

Meeting date: 14th February 2008**Open Govt. Status:** Fully Open**Type of paper:** For debate**Paper File Ref:****Exemptions:**

WATCH COMMITTEE

Proposal for a BMGV for chlorobenzene

Issue

1. Establishment of a biological monitoring guidance value (BMGV) for chlorobenzene based on the measurement of 4-chlorocatechol in urine.

Timing

2. No particular timing issues. The draft EH64 summary is being updated to reflect the inclusion of chlorobenzene in the 2nd IOELV Directive and HSE is taking this opportunity to reconsider setting a BMGV for this substance.

Recommendation

3. WATCH is invited to consider the issues noted in this cover paper and to respond to the actions in paragraph 14.

Background

4. Chlorobenzene is one of the substances for which an EU Indicative Occupational Exposure Limit Value (IOELV) has been established. It was considered by WATCH at its meeting of 12/13 January 2000 because the IOELVs for chlorobenzene that were being proposed in the 1st IOELV Directive (10 ppm 8-hr TWA and 20 ppm STEL) were considerably below the UK occupational exposure limits at that time. At the meeting, WATCH concluded that it was not possible to recommend a health-based limit (an Occupational Exposure Standard, OES) because of uncertainties in the toxicological profile. Following subsequent consideration by ACTS, Maximum Exposure Limits (MELs) of 1 ppm (8-hr TWA) and 3 ppm (STEL) were set in 2002. These became Workplace Exposure Limits (WELs) on introduction of the WEL system in 2005. The IOELVs for chlorobenzene have subsequently been reduced to 5 ppm (8-hr TWA) and 15 ppm (STEL) in the 2nd IOELV directive (2006/15/EC). There has been no biological monitoring value proposed at the EU level.

5. The documentation for the January 2000 WATCH meeting also included a consideration of whether or not a BMGV should be established. Although a BMGV was considered worthwhile, the data that were available were not sufficient to set either a health guidance value or a benchmark value. The toxicological data did not allow the criteria for a health guidance value to be met; and there were no data to link biological levels with the use of good occupational hygiene practices such that the criteria for a benchmark value could not be met. WATCH was therefore able only to endorse the relationship between biological monitoring values and airborne concentrations of chlorobenzene. HSE indicated that if in the future there was scope within the BMGV setting framework to establish a BMGV for chlorobenzene, a formal proposal would be brought to WATCH.

6. The agreement by WATCH (following discussion at the WATCH meetings in January 2001 and May 2002, see WATCH/12/2001 and WATCH/13/2002) to adopt a more flexible approach to the establishment of BMGVs and the introduction in 2005 of the WELs system (replacing the former OES/MEL system of occupational exposure limits) has opened up the possibility to set a BMGV at a level that equates to an 8-hr exposure at the WEL. HSE is therefore proposing to use the relationship between urinary 4-chlorocatechol and airborne chlorobenzene that was endorsed by WATCH in January 2000 to establish a BMGV for chlorobenzene that equates to an 8-hr exposure at the WEL.

Argument

7. Chlorobenzene is predicted to be well absorbed across the skin and carries a skin notation. The toxicology assessment prepared by HSE for the WATCH meeting in January 2000 identified the liver and bone marrow as key target organs for chlorobenzene in experimental animals. From the information available it was not possible to determine the relevance of these findings to humans or to identify a clear NOAEL from the animal data. There was also uncertainty regarding its genotoxic potential based on positive *in vitro* findings and inadequate *in vivo* data.

8. HSE has no recent data on occupational exposures to chlorobenzene. An exposure assessment carried out to support the limit-setting activities in 2000 (see brief details in Annex 2) indicated that chlorobenzene is not manufactured in the UK. The majority of chlorobenzene imported into the UK is used as a process solvent and chemical intermediate in the manufacture of pharmaceuticals and agrochemicals. Exposure is also possible during repackaging and from its use as a laboratory reagent.

9. HSE's justification for considering biological monitoring in 2000 was a potential for occasional situations in which control of exposure relied upon RPE. There is also the possibility for dermal exposure in situations where operators come into contact with surfaces contaminated from splashing or condensing vapour, or as a result of direct contact with the skin. In such situations, biological monitoring may be a useful aid to the assessment of occupational exposure.

10. Annex 1 to this paper summarises the available data and line of argument in support of a BMGV proposal. Published literature shows that there is a good correlation between the levels of the metabolite 4-chlorocatechol in end-of-shift urine and airborne exposure. Based on the relationship between airborne exposure and urinary metabolite levels endorsed by WATCH in January 2000, HSE is now proposing that WATCH should establish a BMGV for chlorobenzene of 5 mmol 4-chlorocatechol per mol creatinine in end of shift urine, which equates to an airborne exposure to 1 ppm for 8 hrs. Annex 1 explains in more detail the justification for this position.

Link to HSC Strategy

11. This work is connected to HSE's statutory responsibilities in responding to EU Chemical Agents Directive and IOELV Directive developments; and maintaining and further developing the UK WEL and BMGV system.

Consultation

12. No wider consultation on these proposals beyond HSE has been undertaken at this stage.

European (EU) Context

13. There are no EU implications for establishing this BMGV, although the European Commission (DG Employment) would be advised of the new UK BMGV.

Action

14. WATCH is invited:

- i. To agree that it is now appropriate to establish a BMGV for chlorobenzene.
- ii. To agree a biological monitoring guidance value (BMGV) of 5 mmol 4-chlorocatechol.mol⁻¹ creatinine in end-of-shift urine, to correspond with the 1ppm (8-hr TWA) WEL value.

Contact:

Nicola Gregg
WATCH Secretariat

References / Attachments

Annex 1 Overview of biological monitoring data available for chlorobenzene.
Annex 2 Draft EH64 summary.