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ADVISORY COMMITTEE ON TOXIC SUBSTANCES
ANNUAL REPORT ON THE WORK OF THE
WORKING GROUP ON ACTION TO CONTROL CHEMICALS
(WATCH)

Issue

1. First annual report to ACTS Members on the activity of its scientific subcommittee WATCH.

Timing

2. Routine

Recommendation

3. That ACTS takes note of the recent activity of the subgroup.

Background

4. Following the dissolution of (old) WATCH on 31 March 2003, (new) WATCH was reconstituted during 2003 and held its first meeting on 18 March 2004. WATCH met again on 10 June 2004 and 13 & 14 January 2005.

5. WATCH is now formally constituted as a scientific advisory committee that is required to adhere to the Office of Science and Technology's Code of Practice for Scientific Advisory Committees (COPSAC). As such, much of the first two meetings of WATCH in 2004 were occupied with reaching agreement on committee arrangements/procedures that are required by the COPSAC. The COPSAC requires some of these arrangements/ procedures to be presented in the Annual Report. Hence the relevant papers are attached in Annexes 1-6.

6. The role of WATCH is aligned with the Chemicals Strategy themes agreed by HSC in November 2002, a key element of which is the HSE Disease Reduction Programme (formerly "Chemicals Programme"). WATCH has been familiarising itself with the main elements of the Programme and establishing its contribution to the objectives of this Programme. Several of the WATCH papers this year have therefore addressed the essential background information. See Annex 7 for the list of papers presented to WATCH in 2004/5.

7. Beyond establishing the procedures and role of WATCH, the committee provided advice on several scientific and technical issues. These issues are briefly summarised below and the advice provided by WATCH is presented. Minutes of each meeting provide more detail and are published on the HSE web site when agreed by Members.

Argument

8. Occupational Health Aspects of Nanotechnologies

Nanotechnologies are concerned with the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale. They involve the production and use of materials that have one, two or three dimensions in the nanometre range (defined as <100 nm). The emergence of nanotechnologies includes the development of novel nonmaterial (e.g. carbon nanotubes), as well as novel applications of existing material in the nanometre range (e.g. use of nanoparticulate titanium dioxide in sunscreens).

9. An integral aspect of the development of nanotechnologies is the occupational health and safety implications of exposure to nonmaterial. Therefore WATCH was asked to consider several different aspects of the health and safety issues associated with nanotechnologies.

10. With respect to the hazard assessment of nanotechnologies, WATCH agreed that the hazard assessment produced by the HSE and presented to WATCH, represented an accurate appraisal of the current extent of knowledge on nanoparticles. However, HSE agreed to take account of some specific points of detail made by WATCH in the ongoing process of keeping abreast of the potential human health hazards of novel nanoparticles.

11. With respect to the most appropriate metric, WATCH agreed that the ability to measure nanoparticulate surface area, either directly or indirectly was important. However, it was also considered necessary to take a case-by-case approach to measurement, as the most appropriate metric for one type of nanoparticle may not be appropriate for another. It was also noted that consideration of routes of exposure other than inhalation was important in undertaking any worker risk assessment.

12. WATCH agreed that in principle, the existing regulatory framework can accommodate all nanoparticles but on a case-by-case basis. As such, there is a need to look at the way each individual case fits within the regulatory framework, such that different elements of the framework may be more or less appropriate for different situations. As new particles and technologies are developed, WATCH considered that there should be an obligation on producers to understand the hazards and risks of their products.

13. Finally, WATCH concluded that there is no need for new risk management approaches, as existing control approaches should be applicable, although again, each situation needs to be considered on a case-by-case basis. In addition, in view of the paucity of hazard data on novel nanoparticles, WATCH

considered that pragmatic approaches such as assignment to hazard and control bands may be worth pursuing.

14. The carcinogenicity of Formaldehyde

The genotoxicity and animal carcinogenicity data on formaldehyde have led to a hypothesis that formaldehyde can produce tumours in the upper respiratory tract, at least in rats, only under conditions of chronic inflammation. There have been over 50 epidemiological investigations of cancer in formaldehyde-exposed workers that have been periodically reviewed by various authorities, covering data available up until 2000. Consistently the conclusion has been that although some individual studies are suggestive of formaldehyde having caused nasopharyngeal or nasal cancer in exposed populations, the overall strength of evidence had fallen short of showing a clear and causal association with formaldehyde.

