## WORKING GROUP ON ACTION TO CONTROL CHEMICALS

Minutes of the 22nd meeting of the Working Group on Action to Control Chemicals held on 21 February 2012, Mallard House York

### Members Present
- Steve Fairhurst (Chair)
- Ching Aw
- Steve Bailey
- Steve Binks
- Robin Chapman
- David Farrar
- Tony Fletcher
- Rosemarie Hutchinson
- Len Levy
- Steve Williams

### Apologies
- Alastair Hay
- Martie van Tongeren

### HSE and HSL Officials Present
- Jayne Wilder (Secretariat)
- Tim Fry
- Chris Snaith

### 1. Introductions and apologies

1.1 The Chairman welcomed everybody to the 22nd meeting of the committee.
   Apologies were received from Alastair Hay and Martie van Tongeren

### 2. Administrative issues

2.1 The Chairman asked for any declarations of interest to be made at the start of each item.

### 3. Ongoing consideration of substances in the context of the EU Carcinogens and Mutagens Directive (CMD) [WATCH/2012/1]

3.1 The Chairman reminded members that, in discussion with HSE in May 2011, ACTS had asked that WATCH should look at the scientific and technical issues in the documents provided to support discussions in the EU.

3.2 HSE introduced this item. The directive covers carcinogens and...
mutagens at present – specifically EU category 1a (formerly category 1) and category 1b (formerly category 2) carcinogens (C) and mutagens (M). There has been a proposal that category 1a and 1b reproductive toxins (R) might also be included in a future amended directive. For the C, M and perhaps R substances covered, it is envisaged that more of them than now will have specified Binding Occupational Exposure Limits Values. There was now an ongoing EU process of considering some substances in these categories with a view to proposing “Binding Limits” and the material associated with such considerations is now before WATCH (it was also suggested by HSE that WATCH members might also consider whether some additional substances should be included in the process). HSE explained that the EU Working Party on Chemicals (WPC) will be considering the substances and associated documentation in batches of about six substances at a time. The WPC would pass its conclusions to its parent committee, the EU Advisory Committee on Safety and Health. Following advice from this body, it is anticipated that the European Commission will make formal proposals for revision of the directive. This is likely to occur no sooner than mid-2013. The advice from WATCH will be used to help HSE develop the UK line in early stage discussions at the Working Party on Chemicals and to enable development of a UK impact assessment. HSE would welcome WATCH’s views on the SCOEL (EU Scientific Committee on Occupational Exposure Limits) assessments, the IOM (Institute of Occupational Medicine) papers and any other pertinent knowledge that WATCH members might have. Members sought clarification as to whether their considerations should include the socio-economic aspects of the papers provided, as this might be considered outside the scope of WATCH. The Chairman recognised this and asked that if a member commented on these aspects, it would be considered as useful additional information provided by an individual (not by the committee), for example based on particular experience in the chemicals industry.

3.3 One member sought clarification about the IOM reports. Each position was presented as if it had to fit into more general constraints. Had the IOM authors been provided with a template for the presentation of their conclusions as a part of the contract specification; or were the reports in an IOM ‘house style’? HSE responded that the project brief provided a list of chemicals, and the contractors were to consider the SCOEL summaries where these were available. For some substances the contractors were asked to consider specific numerical values for prospective “Binding Limits” but for others the contract was less specific. In the latter case it appeared that IOM had identified the existing occupational exposure limits in EU Member States and assessed the impacts of the upper and lower values in this range. It was likely that methodology would have been agreed with the EC even if not necessarily specified within the contract. The Chairman commented that the approach used by IOM was a close parallel to the methodology used in the “UK occupational cancer burden” project that WATCH had considered at the previous meeting.

3.4 Members commented on the general methodology. The reliance upon
national CAREX (CARcinogen EXposure) databases might produce figures for exposures in various industries that are not necessarily up-to-date or accurate, but members recognised that these might be the best available data. Using these data to predict the numbers of cancers expected to be caused by the exposures was also clearly subject to a number of significant uncertainties. The apparent precision created by the output being the numbers of cancers predicted was misleading. The Chairman commented that in the presentation to WATCH of the “UK occupational cancer burden” project it was stated that the main aim of the methodology adopted was to deliver an idea of relative priority for action across numerous different substances and the situations in which exposure to them arises. The work in the IOM reports had taken the application of the approach a step further. He recalled that a member of WATCH who had also been involved in the IOM work had commented previously that the appeal of the approach was that it was transparent and hence open to discussion or critique – it was not being argued that the numbers produced are accurate reflections of the true situation.

