
Background

1. The Carcinogens Directive (90/394/EEC) was one of the so-called "Six-Pack" of Directives made under the terms of the overarching Directive 89/391/EEC "on the introduction of measures to encourage improvements in the health and safety of workers". It has been amended twice; once to include the words "and mutagens" and once to revise the binding limit for benzene. It was then consolidated in 2004 to give the Carcinogens and Mutagens Directive (CMD) 2004/37/EC.

2. The original directive was introduced at a time when it was generally considered by the scientific community that 'no-effect threshold levels' could not be reliably established for carcinogens or mutagens. The control regime presented in CMD is, therefore, based on the principles of occupational exposure occurring only when there is no alternative substance/system available and with the greatest possible reduction in exposure. The binding limits in Annex III of CMD (for benzene, vinyl chloride monomer and hardwood dust) sit alongside the binding limit values in Annex I of the Chemical Agents Directive (CAD) (inorganic lead and its compounds).


“...The Commission, with the assistance of the Advisory Committee, will produce reports on the practical application of the various “health and safety” directives, with a view to identifying any practical problems and improving certain of the provisions to make them more readily comprehensible, more consistent, and to fill the gaps in the existing framework. It will also propose extending the scope of the “carcinogenic agents” directive.”

4. The first stage of Social Partner consultation occurred in 2004 and the second stage in spring 2007. The main proposals as set out in the second stage of Social Partner consultation are:
The scope of the Directive to be extended to cover substances classified as Category One and Category Two Toxic to Reproduction (categories 1A and 1B under the Globally Harmonised System now adopted in Europe by the EU Classification, Labelling and Packaging Regulation, 1272/2008);

The exposure limits for the three substances listed in Annex III of the Directive to be reviewed (para 2 above); and

Additional exposure limits for carcinogenic, mutagenic and toxic to reproduction substances to be placed in Annex III.

5. Thereafter the European Commission put to tender the ‘SHEcan project’\(^1\) - a collaborative research study undertaken by consultants to investigate the potential socioeconomic, health and environmental impact of amendments to the Carcinogens and Mutagens Directive. A synopsis of the work streams and potential chemical carcinogens for inclusion in a revised directive are presented in Annexes 1 and 2 of this paper respectively [see http://www.hse.gov.uk/aboutus/meetings/iacs/acts/240511/acts12011.pdf]. The first reports and Impact Assessments (IAs) from this project were made available in March 2011, with further reports anticipated through 2011.

6. In addition, a separate research study is being undertaken to investigate the potential socioeconomic, health and environmental impact of the possible inclusion of category 1 and 2 reproductive toxins within the scope of a revised directive. This work is due to produce a final report in February 2012.

Action:

7. HSE invites the members of ACTS and WATCH to provide views on the work-streams presented within the SHEcan project and on the IAs for individual candidate chemicals.

8. These views will help to HSE to develop an approach to influence the European Commission’s thinking before a formal text for a revised directive is proposed. At this stage this will be done primarily via the Working Party on Chemicals (WPC), a sub-group of the Advisory Committee on Safety and Health.

9. This group of papers is the second batch of substances for consideration at the Working Party on Chemicals meeting planned for March 2012. HSE are interested in all your thoughts and views but request your particular reflection on:

   a. In terms of the IAs:
      i) Are all relevant papers and information considered?

\(^1\) http://www.occupationalcancer.eu/Home/tabid/56/Default.aspx
ii) Do you agree with the conclusions drawn?

iii) Do you have a view on the impact on the UK of the proposals/conclusions?

**Planned WATCH process**

For each of the 7 substances to be considered at WATCH, up to three documents will be provided to members – with most of the material – (i) and (ii) below - having already been sent out in January. (Additional copies provided with papers for February WATCH meeting for members’ convenience).

Papers provided in each case are:

(i) The most up-to-date SCOEL/SUM we have, if a SCOEL/SUM exists

(ii) The impact assessment produced by IOM under the “SHEcan project”.

(iii) Brief information relating to consideration of the substance by WATCH, including the time of and context for that consideration.

