

New and Emerging Issues 2006

List of potential new and emerging issues identified in 2005, with named proponent and his/her proposition

NB. Shaded topics are those that were identified as a priority during the October 2005 meeting and are already being considered further

Topic No. 1

Monitoring the successes and failures of the newly introduced WEL system for the control of exposure to hazardous substances

(Len Levy)

Much effort has been spent setting up the new WEL system. However, it is not clear, to at least some knowledgeable individuals, what is being done to assess what progress is being made towards successfully achieving the objectives of the WEL system and/or how well it is overcoming the shortcomings of the previous UK OEL system.

If such assessment is being done in-house by HSE, is it possible/ helpful/ necessary for periodical updates to be made to a body to ensure adequate progress is being made ?

If no such assessment is being made, should a body be appointed to help set up such an assessment ?

It is noted that the OEL Framework Group that formulated the new WELs system drew up 7 key criteria for setting up and/or appraising any new system. These criteria might be a useful starting point for any assessment process if it has not already been undertaken and is considered necessary.

Topic No. 2

Potent Pharmaceuticals (eg for Chemotherapy)

(Rob Turner)

The trend would seem to be towards more potent active substances for medicinal treatment such as chemotherapy. This would suggest a potential need for more stringent controls not only for manufacture but also downstream occupational exposures (eg pharmacy, administering the medicine, dealing with wastes).

Is there a need to review the processes involved and the need to use new surface imaging techniques, biological monitoring and (perhaps) biological effects monitoring to estimate exposure and risk and to identify good control practice?

Topic No. 3

The Global Harmonisation System for classification and labelling of hazardous chemicals (GHS)

(Steve Bailey)

The GHS was endorsed by UN ECOSOC in July 2003 (see <http://www.unece.org/press/pr2002/02trans07e.htm>) and is being considered for adoption in Europe.

Implications for the safety of workers in UK and across EU include changes to the safety data sheets, new signs/symbols and labelling phrases in workplaces and new hazard classifications (which will affect COSHH Essentials, NB. Effect of GHS on COSHH Essentials, previously considered by WATCH in May 2001. The conclusion was that COSHH Essentials could be adapted to accommodate GHS classification, in accordance with the approach described in the paper, but that in some respects the changes would result in COSHH Essentials being more precautionary). The changes offer opportunities to improve the management of chemicals but could lead to confusion if not properly planned and implemented.

Is a body within UK responsible for influencing the next developments and activities within this area ?

If not should an appropriate body be charged with such a responsibility ?

Topic No. 4

Recycling

(Rob Turner)

As the pressure for recycling increases there may well be a number of practices giving risk to potential increases in exposure to hazardous substances. For example :

- i) Composting may increase asthma risks.
- ii) There may be an increase in incineration or hot recycling (eg re-melting metals and/or plastics) which could give risk to increased generation and exposure to hazardous substances (eg dioxins).

Is there a need to review the scenarios that may arise from recycling to ensure the technology and working practices are appropriate to assessment techniques and good practice control of exposure to hazardous substances?

[An additional microbiological threat is that there may be an increasing need for workers to manually separate wastes thus creating an increased risk of exposure to microbiological hazard from a wide spectrum of fungi and bacteria. For assay, and control assurance, these may require DNA techniques rather than classical plating and identification.]

Topic No. 5

Grouping / banding of chemicals to assist activities REACH

(Phillip Lewis)

While the EU Chemical Agents at Work Directive covers all the relevant activities that need to be considered for the proper evaluation and control of the health and safety risks of chemicals encountered in the workplace, clearly, there will not be sufficient time and resource to set individual OELs for all the 30,000 (approx) chemicals which will be covered by REACH.

The approach requiring the setting of DNELs for individual chemicals also will be extremely difficult, in terms of effort and resource.

Perhaps the best way forward to deal with such workloads will be to develop a rational approach for determining the exposure ranges or bands to which substances can be assigned. There already exist a range of banding tools or approaches that have been tried and tested. eg COSHH Essentials, the ECETOC Tiered Risk Assessment, etc.

Is it possible to conduct a critical appraisal of such existing tools, as to their effectiveness, relevance and limitations for producing answers for safe and appropriate control solutions, within a reasonable timescale ?