3.5 Members heard that in the ongoing considerations of the “UK occupational cancer burden” work there is a paradox, in that the numerical outputs of the work were never meant to be taken as precise estimates, but they had been published as specific, single numbers rather than, for example, as a range. Debate is on-going in the scientific literature on the methodology and members thus expressed some concern about actions taken at a policy level whilst scientific debate is still underway. Members agreed that it was important that qualifiers about the accuracy of the numerical data were stated and noted.

3.6 Turning next to the SCOEL assessments, members noted that these varied in depth and format because each had been finalised at a different point over a period of several years. The more recent SCOEL reports had adopted a banding approach (A to D), allocating particular carcinogenic substances to different bands reflecting different risk assessment/management options, depending upon the strength of evidence that a particular mode-of-action was involved. Whilst the older reports could be updated to incorporate this banding approach, SCOEL had not yet been asked to do this. Members commented that some SCOEL reports seemed to offer a quantitative estimate of risk and others were based on identifying a threshold dose based on a non-genotoxic effect believed to underlie the carcinogenic process. Members noted that there is a paper by Hermann Bolt (2008) on the SCOEL methodology for dealing with carcinogens. In this respect, the SCOEL paper on crystalline silica looked at fibrosis as the basis for its risk assessment. Trichloroethylene is another example where SCOEL had recommended a limit value for a carcinogen, believing that it had identified a threshold dose for the underlying mode of action.

3.7 Members agreed that in starting to look quantitatively at the impact of different potential limit values, the IOM documents represented a huge step forward in considering all aspects of establishing occupational exposure limits. However, the reports were based on existing data on exposures. Often these data are somewhat dated and/or very limited.
and thus there must be a caveat as to how reliable the conclusions can be. Members agreed that it is very important to explain the uncertainty involved in the estimates involved in, and produced by this work.

3.8 WATCH then turned to examine each substance in turn.

4.1,2-Dibromoethane [WATCH 2012/2]

4.1 Steve Williams declared an interest in this substance.

4.2 A member noted that page 5 of the IOM document referred to an increase in male breast cancer and asked if there were any data on female breast cancer. Another member responded that the evidence for increases in male breast cancer was actually fairly weak. It was taken from a paper considering 50 different categories of occupation with mixed exposures in the occupational groups to a number of combustion products. It was therefore not appropriate to allocate this effect to a single substance. A different point concerned the scope of the IOM’s considerations: in the estimates of costs on page 16 there was no mention of costs associated with protection against the identified skin irritancy of this substance, for example the cost of gloves. Was this because the paper focused exclusively on carcinogenic risk arising from airborne exposure? There are also reports of reproductive effects in humans occurring at very low doses – should this also be taken into account in the analysis? The finding could be used to support an argument for a limit lower than those put forward in the IOM assessment. Members noted that the apparent single focus on carcinogenicity could reflect the contract requirements. Nonetheless, WATCH would expect a regulatory system to consider the whole toxicological profile of a substance. One member noted that when he reviewed the original paper reporting these reproductive effects, it was clear that there was some uncertainty about the levels of exposure experienced by the subjects.

4.3 The socio-economic estimates were transparent, but members noted that they reflected historical exposures. The document reported some exposures in sectors where a member familiar with those sectors believed them not to occur. Thus the information offered on exposures should be taken as a starting point for further consideration, rather than as established fact. This member noted some typographical errors in the document, for example an annex headed “beryllium” in the papers on dibromoethane and a quote ‘< nice people’ which should read ‘< nine people’. These errors suggested the papers had been completed rapidly and he raised the possibility there may be errors in some of the numbers.

4.4 Members noted that there were no exposure data known to the authors since the early 1990s; therefore IOM had applied a presumed 7% reduction per year in exposure. It was not clear how changes within the particular industries involved fitted this extrapolation. Members noted that UK manufacture of 1,2-dibromoethane had now ceased, but there was still known to be one large user in UK.
4.5 Members heard that 1,2-dibromoethane incorporation into fuels is at ppm levels and exposure would be well controlled because of the need for petrol to be handled safely. Aviation fuels still use leaded gasoline; in the aviation sector new technologies require long periods of time for proving and certification.

4.6 Members heard that in the context of REACH, an occupational DMEL (Derived Minimal Effect Level) of 0.00005ppm (0.05ppb) had been included in industry proposals associated with Registration requirements. It was unlikely that the IOM team had access to the REACH Registration dossier in completing their report. Members highlighted the importance of better communication between those involved in REACH and those involved with regulation specific to the workplace. It would not seem sensible for different levels of control to be advocated under different pieces of EU legislation. Given that the DMEL proposed is so low, members considered that this justified a review of current (appreciably higher) OELs in the EU.