**A tabulated summary of conclusions is at table 1 of this document.**

Following an introduction from HSE, it is suggested that WATCH take each substance by turn, with an invitation to the SCOEL members on WATCH to add their general perspective on the SCOEL work on these substances. The Chairman will summarise WATCH conclusions at the end of the discussions.
Table 1:
Summary table of MEL/WEL

<table>
<thead>
<tr>
<th>Substance</th>
<th>SCOEL/SUM</th>
<th>IOM SHEcan</th>
<th>Previous WATCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-bromoethane</td>
<td>Repro effects in workers at 45 ppb (0.045 ppm). Carcinogenicity is already clear-cut at airborne concentrations of 10 ppm. No limits assigned – instead conclude to be a genotoxic carcinogen with no threshold. Any exposure to this compound should be avoided</td>
<td>There are no predicted health benefits from setting an OEL, although we believe the impact of setting a limit at 0.1 ppm would be relatively small because of the relatively low current exposures and the small number of people likely to be exposed above the proposed OEL. The cost of compliance with a limit of 0.1 ppm, aggregated over the period 2010 to 2069, is judged to be between €0.086m and €0.29m. There are also no social or macro-economic costs associated with introducing an OEL.</td>
<td>No previous WATCH consideration. <strong>Current UK OEL (long term)</strong> 0.5ppm 3.9mg/m³</td>
</tr>
</tbody>
</table>
| o-toluidine     | Not examined by SCOEL                                                     | An OEL of 1 ppm could be achieved with no cost implications and introducing a limit of 0.1 ppm would incur limited costs (between €0.03m and €0.09m). However, neither limit is predicted to give rise to | **MEL** 0.2ppm (0.89 mg.m⁻³) 8 hour TWA  
**Notation:** skin                                      |

Notation: skin
any important reduction in bladder cancer deaths or registrations over the baseline assumptions, primarily because exposures are already very low.

**Epichlorohydrin**

- **Sept 2011**
  - Data are not sufficient to derive a conclusive evaluation of the carcinogenicity for humans, nor can a safe concentration be specified for humans at present.

  On the basis of the data on the genotoxicity of epichlorohydrin *in vivo*, particularly cytogenetic findings and findings on the development of epichlorohydrin-specific DNA adducts among persons exposed to epichlorohydrin, epichlorohydrin has been classified in germ cell mutagen.

  Accordingly, the derivation of a health-based OEL is not possible.

- **Current exposures in the EU**
  - Exposures are judged to be well below 1.9 mg/m$^3$ and so there are no predicted health benefits and no important costs associated with compliance with the suggested OEL. There are also no social or macro-economic costs associated with introducing an OEL at either (*sic*) of these levels.

- **MEL**
  - 0.5ppm (2mg.m$^{-3}$) 8 hour TWA
  - 1.5ppm (6mg.m$^{-3}$) 15 min ref period
The Dutch Expert Committee on Occupational Standards (DECOS) has applied a linear extrapolation from the experimental data as a default method and estimated the additional lifetime cancer risk for epichlorohydrin to be $4 \times 10^{-5}$ for 40 years of human occupational exposure to $0.19 \text{ mg/m}^3$, and accordingly $4 \times 10^{-3}$ for 40 years of occupational exposure to $19 \text{ mg/m}^3$. SCOEL strongly recommends avoiding occupational exposure to epichlorohydrin.

| Respirable crystalline silica | The reduction of exposure to $0.05 \text{ mg/m}^3$ of crystalline silica is expected to reduce the prevalence of silicosis, ILO category 1/1, to about or less than 5% whereas an average respirable silica concentration of $0.02 \text{ mg/m}^3$ reduces prevalence of silicosis to about 0.25% or less. It arises that an OEL should lie | The introduction of an OEL of $0.05 \text{ mg/m}^3$ would lead to reductions in the number of predicted lung cancer deaths and registrations in 2060 to 337 and 345 respectively. The introduction of an OEL of $0.1 \text{ mg/m}^3$ would lead to reductions in the number of predicted lung cancer deaths | Hazard assessment documents |
below 0.05 mg/m$^3$ of respirable silica dust.

and registrations in 2060 to 818 and 838 respectively.

The introduction of an OEL of 0.2 mg/m$^3$ would lead to reductions in the number of predicted lung cancer deaths and registrations in 2060 to 1,721 and 1,763 respectively.

The number of “avoided” cancers associated with the introduction of an OEL of 0.05, 0.1 or 0.2 mg/m$^3$ would be 5,479, 4,985 and 4,061 respectively.

The estimated costs of compliance are thought to be lower or within the range of the estimated benefits, indicating that the benefits of introducing an OEL may outweigh the costs of compliance.

The total costs of compliance over the period 2010-2069 with an OEL of 0.05mg/m$^3$ are estimated to be €34bn over the period 2010-2069.
The compliance costs for an OEL of 0.1 mg/m³ are estimated to be substantially lower at €19bn over the same period.

The estimated costs of compliance with an OEL of 0.2 mg/m³ are estimated to be €10bn.

The increased use of local exhaust ventilation (LEV), however, in order to achieve an OEL could lead to increased fossil fuel consumption and greenhouse emissions.