15. However, a number of new epidemiology studies have been reported since 2000. Some of these provide further evidence in relation to formaldehyde exposure and cancer of the upper respiratory tract and also there are some concerns raised for leukaemia. In 2004 IARC reappraised its position on the carcinogenic potential of formaldehyde, taking these new studies into consideration, and reached the following conclusion in relation to nasopharyngeal cancer:

“Overall, the Working Group concluded that the results of the study of industrial workers in the USA, supported by the largely positive findings from other studies, provided **sufficient** epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans.”

16. This development has triggered a number of reactions, one of which is the French Competent Authority declaring its intention to put a classification proposal for formaldehyde to the EU Classification and Labelling Working Group in spring 2005. Given the importance of formaldehyde as a chemical and the significance and consequences of pronouncing a substance as a “human carcinogen”, WATCH was asked to consider the strength of evidence that formaldehyde has caused cancer in humans.

17. WATCH concluded that formaldehyde has probably caused nasopharyngeal cancer in humans via a mechanism to which it can be predicted that both chronic inflammation (provoked by irritancy) and genotoxicity contributed.

18. In relation to the apparent association seen in some studies between formaldehyde exposure and leukaemia, based on recent reviews of the evidence, and also considering biological plausibility, WATCH concluded that there is no basis for any significant concern for this cancer.

19. Assessment of the Respiratory and Carcinogenic Hazards of Portland Cement

WATCH first considered Portland cement in 1991 (WATCH/05/91) and the review considered by WATCH was published as an HSE criteria document in 1994. HSE has now produced an updated assessment of the health effects information presented in this earlier HSE (1994) review, focusing on the evidence for respiratory and carcinogenic effects. One reason for undertaking this assessment was in the context of the developing plans for the Occupational Respiratory Disease (ORD) sub-programme of the Disease Reduction Programme. A particular issue was to see if the evidence published since 1991 is now better able to characterise exposure-response relationships for the respiratory effects of cement dust.

20. WATCH agreed that it is clear that occupational exposure to Portland cement dust has produced deficits in respiratory function. However, the evidence available at the present time is insufficient to establish with any confidence the dose-response relationship for these effects.

21. With respect to cancer, WATCH agreed that a causal association between Portland cement exposure and cancer has not been established.

22. WATCH noted that as a highly alkaline substance, cement can cause irritation at sites of contact, such as the mouth, throat and lungs. Persistent chronic irritation will cause repeated cycles of cell death, cell proliferation and other inflammatory responses. WATCH recognised that this process can be a step on the pathway to cancer. Thus, WATCH considered it biologically plausible that cement dust could have the potential to cause cancers at sites of contact in the respiratory tract. WATCH considered that the findings of the recent data epidemiological maintain the uncertainty concerning possible carcinogenic potential raised by the earlier data reviewed by HSE (1994).

23. Biological Monitoring for Isocyanates

As isocyanates have a SEN notation and R42 applies, the new UK "Workplace Exposure Limit" OEL framework will require that exposure be controlled to as low as is reasonably practical (representing the same level of control as currently applies). Adequate control of exposure to isocyanate-based spray products normally requires the use of air-fed RPE. Monitoring of airborne exposures to total isocyanate requires considerable expertise for analysis, is relatively costly, and cannot be used to assess the effectiveness of protection for workers wearing respiratory protective equipment (RPE).

24. Therefore WATCH was invited by the ACTS subgroup on COSHH Essentials to consider the appropriate role of biological monitoring in the assessment of effectiveness of the control measures for isocyanate exposure and a suitable value for a Benchmark BMGV.

25. WATCH recommended that biological monitoring is used as appropriate, within a well-considered risk management strategy, to assess the effectiveness of control measures for isocyanate exposure. However, from the

data available, WATCH could not recommend a value for a Benchmark BMGV at this time.

26. Chromium VI Biological Monitoring Guidance Value (BMGV)

'Old WATCH' recommended a Benchmark BMGV of 10µm chromium/mol creatinine, based on measurements in post-shift urine samples. However, the sole EU manufacturer of chromium VI compounds raised concerns about the interpretation of such a value among its workforce. Following further debate between the manufacturers and HSE, the manufacturers accepted the proposal for a BMGV but asked that HSE provide additional guidance on interpretation of the results of biological monitoring to assist in explaining results to the workforce. A draft of this guidance was made available to WATCH for comment.

27. Overall, WATCH endorsed the BMGV and associated guidance and asked that the guidance point out that potential confounding from chromium in dietary supplements may be a problem.

28. Diacetyl as a Flavouring in Popcorn

Following a NIOSH alert of outbreaks of severe lung disease in workers exposed to diacetyl in the food industry, a WATCH Member raised this as potential concern for the UK workplace. Having contacted various stakeholders, HSE was able to confirm that there was no evidence of diacetyl being used in the manufacture of popcorn in the UK.