It is also noted that REACH may call into question the justification for the effort currently being devoted to setting OELs for individual chemicals, apart from exceptionally problematical ones.

Topic No. 6

Fisheries

(Rob Turner)

As traditional fisheries decline there has been an increase in shell fisheries. Exposure to shellfish proteins can cause asthma.

Is there a need to review the exposures and working practices in shellfisheries to ensure adequate exposure control is being achieved and to establish good practice approaches?

Topic No. 7

Beryllium

(Gareth Evans, HSL)

Occupational exposure to beryllium and its compounds has been associated with acute beryllium disease, caused by short-term exposures to high concentrations of beryllium; beryllium sensitisation (BeS); chronic beryllium disease (CBD), a delayed and potentially fatal type IV hypersensitivity reaction in the respiratory tract; and cancer. It has been suggested that skin absorption may be a route for development of sensitisation to beryllium.

Beryllium and beryllium compounds were reviewed via the WATCH/ACTS process in the early 1990s, which resulted in a Maximum Exposure Limit of 0.002 mg/m³ (8-hour TWA); this has now become the WEL value in the new UK OELs system. Up until now, HSE has regarded the population of the UK workforce exposed to beryllium as small; about 250 workers regularly exposed and about 1000 exposed on an occasional basis and to lower concentrations.

In 1999 the ACGIH TLV Committee lowered its TLV to 0.0002 mg/m³ 8h TWA (inhalable particulate mass) and in 2005, proposed a further reduction to 0.00002 mg/m³. These developments have arisen in light of recent studies claiming that sensitisation to beryllium and development of chronic beryllium disease may occur in those exposed to lifetime weighted average occupational exposures between 0.024 and 0.6 µg/m³. Concern has also been raised by studies that have demonstrated sensitisation amongst workers who did not belong to the exposure groups (such as machining and milling of beryllium metal alloys / beryllium oxides) traditionally associated with this disease. This raises an issue for exposure to beryllium in those machining copper alloys, for those working with alloys in electronic components in computers and mobile phones and for dental technicians handling dental amalgams.

Within the Cancer Project of the Disease Reduction Programme beryllium has been included on a priority list of substances for which investigation of the UK exposed populations and profiles of exposure may be examined.

Should beryllium be an issue to be pursued on a broader basis ?

This might include consideration of whether the UK WEL value is appropriate and whether reliance on the reported incidence of CBD in the UK is a sufficiently robust means to monitor beryllium related disease (particularly considering the inconsistencies in occupational disease reporting schemes and the insidious onset of this condition with potential for confusion with other more common respiratory diseases).

Topic No. 8

Solvents Directive

(Rob Turner)

The introduction of the Solvents Directive, aimed at controlling volatile organic compounds (VOCs), may lead to less commonly used solvents, including those with the potential to cause significant harm to people (eg inorganic solvents such as those based on fluoroborates), being more widely used. Do the implications of their use bring increased potential health risks and is there the need for appropriate control measures to be explored, clarified and communicated ?

The Directive is also likely to lead to alternative technologies. Might these give rise to new issues and areas of concern that need to be evaluated ?.

Will new assessment methodologies be needed and good practice controls identified?

If so what are the highest priority areas that need to be investigated ?

For example automotive paints :

The Directive is likely to restrict the use of solvent based (cellulose) paints and the probable alternatives giving adequate performance and finish are based on isocyanate technology (~ 40% solvent) or UV – curable technology (no solvent). Isocyanates give rise to a risk of asthma and dermatitis if exposures are not well controlled; UV-curable materials are currently based on complete polyfunctional acrylates that can cause severe dermatitis.

Exposure evaluation and good practice control for isocyanates has been looked at but is there a need to investigate the development of suitable methodologies for assessing exposure (all routes), risk and good practice control for acrylates (possibly based on the functional group rather than any individual substance)?

Topic No. 9

Effectiveness of Control

(Rob Turner)

With the emphasis on good practice controls in the WEL framework verification of the effectiveness of control will be important not only for good control but also for the credibility of the WEL systems.

