement with the two members’ comments posted previously on the web community. He considered that it was very difficult to provide a reliable answer to the points in paragraph 9 of the WATCH paper. He also expressed a concern that many people, including medical doctors, consider mesothelioma to be exclusively caused by asbestos, but it seemed to him unlikely that any type of cancer could have a single, unique cause. He also expressed dislike for the use of the term “spontaneous mesothelioma” as the reason(s) why such cases arise and the mechanism of disease progression is not known. Regarding the suggestion made prior to the meeting by a member, that the opinion of the Committee on Carcinogenicity (COC) should be sought, he did not see the value in so doing; with reference to Annex 5 of the WATCH paper, he thought that it was already clear what the opinion of the COC would be.</p>
3.14	<p>The next WATCH member indicated that in his view the extrapolations used in Annexes 2 and 3 to derive predictions of risk are reasonable, as long as the wide uncertainty ranges are emphasised. It is not possible to say that the risk values derived in this way are precise and the figures emerging should not be taken as the actual levels of risk, but the figures do give a useful, rough estimate of the scale of the risk in different situations.</p>
3.15	<p>He also expressed a concern regarding cases of mesothelioma deemed non-attributable to asbestos exposure and questioned why that might be. He wondered if it was due to insufficient occupational history, thereby missing potential contact with asbestos. He wondered if general background exposure (i.e. not occupational) starting at birth and prevailing throughout a lifetime would result in an extent of exposure, leading to a risk of developing mesothelioma, that is greater than negligible?</p>
3.16	<p>The next WATCH member felt that from a toxicological perspective the Committee has gone as far as possible with the available data. He expressed his concern about uncertainties in our understanding of historical exposure of</p>

	<p>the occupational cohorts and the mesothelioma disease process, including what is happening during the apparent latency of the disease. Overall, he believed that the WATCH conclusion of October 2008 was acceptable but was not confident to go beyond that.</p>
3.17	<p>This member suggested that a key issue is the acceptable exposure/risk level for workers to re-enter buildings after asbestos removal or other renovation work. For example, if there was any potential for measureable crocidolite exposure, would one say that the risk level is too high and re-entry should be prohibited? Conversely, if the potential asbestos exposure was to chrysotile fibres, could a position be developed that is more quantitative than at present, for when re-entry could be allowed, with suitable accompanying guidance?</p>
3.18	<p>The next WATCH member raised the issue of long-term low level exposure to asbestos and reiterated the point made to WATCH previously, that the current incidence of mesothelioma in teachers and nurses is higher than the general population background rate. In his opinion there is a responsibility to reduce the potential for exposure to asbestos, regardless of whether the origin of the potential exposure is environmental or occupational. In this respect he considered that the H&D model is the best available and he thought it acceptable to use the model to extrapolate as far as necessary to address real-life exposure situations, accepting that the confidence intervals might be wide - he suggested a suitable level to extrapolate down to would be 0.0001 fibres/ml.years.</p> <p>He suggested that any errors in the model might tend to underestimate the risk at particular exposure levels.</p> <p>He indicated that crucial issues are what is the level of risk at:</p> <ul style="list-style-type: none"> - the clearance level, at which people can be allowed back into buildings; and - the action level, triggering informing people that asbestos exposure has occurred <p>In each case he considered that the risk estimates used should be above the average and towards the upper end of the confidence intervals, to encompass almost all the population.</p>
3.19	<p>The next member said that the new papers and the data within them didn't change his perspective. He considered that chrysotile exposure below 0.1 fibre/ml.years does not pose a concern. He thought that the H&D model currently provided the best means of estimating risk levels and preferred the values so derived in Annex 2 to those in Annex 3. He felt that WATCH needed to address the risk at the background, ambient level of asbestos exposure arising in buildings containing asbestos; and the risk at the clearance level. He was of the opinion that the residual risk from background exposure in buildings might not be negligible and that there should be more emphasis on the need for precautions in the committee's final conclusions.</p>
3.20	<p>The next member restated the key points that the H&D model is the best model available for addressing workplace situations involving the associated range of occupational exposures, but that it was not created to address the different exposure scenarios that WATCH is now being asked to consider. Uncertainties about the underlying disease process make it difficult to know what conclusions are appropriate for such different scenarios. This member thought that, given the lack of data for these situations, a pragmatic approach to risk management should be taken, rather than trying to base approaches on what purport to be scientific positions. This member was keen to know the</p>