Action

29. ACTS members are asked to note the information in this paper.

Contact

Nicola Gregg HSE FOD (CHSD A1)
WATCH Secretary
Tel: 0151 951 5800
Email: nicola.gregg@hse.gsi.gov.uk

References / Attachments

COPSAC December 2001, Office of Science and Technology, Code of Practice for Scientific Advisory Committees, Department of Trade and Industry

- Annex 1 WATCH Membership Template 2004/5
- Annex 2 Register of Member's Interests 2004
- Annex 3 WATCH Terms of Reference
- Annex 4 WATCH Financial Statement 2004/5
- Annex 5 Methods of Resolving Conflict
- Annex 6 Glossary of Terms
- Annex 7 Papers Issued to WATCH in 2004/5

Annex 1

WATCH Membership Template 2004/5

MEMBERS

TUC Nominees

Dr T Fletcher

Prof A W M Hay

Dr M J Nieuwenhuijsen

Area of Expertise

Epidemiology

Toxicology

Occupational hygiene/epidemiology

CBI Nominees

Dr S P Binks

Mr R Chapman

Mr S D Williams

Toxicology

Occupational hygiene

Toxicology

Independent Members

Mr S R Bailey

Mr D G Farrar

Dr L S Levy

Dr E A Smith

Dr S R Hutchinson

Occupational hygiene

Toxicology

Toxicology

Occupational hygiene

Chairperson

Dr S Fairhurst

Toxicology

Ad hoc Members co-opted in 2004/5

Prof K Donaldson

Dr R Aitken

Prof D Coggon

Toxicology

Occupational hygiene

Epidemiology

Annex 2

On Appointment Register of Interests 2004

Members have declared the following interests (ie share holdings or fundings received)

Name and Employer or Nominating Body	Declaration	Personal Profile (optional)
Dr S Fairhurst HSE	None	
Dr T Fletcher TUC	None	
Prof A Hay TUC	None	
Dr M Nieuwenhuijsen TUC	None	
Dr S P Binks CBI	Employee and Share Holder of GlaxoSmithKline	
Mr R Chapman CBI	Employee of BASF plc	
Mr S Williams CBI	Employee of BP Chemicals Ltd Share Holder of BP plc (relates specifically to petrochemicals, oils and chemicals associated with oil exploration, refinery products and lubricants)	
Mr S Bailey	Employee and Share Holder of GlaxoSmithKline (relates principally to pharmaceuticals)	
Mr D Farrar	Employee of Ineos Chlor Limited. Consultant to Ineos Chlor Enterprises, Ineos Fluor, Ineos Silicas, Asahi Glass Fluoropolymers UK Ltd and Saffil Ltd. Share Holder of ICI plc	
Dr L Levy	Scientific Adviser on Occupational & Toxicological research to International Carbon Black Association (relates specifically to carbon black)	
Dr E Smith	None	
Dr S R Hutchinson	Share Holder of Johnson Matthey	
Ad Hoc Members		
Prof K Donaldson	None	
Dr R Aitken	None	
Prof D Coggon	None	

Annex 3

WATCH Terms of Reference

**TERMS OF REFERENCE FOR
THE WORKING GROUP ON ACTION TO CONTROL CHEMICALS
(WATCH)**

1. To be the ACTS' scientific sub-committee to advise ACTS and HSC/E on issues relating to the assessment and control of health risks of chemicals.

2. WATCH's terms of reference are:

To provide scientific and technical advice to ACTS and HSE on matters within its competence. In particular, to provide scientific and technical advice to ACTS and its other sub-groups and where requested, HSE, on issues relating to chemicals, their actual or potential health impact and the means of their control in the workplace.

3. Should issues arise which require additional expertise, the Chair and the Secretariat, in consultation with WATCH members, may appoint other persons to attend meetings of WATCH to meet particular needs, including co-opting independent experts for particular issues/meetings.

4. WATCH will provide annual reports on its work to ACTS.

Annex 4

WATCH Financial Statement 2004/5

Costs incurred are travel and subsistence reimbursements to Members, hire of conference facilities and equipment, refreshments and meals during meetings and overnight rooms for residential meetings.

Members do not receive a fee for time spent preparing for or attending WATCH meetings.

In 2004/5 WATCH met on three occasions, two 1-day meetings at HSE's offices in London and one 2-day residential meeting at a hotel in Liverpool.