Is there a need to review generic control arrangements to assess relative effectiveness and weak points leading to control failure?

Topic No. 10

Risk Assessment under REACH

(Steve Bailey)

The EU REACH Regulation will have significant effects on the way that exposure to chemicals in the workplace is assessed, managed and controlled. In particular, manufacturers will acquire new responsibilities to conduct risk assessments for downstream users, with the introduction of Chemical Safety Reports as a new vehicle for communication.

Detailed requirements for the conduct of risk assessments and the determination of Derived No-Effect Levels (DNELs) will differ from the Margin of Safety (MOS) approach currently used in UK and EU (see background information below). The use and adequacy of uncertainty factors within the MOS approach has been contentious over the preceding years and will no doubt be subject to further controversy if/when the DNEL approach is adopted. There are also likely to be consequences for uncertainty factors used in limit-setting processes within the EU.

Which body in UK is considering such matters, and how ?

Background Information :

Text taken from Discussion document on: DNEL, Prepared by the (RIP-3.2) Consortium for discussion at 2nd Stakeholder Experts Group meeting on REACH implementation

Under REACH manufacturers, importers and downstream users should demonstrate that the manufacture/import/use of a substance does not adversely affect human health and that risks are adequately controlled. In other words, they have to demonstrate that the identified exposures for that substance are below a certain 'safe, health-based exposure level'. Under REACH this level has been defined as DNEL, in analogy to the PNEC used in environmental risk characterisation. From Annex I it appears that, based on an integration of all available and relevant human health hazard data, the DNEL is a sort of 'overall' NO(A)EL (or LO(A)EL, etc.) for a given exposure pattern (route, duration, frequency) corrected for uncertainties/variability in these data. The exposure/DNEL comparison in principle presents a simple tool for risk assessment, especially for downstream users who do not have the hazard data at their disposal. Moreover, once established, the DNEL is 'ready-to-use', like the AOEL (Acceptable Operator Exposure Level) used in the risk assessment of pesticides and biocides or the TDI/ADI (Tolerable or Acceptable Daily Intake) and ARfD (acute reference dose) used in the risk assessment of food additives and contaminants. It is, however, unlike the MOS (Margin of Safety) used currently in the risk assessment of new and existing chemicals, where a NO(A)EL/exposure comparison needs to be followed by an interpretation of the magnitude of the MOS by taking into account uncertainties/variability in the hazard and exposure data.

Topic No. 11

Intelligence gathering

(Rob Turner)

A key to proactive action to anticipate risks and in priority setting for focussing resource on key areas and actions is the collection and analysis of sufficient relevant intelligence on substances, uses, exposures etc.

How best might appropriate intelligence of sufficient quality be collected, collated and analysed ?

Topic No. 12

Exposure Data

(Steve Bailey)

The quality of occupational exposure data is a perennial issue, affecting the interpretation of epidemiological studies, limit setting process, assessment of priorities for control and choice of risk management measures.

Is there the need for a body to proactively initiate an improvement in the quality of such data ?

**List of potential new and emerging issues identified in 2006,
with named proponent and his/her proposition, where available**

Topic No. 13

Limit setting for genotoxic and non-genotoxic carcinogens

(Len Levy)

DG Employment is apparently intending to address this issue in October (postponed from earlier) but it may be useful to have a UK position on the guiding principles.

It is noted that in the UK we have WELs for many carcinogens. Also, the REACH proposals for downstream users will include the need for a risk assessment for such substances.

Topic No. 14

Nuisance Dusts

(Tony Fletcher)

There is ongoing concern about dust exposure and COPD, in particular the role of so-called nuisance dust. It may be this is already in hand in DRP for respiratory disease, if not we should consider whether it should be looked at carefully. Specifically:

- a) what is the evidence for the association between general dust (ie not silica/asbestos/etc) and COPD?
- b) how adequate is the "nuisance dust" standard (10/4 ug/m³) ?
- c) some people consider "nuisance" an inappropriate label - can we find a better name?
- d) what is the adequacy of existing control guidance for nuisance dust?
- e) to set this in context, what is the state of play of the COPD DRP?