5. **Epichlorohydrin [WATCH 2012/3]**

5.1 Members noted that this substance reinforced their concern that the substances should be considered holistically. The main thrust of the papers was carcinogenicity and mutagenicity, probably in line with the brief given in the contract. However epichlorohydrin is well known as a skin sensitiser.

5.2 Members noted that most exposures to this substance would be accidental and thus an OEL was not a particularly relevant means of control. There was thus no relevant cost-benefit analysis.

5.3 Experimental animal studies demonstrated this substance to be a direct-acting carcinogen resulting in local tumours. Although there was epidemiology suggesting that tumours occurred in exposed humans in the central nervous system, members advised that this seemed biologically implausible.

6. **Hexavalent Chromium [WATCH 2012/4]**

6.1 David Farrar declared an interest in this substance.

6.2 Members noted that this substance was also under consideration for Authorisation within REACH. Reflecting on the point made earlier (para 4.6) HSE agreed to highlight the need for better communication between EU directorates in EU regulatory considerations, to prevent duplication of effort and/or obvious conflict between the outcomes of parallel, unconnected processes.

**Action:** HSE to highlight the need for communication between the revision of Carcinogens and Mutagens Directive and REACH.

6.3 The Chairman noted that it would be a number of years before an Authorisation application under REACH would arrive from industry for consideration by the regulatory bodies involved – probably after 2013. Later in the discussion, members were advised that the current Authorisation procedure for chromate VI salts under REACH requires applications by November 2014 and use without authorisation must
cease in May 2016]. HSE commented that the start of formal EU consideration of a proposed “Binding Limit” under the Carcinogens and Mutagens Directive might only commence in 2013, with a final decision being taken sometime later. Hence the timings of the two regulatory processes might not be that far apart.

6.4 Members noted that the IOM document proposes that all hexavalent chromium compounds share the same limit value, but recognises a variation in the hazardous potency of different hexavalent chromium compounds, related to their solubility. It was argued that some discrimination between the various compounds might ensure a focus on the more toxic compounds and thus bring down the total costs of control measures that would otherwise be applied across all industries and situations in which hexavalent chromium arises.

6.5 Other members suggested that the analysis would get too complex if attempts were made to differentiate between individual compounds. For carcinogenicity, the medium-solubility compounds are probably of most concern and strict controls are already applied. Hexavalent chromium carcinogenicity is expressed at the initial site of contact; highly soluble compounds are rapidly processed out of the body and insoluble compounds are not readily bio-available. However, other effects of hexavalent chromium would also need to be considered, for which the relationship with solubility might be different.

6.6 One member suggested that, nevertheless it was a shame that the potency of this group of compounds depending upon their bioavailability could not be tackled; such an approach had been followed for inorganic fibres. He also commented that occupational exposure limits for this group of compounds were already low in the EU, including the German position being an approach of ‘lowest exposure technically possible’. The OEL of 0.1mg/m³ considered in the IOM document is higher than the exposure limits already being applied in the EU, and thus there should be no new costs associated with this position. It is not apparent from the document that existing EU control positions have been taken into account.

6.7 Members noted disappointment again about the information available on the industry profile and the reliability of the information used. The Chairman reflected that this was another illustration of the general point that information was not being shared across different parts of the European Commission.

6.8 One member suggested that the very high projected costs of control to the lower limit values being considered might justify a research project to get better data. For example is establishing an airborne exposure limit the best approach to securing good control? Would the regular use of biological monitoring be more appropriate? Other members commented that biological monitoring could not differentiate between exposures to hexavalent and trivalent chromium. Some members considered that it was difficult to identify additional research that would add value to these considerations - it was possible that the problems posed by these compounds may have now become well-managed.
without a full understanding of all aspects.

7. o-Toluidine [WATCH 2012/5]

7.1 A member noted the surprising apparent accuracy in some parts of the IOM document – on page 8 it was suggested that it was known that only 2 workers are exposed to this substance in one EU member state. He also asked whether there was any information about the meta- and para- isomers of toluidine. Other members speculated that, as related molecules are used in industry only as the ortho-isomer, it was likely that there was an important structure-activity relationship favouring the ortho-form. Members noted that IARC had revised its position on this substance, such that it was made an IARC Group 1 carcinogen in 2010. No other comments were made.