Total travel and subsistence costs	=	£1532.65
Total conference expenses including meals, room/equipment hire, overnight rooms	=	£4294.70

Total WATCH expenditure in 2004/5	=	£5827.35

NB. Several members have not claimed for travel and subsistence reimbursement in 2004/5 as expenses have been by their employers.

Annex 5

Methods of Resolving Conflict

Extract from Members' Terms and Conditions (WATCH/2004/8) :

8. Handling conflict of interests

WATCH members are appointed on a personal basis, even when nominated by stakeholder groups. However, to avoid any public concern that commercial interests might affect the advice of WATCH, HSE has decided that the arrangements that govern relationships between members and the chemicals industry and information on significant and relevant interests should be on public record. Members will be required to declare any interests on appointment and at relevant meetings. Such interests can be direct or indirect. Examples of a direct interest would be employment at a company that manufactures chemicals and personal involvement in the subject under discussion or being retained as an expert witness in a legal case involving the subject under discussion. An example of an indirect interest would be when a member, working at a University Department, is aware that the Department is part-funded by grants from a particular company, but where the member is not involved in the work funded by that company.

If an interest is declared the member should seek the Chair's guidance on whether they should take part in the proceedings

To avoid any danger of WATCH members being influenced, or appearing to be influenced, by their private interests in the exercise of their public duties, all members should declare commercial interests on the basis set out below.

Annex 6

Glossary of Terms

BMGV	Biological Monitoring Guidance Values
COPD	Chronic obstructive pulmonary disease
COPSAC	Code of Practice for Scientific Advisory Committees
HSC	Health and Safety Commission
HSE	Health and Safety Executive
ORD	Occupational Respiratory Disease
WATCH	Working Group on Action to control Chemicals

Annex 7

Papers Issued to WATCH in 2004/5

- WATCH/Agenda/2004/1 - Agenda for 1st meeting, 18th March 2004
- Presentation on Role of Scientific Committees in Government/HSE
- WATCH/2004/5 - Terms of Reference for the Working Group on Action to Control Chemicals (WATCH)
- Draft Members Terms and Conditions
- Draft Members Terms and Conditions : Proposal to amend section on declarations of interest
- Presentation on The HSC's Chemicals Strategy
- Presentation on HSE/C's Respiratory Strategy
- Presentation on the Skin Disease and Strategy for Cancer
- WATCH/Min/01/2004 - Final Minutes to 1st meeting on 18th March 2004

- WATCH/Agenda/2004/2 - Agenda for 2nd meeting, 10th June 2004
- WATCH/8/2004 - Draft Members Terms and Conditions: Secretariat Proposals following 1st Meeting
- WATCH/9/2004 - Circulation of Papers to Members
- EU Scientific Committee on Occupational Exposure Limits : presentation on EU Limit Setting Process in Brief
- EU Scientific Committee on Occupational Exposure Limits : presentation on Requests for/receipt of Topics and Documents
- EU Scientific Committee on Occupational Exposure Limits : presentation on How are we trying to improve EU Limit Setting
- Presentation on COSHH Essentials
- WATCH/10/2004 - Benchmark BMGV for ChromiumVI
- WATCH/11/2004 - Health significance of occupationally-induced declines in FEV₁
- WATCH/12/2004 - Early Identification of New and Emerging Issues, Proposals for Handling
- WATCH/13/2004 - Horizon Scanning – Popcorn Flavourings, Progress Report for June 10th Meeting of WATCH
- WATCH/14/2004 - OSHA website information on diacetyl (popcorn flavouring)
- WATCH/Min/2004/2 - Final Minutes of 2nd meeting on 10th June 2004

- WATCH /Agenda/2005/1 - Agenda for 3rd meeting, 13 &14th January 2005
- WATCH/2005/1a - presentation on HSE's Future Work on Chemicals and Occupational Ill Health
- WATCH/2005/1 - Role of WATCH
- WATCH/2005/2 - Occupational Health Aspects of Nanotechnologies
- WATCH/2005/3 - Portland Cement
- WATCH/2005/4 - Biological Monitoring of Isocyanates
- WATCH/2005/5 - presentation on the Disease Reduction Programme: Skin Disease

- WATCH/2005/6 - The Carcinogenicity of Formaldehyde
- WATCH/2005/7 - Evaluation of COSHH Essentials
- WATCH/2005/8 - Communications Strategy for the New OEL Framework
- WATCH/2004/12 - Early Identification of New and Emerging Issues and Review of Existing Advice
- Presentation on Communications Strategy for the New OEL Framework
- WATCH/Min/2005/1