Topic No. 15

Role of WATCH in REACH

(Tony Fletcher)

Assuming that HSE will have a regulatory role within REACH, what might the role of WATCH be, for example in relation to assessing the quality of manufacturer/supplier generated recommended exposure limits?

Topic No. 16

Lead

(Dil Sen, HSE)

Lead and its compounds are used in a variety of industries: mining, smelting, alloying & casting; lead-acid battery manufacture & recycling; leaded-glass manufacture; manufacture of pigments & colours; repairing & breaking of ships; demolition industry; some painting/refurbishment of buildings and other structures; scrap industry; vehicle radiator repair; antique restoration (stripped pine) and many more. Organic lead (tetraethyl & tetramethyl) is used as antiknock agents in petrol though since the introduction of unleaded petrol the use of such lead-based compounds has fallen. Significant exposure to lead in the workplace is therefore not uncommon even today.

The Control of Lead at Work (CLAW) Regulations 2002 protects the health of people at work by preventing or, where this is not reasonably practicable, adequately controlling their exposure to lead. Statutory medical surveillance (to include biological and bio-effect monitoring) is required when exposure is deemed to be 'significant'.

All employees who are liable to be exposed to lead at work are subject to a suspension level. This is the blood-lead concentration (or urinary lead in the case of lead alkyls) at which the doctor decides whether to certify that the employee should no longer be exposed to lead. The suspension level for different groups is as set out below:

- women of reproductive capacity – 30ug/dl
- young persons (16 and 17yrs) – 50ug/dl
- any other employee – 60ug/dl

At its last revision (early 2000), it was agreed that the Regulations would be reviewed along with the levels, as above.

At a recent meeting with Dr David Gidlow (who is an Appointed Doctor under CLAW, an authority on lead and human health effects, and medical adviser to the Lead Development Association (industry body) he raised the following three issues:

- a) when are we going to review CLAW and in particular the various 'levels' within the Regulations?
- b) most industries in the West have voluntary standards for suspension, often at/around the 40 mark. Indeed France and Germany have reviewed their legislation recently and set suspension limit of 40
- c) recent judgement in the Civil Courts went against Britannia Lead in a case of infertility in a male employee with a blood lead of 47ug/dl, the Judge making specific mention of the validity or otherwise of the current suspension level.

Should we now be reviewing CLAW, as previously agreed?

Are the suspension levels evidence-based? (Industry believes it can achieve a suspension level of 40ug/dl.)

Topic No. 17
Asbestos
(Steve Bailey)

Given recent WATCH discussions on asbestos, it is considered important that WATCH revisits the question of low-level asbestos exposures (below current limits) that may be associated with disease.

Topic No.18
Acetonitrile
(Robin Chapman)

The current consultation on implementation of the second list of IOELVs in UK includes a recommendation derived from SCOEL that acetonitrile should be assigned a "SK" notation. There is a belief that this assignment was based on an assumption that acetonitrile would act like other nitriles and other organic solvents and be readily permeated through human skin, although it is not clear if there is any evidence to support this assumption. However, recent laboratory work commissioned by industry has shown that acetonitrile does not pass readily through human skin.

This topic is an example of significant new information coming available in the time between the SCOEL review and the implementation in Member States.

Topic No.19
Risks from asbestos in soil
(George Kowalczyk, COPI, HPA)

Assessing environmental public health risks from asbestos in contaminated land is proving difficult as it is not easy to predict air levels from soil concentrations. Environment Agency is working on the issues and HSL may also be involved; guidance is being produced. In the meantime local HPA advice, mainly to local authorities and developers has to be precautionary; invoking alarp etc.

Recently it has come to HPA's attention that LA EHOs are circulating a paper by Hoskins and Lange (not published or peer reviewed; was produced for "asbestos watchdog") which calls for a re-evaluation of chrysotile risk and suggesting that a threshold approach might be appropriate for risk assessing this form of asbestos. They are also asking local HPA units for an opinion on the paper.

Although the paper is not published, an earlier similar paper by Bernstein and Hoskins¹ has been published. Might WATCH be able to provide advice to HPA advise on the content of the papers ?

