FORMALDEHYDE

22. Previous drafts of the 3rd IOELV (Indicative Occupational Exposure Limit Value) Directive contained a proposed IOELV for formaldehyde, set at 0.2 ppm (8-hour TWA) and 0.4 ppm (STEL). This entry was removed from the Annex in mid-2009 following doubts being expressed about the scientific validity of the value determined by SCOEL, and about the difficulties of compliance by certain industry sectors. There is an on-going industry-sponsored scientific study on formaldehyde, the results of which are due to be published in 2010. The European Commission has therefore decided to await the results of this study, and its evaluation by SCOEL, before progressing with an IOELV for the substance.

23. The existing UK WEL for formaldehyde is 2 ppm (2.5 $mg.m^{-3}$) for both the 8-hour TWA limit and the STEL, a limit that has remained unchanged for over 20 years. In the 2003 Supplement to EH40/2002, HSE recognised that the then Maximum Exposure Limit (MEL) for formaldehyde was one of 15 MELs where the numerical value could be reduced. The Advisory Committee on Toxic Substances (ACTS) had concluded that, with improvements in control technology, it should be reasonably practicable to control exposure to these substances to a lower value than the MEL. It was determined that the limits for all these substances would be reviewed over time.

24. HSE proposes that, as part of its overall review of the former MELs, and in view of the fact that there will eventually be an EU-wide limit for formaldehyde, that the current WEL be reduced, on a short-term basis, from 2 ppm (2.5 $mg.m^{-3}$) to 1 ppm (1.25 $mg.m^{-3}$). A further reduction may prove necessary in the future. HSE believes that workplace exposures to formaldehyde can be reduced to this level without excessive additional cost. The position is considered in greater detail in the Supplement to the Impact Assessment at Appendix 2.

Question 21: Do you agree that the WEL (8-hour TWA) for formaldehyde should be reduced from 2 ppm (2.5 $mg.m^{-3}$) to 1 ppm (1.25 $mg.m^{-3}$) ? If you disagree, please explain why.

Question 22: Do you agree that the STEL for formaldehyde should be reduced from 2 ppm (2.5 $mg.m^{-3}$) to 1 ppm (1.25 $mg.m^{-3}$) ? If you disagree, please explain why.

IMPACT ASSESSMENT

25. Before introducing any new piece of legislation, the HSE carries out an assessment of the costs this legislation would impose on industry and other stakeholders, and of the benefits it is expected to bring. This assessment is contained in the Impact Assessment. An Impact Assessment is not carried out, however, when the legislation does not impose additional costs to industry.

26. In relation to the IOELV proposals for the substances set out in this Consultative Document, HSE has examined what costs and benefits would result from their implementation, as proposed, into the national limit-setting system. This Impact Assessment is at Appendix 2. HSE estimates that, for most of the substances, no additional costs will arise, and that implementation of the Directive will not have adverse effects on British industry. A Supplement to the Impact Assessment considers the separate issue of a reduced limit for formaldehyde.

IMPLEMENTATION DATE

27. The HSE proposes to apply the new limits on [1 October 2011], the common commencement date prior to the final date for implementation required by the Directive.

INVITATION TO COMMENT

28. The HSE invites comments on these proposals. For your convenience, a response form is included at Appendix 4, which contains all the questions on pages x to y, and you may find it helpful to use this for your reply. We are happy, nevertheless, to receive your written comments in any form convenient to you. We will acknowledge receipt of all comments sent to us and will give them careful consideration. The HSE would also like to know what you think about this consultation, both in terms of content and layout. You views will help us to improve future consultations.

29. Please send your comments by [date/month/ 2010] to Richard Pedersen whose contact details are below.

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- Embalming - The aim of the embalming process is to disinfect, restore and cosmetise as necessary and to preserve - the latter so as to present the body in an acceptable state for viewing by the family.

Embalming fluid is injected into an artery of the body and excess blood drained via a vein or directly by a trocar into the heart. The embalming fluid contains a small proportion of formaldehyde along with other constituents such as glycerol, methanol and emollients, and a dye as a colourant.

Bodies are stored in fridges and brought into the mortuary room for preparation. The room visited by HSE hygienists had wall extraction, and embalming took place on a stainless steel table with a drainage point.

The embalming fluid is made up by dilution from concentrate in situ, and the fluid is pumped via cannula into a convenient artery such as the brachial, femoral, or carotid. Exposure to formaldehyde at this stage is short-lived. The content of the embalming fluid depends on the proposed time for storage. Routine embalming fluid consists of between 1 and 5 % formaldehyde, although between 1 and 2% is most common.

In the simplest case, once embalming fluid has been satisfactorily injected, drainage begins via either a vein or the heart back into a waiting drainage jar containing disinfectant. Now, the body needs to be emptied of any excess residual body fluids present in cavities. Once aspirated (into a lidded, disinfectant - containing jar), the body cavity is treated with cavity fluid; this fluid does not have to contain formaldehyde although the majority still do. At the end of the procedure, the jars are emptied into the drainage sluice and then washed but formaldehyde exposure here is likely to be low.