**Refractory ceramic fibres**

Note, in October 2010, SCOEL recommended a limit of 0.3 fibres/ml. (8 hour TWA)

Introducing a OEL of either 0.1 or 1 fibres/ml has no important effect on the predicted cancer deaths or registrations from RCF. For both potential OELs, the estimated DALYs decrease from 29 years in 2010 to zero years by 2060; with no Carc cat 2 (and poss more stringent MEL)
intervention there are two DALYs predicted in 2060.

EU-wide OEL of 1.0 fibres/ml could be met through greater uptake of currently applied techniques within the industry. The associated costs are likely to be relatively low. There is calculated to be a small health benefit associated with such an OEL, valued at up to €1-2 million in total over the period 2010-2069. The value is relatively low because of the low level of assumed cancer incidence under the baseline and the existing controls in place. It is not expected that there would be any important social, macro-economic or environmental impacts with an OEL at 1.0 fibres/ml.

0.1 fibres/ml, could have much more significant impacts upon the industry. To achieve exposure at this level would require a degree of automation and enclosure that is unlikely
to be feasible, especially for certain downstream users. The compliance costs associated with an OEL of 0.1 fibres/ml are estimated at:
- Around €60 to €140 million over the period 2010 to 2069 associated with controlling exposure.
- If achieving the OEL is technically or economically infeasible, companies may decide to substitute RCF with alternatives such as AES and PCW. The associated costs could be of the order of €2.5 billion over the same period.

OEL of 0.3 fibres/ml. This recommendation was issued after the OELs for analysis in the study (1.0 and 0.1 fibres/ml) were agreed, some indicative estimates have been derived for the costs of compliance, including: €6 to €20 million for an OEL at 0.2 fibres/ml and €4 to €17 million for an OEL at 0.3 fibres/ml. The latter OEL could be more
<table>
<thead>
<tr>
<th><strong>Acrylamide</strong></th>
<th>The uncertainties surrounding the risk of cancer and genotoxicity (in particular heritable mutations) in workers exposed to acrylamide suggest that a health-based OEL cannot be derived. Skin notation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>We judge that there are no expected additional health benefits from introducing an OEL of 0.03 mg/m$^3$ and only minimal economic costs given that the industry has generally already invested to control exposure in connection with the REACH Regulations.</td>
</tr>
<tr>
<td></td>
<td><strong>WEL</strong> 0.3mg.m$^{-3}$ 8 hour TWA <strong>Notation:</strong> carc, skin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hexavalent chromium</strong></th>
<th>The available evidence, albeit incomplete, strongly suggests that poorly soluble hexavalent compounds carry a lesser lung cancer risk although the size of such a reduction cannot be quantified. Thus, in establishing occupational exposure limits, a pragmatic approach may be appropriate. As an example, an exposure limit of 50µg/m$^3$ of hexavalent chromium may well provide adequate protection for workers exposed to poorly</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The introduction of an OEL of 0.025, 0.05 or 0.1 mg/m$^3$ would lead to reductions in the number of lung cancer registrations in 2060 of 80, 57 or 20 respectively and reductions in the number of sinonasal cancer registrations of 8, 6 and 2 respectively. The total net health benefits from setting an OEL at 0.1 mg/m$^3$ are estimated to be between €157m and €445m, benefits of between €339m and €966m associated with an</td>
</tr>
<tr>
<td></td>
<td><strong>WEL:</strong> 0.05mg.m$^{-3}$ 8 hour TWA <strong>Notation:</strong> Carc, sen <strong>Biol monitoring guidance value:</strong> 10µmol chromium/mol creatinine in post shift urine</td>
</tr>
</tbody>
</table>
soluble hexavalent chromium compounds but, on the basis of the risk assessments described in Appendix 1, consideration could be given to setting exposure limits at 25μg/m³ or 10μg/m³ for other hexavalent chromium compounds.

<table>
<thead>
<tr>
<th>OEL of 0.05 mg/m³ benefits of between €453m and €1,294m associated with an OEL of 0.025 mg/m³.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most EU countries already have an OEL in place for hexavalent chromium and we estimate that nearly 90% of exposed workers already have exposures that are below the most stringent proposed EU-wide OEL. It is estimated that the proportion of enterprises that will require additional control measure to meet the proposed OELs of 0.1, 0.05 and 0.025 mg/m³ is 9%, 16% and 27% respectively. Total compliance costs over the period 2010-2069 (Net Present Value) are estimated to be €7bn to €37bn, €18bn to €67bn and €30bn to €115bn respectively.</td>
</tr>
</tbody>
</table>