1. Bernstein,D.M. and Hoskins, J.A. The health effects of chrysotile: current perspective based on recent data. Regulatory Toxicology and Pharmacology, 45 (2006), 252-264

Topic No. 20

The development of nettle fibre crop production in the UK:
potential health implications for workers – an emerging issue?
(Mark Woods, HSE)

The use of the common stinging nettle (*Urtica dioica*) for its fibre has an historical basis. Applications for nettle fibre may include cloth, rope and paper. The final fine processed fibre suitable for spinning is known as 'Ramie' and has properties similar to silk. It has been used for a considerable time, more recently in exclusive fashion houses. Other applications for the nettle include culinary use as a green vegetable when very young and production of protein. It may also have medicinal properties.

Currently, DEFRA is involved in a collaborative research project - 'Sustainable Technology in Nettle Growing'¹. It will consider several aspects: *U. dioica* physiology; physical and chemical characterisation, mechanical properties; fibre extraction techniques; potential for UK production of *U. dioica* as a sustainable supply of fibre; economic and environmental impacts. The brief description of the DEFRA project makes no reference to potential health effects for those handling the crop. The stinging nettle is widespread in the British Isles and skin exposure to the plant is a frequent cause of contact urticaria².

There are two types of hairs on nettle plants – stinging hairs (trichomes) which can be 1.5 mm or more in length and shorter, finer hairs. Both types contain silica, the stinging hairs possessing a silica rich spine. A recent paper has raised the question of whether these hairs could detach during harvesting or processing and present an inhalation hazard to workers³. The authors reported that Chinese Hamster Ovary cells showed a similar response to nettle hairs and blue asbestos fibres in culture – they aggregated around the hairs and fibres and some cells grew along them to become spindle shaped. The paper concluded that if stinging nettles are to be produced on a commercial scale, an assessment of the health risks should be conducted.

1. DEFRA. Sustainable Technology in Nettle Growing – STING (LK0820)
http://www2.defra.gov.uk/research/Project_Data/More.asp?I=LK0820&M=CFO&V=CSL.

2. Oliver F, Amon EU, et al. Contact urticaria due to the common stinging nettle (*Urtica dioica*) – histological, ultrastructural and pharmacological studies. *Clinical and Experimental Dermatology* 1991;16(1):1-7.

3. Whitney PJ, Gibbs G. The common stinging nettle: resource or risk? *Biologist* 2006;53(4):178-182.

Topic No.21

Occupational exposure standards, limits or guidance for respiratory exposure to metalworking fluids?

(Mike Burd,HSL)

Recently (2004-2006) 3 outbreaks of respiratory disease linked to metalworking fluids in more than 100 workers have so far been diagnosed with respiratory disease. In these workers about 85 cases are of occupational asthma, 26 of extrinsic allergic alveolitis and 7 of humidifier fever have been diagnosed.

The investigations have not yet identified the precise causative agent or agents, but links to used metalworking fluids containing bacteria and fragments of bacteria have been established. Many chemical constituents of metalworking fluids are themselves hazardous and can present a risk to health if inhaled in sufficient quantities, although generally these levels may be too low to cause adverse health effects.

Levels of metalworking fluid in the air were monitored during 2 of the outbreaks and were found to be below the guidance values of $1\text{mg}/\text{m}^3$ for metalworking fluid concentrate in air and $3\text{mg}/\text{m}^3$ for mineral oil in air, introduced in new HSE guidance (HSG 231) in October 2002.

That guidance has now been withdrawn, along with the guidance values, and been replaced by new web-based "Metalworking Fluids Topic Pages" on the HSE Web Site. The new guidance requires exposure to mist from metalworking fluids to be "prevented or controlled", but does not give any guidance on levels of exposure.

The absence of a guidance value or a workplace exposure limit poses practical difficulties for both industry and Inspectors as zero exposure is either impossible to achieve or cripplingly expensive for most companies involved. About 50,000 workers may be exposed to metalworking fluids and minimising the risks of respiratory disease is an important part of HSE's Disease Reduction Programme as part of the Fit3 strategy.

How might practical guidance on levels of exposure be arrived at? What should this guidance recommend? Is there a need to review the application of MDHS 95 relating to the measurement of exposure to metalworking fluids?