Complications can always arise in routine cases, and where the body has been post-mortemed, there will always be extra problems in reducing exposure. During post-mortems (which are never performed by the embalmer), the internal organs (and this often includes the brain) are completely removed and may be replaced in a plastic bag back into the abdomen before the body is re-sutured. The embalmer has to remove the bag and add an appropriate quantity of cavity fluid. The body to be embalmed is open to the atmosphere and embalming fluid has no obvious containment. The carotid, or a nearby artery is used to inject the face and scalp with embalming fluid, but if the brain is missing and the top of the skull removed the vessel needs to be clamped to prevent excess fluid leaking onto the table. Constant sluicing down with cold water may help to reduce exposure. There is a similar problem when the body and limbs are perfused, as any leaking fluid will form a puddle in the body cavity. Packing is used to bulk out the body before re-suturing and sealing powder is added to dry up any potential leakage.

No formaldehyde measurements were taken on the visit undertaken by the HSE hygienist but there was no obvious smell of formaldehyde. However, the operator was skilled and experienced and this may have reduced exposure.

In conversation afterwards, there was some doubt expressed about the effectiveness of tables with extraction slots. Often, the embalmer has to lean close into the body to find a convenient artery in which to insert the fluid line. This is likely to cause turbulence and, in the case of post-mortem bodies, the empty body cavity can act as a receptacle for the embalming fluid, unless it is rapidly aspirated away.

The use of non-formaldehyde alternatives such as Aardbalm was discussed. Although possibly suitable for short-term preservation, there are serious reservations about its use for long-term storage.

In Great Britain, the embalming industry in dominated by two major companies who handle about 50% of the bodies that are embalmed. The other 50% are handled by small businesses who tend to have fewer overheads but may also have less routine access to control measures.

A COSHH Essentials guidance sheet (SR 10) is available on the COSHH Essentials website (www.coshh-essentials.org.uk). These UK recommendations include a well-ventilated room and the use of a table fitted with extraction slots running along the long side of the table. The American National Funeral Directors Association (NFDA) have produced Best Management Practice Sheets for formaldehyde which propose room ventilation of between 10 and 20 air changes an hour in the preparation room, continuing negative pressure, and handling precautions similar to the UK guidance.

HSE has little recent data on formaldehyde exposure during embalming; the two recent (post 2002) formaldehyde exposure values available from embalming being 0.39 and 0.5 ppm.

Despite this lack of exposure data, HSE believes that the major companies already use good control practice and should face no increased costs in complying with the new proposed limit. The smaller companies are active across the length and breadth of the country and provide a service even in the more remote regions. It is difficult to assess the extent of compliance with industry guidance, but if it is being followed, there should be no increased costs to comply with the new proposed limit.

A related sector involves the use of cadavers for medical teaching. The regional centre visited by HSE was opened with the intention of providing facilities for the training of registrars and senior registrars in orthopaedics, but the services offered have increased since then. First and second year nursing trainees on placements, FRCS (orthopaedics) and ENT trainees are now taught surgical anatomy there.

Bodies are provided from various sources already embalmed, and they are pre-dissected for the trainees. Since the introduction of the Human Tissue Act (HTA) in 2004, the supply of cadavers has declined, but the range of use allowed is now wider. For instance, research prostheses can now be tested on cadavers by surgeons. HTA Inspectors check on the storage records and ensure compliance with the Act by ensuring that Standard Operating Procedures are observed, and that associated paperwork such as policies, risk assessments, COSHH assessments, records of human material held, records of material transfers and service contracts are up to date. In addition, they assess the competence of the Licence Holder, the Designated Individual (DI) and the Person Designated (PD).

There is no time limit on the use of the bodies but the this centre works on an assumed storage of three years – thus the embalming fluid needs to be strong enough to cope with this (a formaldehyde concentration of around 2% is used). Formaldehyde replacements have not yet been shown to be suitable this length of storage.

The Centre also hosts a museum of orthopaedic conditions and this collection is steadily increasing; many are rare and some are irreplaceable. They are stored in formaldehyde solutions of about the same concentration as embalming fluid (1-5%).

The cadavers, covered in sealed plastic sheets are stored in refrigerators until needed. Once unwrapped, they are taken into the dissection room, dissected to show the nerves, muscles or bones and then sprayed with a wetting agent (glycerine, water and alcohol). The room has air conditioning with fans in the roof and extraction at floor level (between 8 and 12 air changes an hour), and there is a maximum of four tables available.

Previous static sampling suggests that formaldehyde concentrations are usually maintained below 0.5 ppm. There may be some short-term peak exposures when the cadaver is initially opened but these should quickly reduce.

The centre visited by HSE is a relatively modern facility and should be able to comply with a formaldehyde WEL set at 1 ppm. However, European moves to establish an Indicative Occupational Exposure Limit Value (IOELV) much lower than this may cause this sector and the embalming sector severe problems in the future.