8.1 David Farrar declared an interest.

8.2 Members noted the documents included relatively recent measures of occupational exposures. This was better exposure information than had been available for other substances assessed in this tranche; the results looked reliable and indicated only low exposures. The information on use is also more up-to-date and this probably reflects having available the recent IARC consideration. Members noted that under REACH there was a proposal from Germany that at least some types of these fibres should be considered for Authorisation. No other comments were made.

9. Respirable Crystalline Silica [WATCH 2012/7]

9.1 A member observed that the papers had used very broad categories for workers using this material. As an example, three substantial and different sectors - coke manufacture, petrol refining and nuclear fuel manufacture - are grouped into a single category. Whilst there might be some exposure in coke manufacture, there would not be expected to be exposure in petrol refining, so the estimates of numbers exposed are likely to be overestimates.

9.2 An error in the units (mg/m³ rather than mg/m³ hr) was pointed out in the SCOEL summary that was repeated in the IOM report. Members noted that SCOEL had considered silicosis as an easier end-point than lung cancer to use as a basis for providing quantified risk estimates. It was commented that, with respect to the IOM report, a level of about 5% silicosis seemed inappropriately high to use as a benchmark for considering one potential occupational exposure limit.

9.3 Members noted the assumption in the IOM calculations of full compliance with occupational exposure standards. Whilst clearly this would be ideal, much of the exposure to silica occurs in sectors such as mining and construction where experience has suggested that compliance is not always as good as this. Members commented that control to the 0.01mg/m³ level would not be feasible in these sectors.

9.4 A member commented that the papers presented assume a link
between silicosis and lung cancer. However there is some suggestion that lung cancer can occur in the absence of silicosis. Members commented that the data on this issue are variable. It appears that the development of lung cancer might occur either secondarily to fibrosis or independently of it. One possibility is that the two effects arise from the same background of inflammation, but originate in different cell types. It is perhaps the case that development of overt silicosis is an indicator of relatively high exposures. The Chairman asked how similar was the picture created in the IOM document to that in the case study presented to WATCH last year, taken from the Rushton et al work on UK occupational cancer burden. In response, it was stated that in the cancer burdens paper there had been no use of silicosis as an endpoint for risk estimation.

10. **Acrylamide [WATCH 2012/8]**

10.1 Robin Chapman declared an interest in this substance.

10.2 A member commented that contacts with people in acrylamide-related industries had resulted in a large volume of comments on the documentation provided. A key query was the justification for the skin notation, the industry analysis suggesting that uptake via skin was quite low. HSE asked if this industry information could be made available to them – perhaps in anonymised format.

10.3 It was observed with surprise that there was a human volunteer study reported in 2006. It was not clear why such studies had been allowed to go ahead, given the toxicological profile of acrylamide.

10.4 Members were pleased to see that industry groups had been contacted by IOM, as it was important to ensure that up-to-date information on current processes is available in this exercise. Members were informed that there was an in-depth study of occupational exposure to acrylamide, including biological monitoring, being undertaken by HSL at the moment. It was stated that nowadays about 99.9% of acrylamide production is used in polyacrylamide manufacture. This was a ‘captive market’ using continuous processes and having good control measures in place. Biological monitoring indicates that under such controls the level of exposure is lower than the limit of detection; exposure can only be detected where there has been some form of upset to normal controls. This suggests that a routine requirement for biological monitoring is not realistic, but it could be used in the event of incidents.

10.5 Members commented that despite the assessment suggesting little total cost impact even for a relatively very low limit value, it was important not to set limits unjustifiably low, in case this resulted in a single, relatively small industry sector having to bear disproportionate costs.

10.6 Members noted that the IOM quoted ESIS (European chemical Substances Information System). This reflects information from the original EU Existing Substances Regulation (ESR) in 1993, and is thus rather dated.

10.7 When WATCH considered the UK draft ESR risk assessment of
acrylamide in the 1990s there had been concern about its use in tunnelling grouts. Members noted that this is a specialist application; and that not all tunnelling involves this type of grout being used in a confined space, the scenario giving rise to most concern.

10.8 Members heard that the DMEL suggested for acrylamide by companies registering this substance under REACH was 0.07mg/m³. Again it was clear there was a mismatch between the thinking of SCOEL and that behind the recommended DMEL. In the context of the need to link up different regulatory activities, a member referred to a forthcoming EU workshop considering the control of chemicals in the workplace and the relationship to REACH. An HSE representative had been invited to speak at this workshop: WATCH asked to receive feedback.

10.9 HSE commented that one common theme in its comments on the documentation provided for these substances was the evident difficulty in getting up-to-date, reliable information on usage, both in terms of volumes used and current industrial practices. Pressure on resources means that both HSE and industry are facing similar difficulty as effort becomes focused on the day-to-day essentials rather than on more general gathering and sharing of intelligence.