	<p>opinion of Andy Darnton (HSE) on utilising the model to extrapolate down to such low levels of exposure for sectors of the population with different characteristics and exposure periods from the occupational cohorts studied.</p>
3.21	<p>The final member also voiced concerns about the amount of confidence that can be placed on risk levels derived by large extrapolations beyond the currently available data set and for different exposure populations and scenarios. He agreed with the previous member's view that a pragmatic approach, without any implied precision in the associated numbers, is the most appropriate expression of the WATCH position.</p> <p>In this context he also voiced concerns about the lack of knowledge of the details of disease progression culminating in mesothelioma; and he questioned the idea of the so-called "spontaneous" development of mesothelioma.</p>
3.22	<p>Having obtained a view from each WATCH member, the Chairman then brought in Andy Darnton (HSE) for his observations. Andy stated that the data available from historical worker cohorts had been used in an unbiased way in constructing the H&D model; and that the model contains all of the faults of the data set. Like the majority of the WATCH members, he was concerned about the extrapolation of the model based on historical worker exposure scenarios to make predictions for very different situations – some statements might be made, but the uncertainty of extrapolations should be explicit.</p>
3.23	<p>Having heard views from all the members present, the Chairman attempted to reflect back to the committee some potential conclusions. Firstly, he asked WATCH if there was anything from the new epidemiology papers published since 2008 that undermined the WATCH position of October 2008? Members agreed unanimously that there wasn't.</p> <p>Then, in relation to making predictions about risk under various circumstances, particularly those in paragraph 9 of the main WATCH paper (WATCH/2010/3), he suggested that the balance of views expressed was towards using the H&D model but emphasising that the numerical values so derived should not be taken to be accurate risk estimates but rather used as 'practical reference points' that can aid decision-making on prioritisation and risk management.</p>
3.24	<p>He asked members to work over the lunch break to draft a potential position statement. He asked them to consider if they wanted numerical values emerging from the model to be used as "low-level exposure" risk estimates, or if they preferred not to present numbers, but instead attach qualitative risk statements to different "low-level" exposure levels and situations?</p>
3.25	<p>On reconvening after lunch a first draft of a potential statement was shown to all attendees. The Chairman asked the committee to consider the draft text, emphasising that he was trying to gauge the overall level of agreement with the general messages conveyed in the draft – he was not at this stage expecting the committee to produce an editorially refined final statement.</p>
3.26	<p>One member suggested expanding the table in the WATCH statement of 2008 to include risk estimates for lower exposure levels, and to shade the lower exposure cells to indicate that the numbers within them are particularly uncertain, due to extrapolation of the H&D model well beyond the currently available data set. Some members supported the presentation of risk estimates for lower level exposures in the WATCH conclusion, but other members were against this.</p>

3.27	There was a suggestion that numerical risk estimates for “low-level exposures” derived using the H&D model should only be used when communicating with regulatory bodies, when all of the necessary qualifying statements surrounding the numbers could be maintained. When communicating with the public, simple qualitative expressions should be used, to avoid misrepresentation and misunderstandings.
3.28	<p>From the subsequent discussion the following key points emerged that members considered should be captured in the concluding statement:</p> <ul style="list-style-type: none"> • WATCH agreed that the committee’s position of October 2008, backed by use of the H&D model, remained valid; the new epidemiological data published since then does not challenge the 2008 statement. [One member proposed that, rather than producing a new 2010 position statement, the 2008 statement could simply be updated with modest amendments]. • In relation to the exposure scenarios and questions posed in paragraph 9 of the WATCH paper, there was a spread of opinion, with no consensus, regarding the merit of producing numerical risk estimates for the various “low-level exposure” situations. • Important sources of uncertainty are the underlying process and disease progression for mesothelioma, and their relationship with the age of subjects experiencing exposure (particularly to amphibole forms of asbestos); and whether or not risk is proportional to cumulative dose, i.e. the same for lifetime exposure at a constant low level and for a higher-level exposure over a shorter time period. • The level of risk associated with exposure to 0.01 fibres/ml.years of amphibole forms of asbestos is not negligible; there is likely to be a discernable risk and all that is possible should be done to reduce exposure in such potential situations to a substantially lower level.
3.29	<p>The Chairman concluded the discussion by thanking members for their contributions. Based on what had been drafted and said, the WATCH Secretariat would produce a revised draft position statement. This would be posted on the web community and also sent to members by e-mail, in the following week, with a request that all members respond by 19 November. The Secretariat would then endeavour to agree with the committee a final version of its position</p>
<p>Action: WATCH Secretariat</p>	
4.	<p>Future role, work and operation of WATCH; and relationship to ACTS</p>
4.1	<p>The Chairman outlined to WATCH that following the recent government spending review HSE was expected to reduce its spending by 35% over the next 4 years. At this stage it is unclear how this will affect HSE’s overall work on chemicals and if there will be implications for the functioning of WATCH. However, funding constraints might, for example, necessitate the increased utilisation of the WATCH web community and discussion/clearance of some issues by correspondence, instead of face-to-face meetings. Some members voiced concerns about relying solely on the web community as means of discussion and stated a preference for some face-to-face meetings.</p> <p>In terms of its relationship with ACTS, the Chairman confirmed that WATCH and ACTS have now been separated, WATCH no longer being a subcommittee of ACTS. WATCH will operate as a stand-alone scientific advisory committee to HSE, although ACTS can also recommend referral of</p>

	issues to it. ACTS is currently re-defining its remit and would meet next in mid-November.
4.2	<p>Individual WATCH members briefly outlined a number of issues that they considered would be appropriate for attention by WATCH in the near future:</p> <ul style="list-style-type: none"> ➤ REACH – the impact of DNELs (Derived No-Effect Levels) on occupational exposure limits and occupational risk management. ➤ Standards for defining and measuring nanoparticles. ➤ The scope for removing the need for a 90-day toxicity study in instances when a 28-day study does not show any significant toxicity. ➤ An analysis of the recent TUC proposal for an interim dust standard to replace the conventional “10/4” mg/m³ position. ➤ The new EC proposals for amendments to the Carcinogens and Mutagens Directive. ➤ Potential for aerosol generation when water is used as a dust suppressant, e.g. in cutting silica-containing stone – what might be the health implications?. ➤ Examination of proposals emanating from SCOEL (EU Scientific Committee on Occupational Exposure Limits)
5.	Minutes of the 18th WATCH meeting
5.1	Members reiterated their agreement with the draft minutes from the 18 th WATCH meeting held in February 2010, which were then confirmed as final.
5.2	There were no significant “Secretary’s Report” matters
6.	Date of the next meeting
	The Chairman requested members’ availability in order to set provisional dates for the next two WATCH meetings. The general consensus was that the last weeks of February and June 2011 would be suitable; the Chairman asked members to mark these in their diaries – precise dates would be confirmed as soon as possible.