10.10 The Chairman drew this item to a close by reminding members that this group of substances form part of an ongoing stream of work. Wherever timing allows, it is planned to include further items of this work on WATCH agendas. Where this was not possible members would be consulted electronically.

11. Environment Agency (EA) consultation on the derivation of new Environmental Assessment Levels (EALs) in air. [No WATCH paper]

11.1 Members’ attention was drawn to this consultation. In the past, environmental air standards had been derived from UK occupational exposure limits (OELs). Given the withdrawal of some UK OELs some years ago and the lack of activity in updating others, EA is now consulting on a possible new approach to develop EALs in future. Members agreed that it would be important for those concerned with workplace standards to be aware of the proposals, as environmental air limits (considered in relation to the environment surrounding a place of work) can have an impact on workplace controls.

11.2 The Chairman also suggested HSE might wish to flag up the importance of pursuing consistency and coherence between different regulatory activities concerned with establishing controls on the level of substances in the air.

**Action: Secretary to circulate the link to the consultation to members.**


12.1 Members confirmed the minutes subject to minor amendments at 3.11, 4.11 and 5.5. The secretary will update the website with these
amendments.

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<td><strong>13. Matters arising</strong></td>
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<td><strong>13.1</strong> The secretary advised members that an update on HSE actions on the WATCH recommendations on the Long Latency Health Risks in Foundries project had been tabled as had the report on the last consultative workshop held in 2008 requested at the previous meeting.</td>
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<td><strong>13.2 Matters arising: C.I. Solvent Red 164.</strong></td>
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<td><strong>13.2.1</strong> HSE reported that the information provided to WATCH on the structure of this dye in 2008 was the definitive structure. However since the WATCH meeting in October 2011, when a different structure appeared as part of a presentation, HSE had been in liaison with a UK formulator of dyes used in non-destructive testing (NDT) of metals for cracks. Information obtained suggests there are different “variants” of red dyes in use and that there is difficulty for formulators in getting accurate information on the substances supplied. It seems likely that different compounds are in use and whilst it is clear exactly what C. I. Solvent Red 164 is, it is not clear that this is what the formulators always receive from their overseas suppliers. Although the biological monitoring work done by HSE/HSL has been reassuring, HSE is considering whether there is a need to consider further work. HSE will continue to encourage formulators and duty holders to pursue clear and reliable information from their suppliers. It is apparent that some safety data sheets include only general information on aromatic amines as a class of substance. HSE need to consider supporting formulators in getting better, more comprehensive information and what further work, if any, needs to be done in relation to the detection of other possible metabolites of molecules other than C.I. Solvent Red 164 that seem to be arising in some of these dye products.</td>
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<td><strong>13.2.2</strong> The Chairman commented that there had been consistency in the thinking and the conclusions reached in the WATCH process. HSE had now been able to identify that there are some links in the supply chain where there is a lack of clarity about exactly what substance is being received and, after formulation, is being supplied to others. Members noted that it is possible this occurs as a result of reliance on common names for substances and because of a shift in the manufacturing source to Asia. Members asked whether REACH would help clarify the position. The Chairman confirmed that C. I. Solvent Red 164 was subject to coverage by REACH but, as supplied in quantities only a little above 1 tonne per annum, would only be Registered towards the end of the decade (unless it was identified as a substance of concern, which seems very unlikely).</td>
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<td><strong>14. Committee on Carcinogenicity (CoC) examination of risk of asbestos-induced cancer in children, relative to adults</strong></td>
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| **14.1** The secretary reported that minutes of this discussion are still awaited but will be circulated to WATCH once they are available. The Chairman
understood that following a first discussion at CoC in July focussed on scoping the further work required, in January 2012, the CoC discussed asbestos levels in school buildings, epidemiology and case-reports in children, the WATCH position statement on asbestos and the view of HSE scientists on the 2010 risk assessment by the Health Council of the Netherlands.

14.2 For information, the Chairman reported that the Secretary of State for Education had received a complaint about information provided by HSE, both to the CoC and previously to WATCH, on airborne asbestos fibre levels in schools. It was claimed that the picture presented by HSE was biased because it did not include data from some sources reporting relatively higher levels.

15. **Date of the next WATCH meetings 2012**

15.1 The next WATCH meetings will be held on 20 June and 18 Oct in York. Members agreed to discuss the revised code of practice for scientific advisory committees and its implications for WATCH at the next meeting.

16. **Any other business**

16.1 No additional business was considered.