Opinions sought on EC documentation

Background:

1. The European Commission (DG Employment, Social Affairs and Equal Opportunities) is seeking to amend the Carcinogens and Mutagens Directive, which is implemented in the UK by COSHH/COSHH (NI).

Latest position:

2. Progress at EU level is slow with no formal proposal for revised text having been made yet. However, HSE understands that the Commission are now working towards publishing a formal proposal in June 2013. At this stage the likely content is still open but we understand the scope of the revision may now be limited to:
   a) Clarifying the key duties to prevent and control exposure, including making clear that there is a duty to minimise exposure below an exposure limit;
   b) Revised binding exposure limits for the three substances listed in Annex III of the Directive;
   c) Additional binding exposure limits for around 6 carcinogenic and mutagenic chemicals selected from a candidate list of 23; and
   d) Possible extension of scope to substances toxic to reproduction.

3. A more fundamental revision may follow at a later stage.

4. HSE will continue to engage UK stakeholders, including WATCH/ACTS, to gather data and collect views. The information will also inform the preparation of a UK impact assessment when the content of the Commission’s proposal is clearer. However, please note we are at an early stage of the process and it will be possible to input views and comments to HSE and the Commission as the process continues.
<table>
<thead>
<tr>
<th>Substance</th>
<th>SCOEL/SUM</th>
<th>IOM SHEcan</th>
<th>Previous WATCH/other</th>
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<tbody>
<tr>
<td>Diesel engine exhaust emissions (DEE)</td>
<td>No document available</td>
<td>IARC cat 2a (Lung and bladder cancers). Not classified under EU classification and labelling and therefore not currently included in scope of EU Carcinogens directive. A typical OEL of 100μg/m³ (measured as elemental carbon) is examined. Typical exposures already below this level (except in mining) so no predicted health benefits and no significant costs. This level likely to deliver benefit in the mining sector but not possible to quantify effect. To deliver effect on cancer incidence a lower level would be likely to be required with requirements for greater exposure controls to enable compliance.</td>
<td>Report on air pollution in airports published by the Danish ecocouncil (March 2012) recommends setting a limit value for ultrafine particles under HSW. This report also includes the EU limits for air pollution at table 2 and for vehicle emissions at table 3. No recent WATCH consideration</td>
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<tr>
<td>Benzo(a)pyrene</td>
<td>No document available</td>
<td>IARC cat 1; EU classification and labelling Cat 2 carcinogen.</td>
<td>See also references in the Report on air pollution in</td>
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| Mineral oil (used engine oils), MDA | No document available | Untreated or mildly treated mineral oils are IARC Cat 1. Used engine oils are not classified but there is evidence they can cause non-melanoma skin cancer probably due to PAH contamination. Not currently in the scope of the EU carcinogens directive. Suggested action: application of preventative work practices and PPE with appropriate health monitoring. Estimated cost over 60 years between €46-920million. Treatment is relatively straightforward and survival rates high so no specific calculation of benefits, but there are estimates annual incidence of up to 3554 cases | No document available | No recent WATCH document available |
| Vinyl chloride monomer | Carc cat 1; R45  
Continuous exposure for working life to 1ppm vinyl chloride associated with a cancer risk for hepatic angiosarcoma of about $0.3 \times 10^{-3}$ | IARC group 1; EU cat 1 carcinogen.  
Existing EU OEL is 3ppm.  
Considers impact of reducing to 2ppm or 1ppm.  
Current geomean exposure $0.14 \text{mg/m}^3 (0.05 \text{ppm})$.  
90th percentile below 2ppm in most plants but 90th percentile below 1ppm in about 25% plants.  
Countries recently joining EU would face most adaptation to comply with 1ppm.  
Costs of compliance with 2ppm over period 2010-69 €15-30m  
Costs of compliance with 1ppm (investments made sooner) over period 2010-69 €90-185m.  
OEL of 3ppm is associated with 3 years loss of life expectancy.  
OEL of 2ppm is 8 hour TWA 3ppm.  
Current exposures are within the annual limit.  
Critical effect is angiosarcoma with steep dose response and no identified threshold. |
| 1,3 Butadiene | IARC 2a  
Significant differences in toxicity between rats and mice.  
Genotoxic.  
Greater than 2-fold increase in Leukaemia mortality in long term workers in N America.  
Significant dose response to cumulative exposure after adjusting for styrene and dimethyldithiocarbamate exposure.  
Table with estimates of excess death and SMR for different levels of exposure | IARC 1  
EU Cat 1Carcinogen  
Consider an OEL of 0.5, 1 or 5ppm (TWA) and concludes introduction of an OEL at any of these levels will have little impact on risk of lymphohaematopoietic cancer.  
In 2010 estimated about 1 death in the EU that might be attributable to past exposure (0.0014% of all LH cancer deaths amongst exposed workers).  
By 2060 there is estimated to be 2 attributable deaths if no action taken.  
Estimated health costs €41-167m.  
Estimates assume steady reduction in exposures.  
But low exposed workers still have elevated relative risk of LH cancer of 1.05 | 8 hour TWA 10ppm (22mg.m$^{-3}$)  
Genotoxic in vitro in presence of metabolic activation, genotoxic in vivo in mice.  
Germ cell mutagen in mice but not rats.  
Potential human carcinogen (based on the N American epidemiology study). |
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<th>Description</th>
<th>IARC/EU Classification</th>
<th>Health Implications</th>
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| Bromoethylene (vinyl bromide) | Not feasible to set an OEL or STEL  
Non threshold carcinogen  
For quantitative risk assessment advises using the Vinyl chloride risk assessment for hepatic angiosarcoma risk (3x10^-4 for exposure to 1ppm for a working lifetime) but considering a 3-fold higher potency of vinyl bromide. Thus resulting angiosarcoma risk for working lifetime exposure to 1ppm vinyl bromide is estimated as 9x10^-4. | IARC cat 2a  
EU cat 2 carcinogen  
Assumes current highest exposures probably about 3mg/m^3.  
Relative risk estimated for high exposure as 2.86 and low exposure 1.89.  
No predicted health benefits from setting an OEL at 22mg/m^3, but impact small as current exposures estimated as much lower | No recent document available |
| 2-nitropropane         | No recent document available                                                 | IARC 2b  
EU Cat2 carcinogen  
Estimate exposure below 6mg/m^3 in manufacturing  
Data inadequate to complete a suitable risk estimate or health impact assessment, but assumed health impact is unlikely to be large.  
Assumed no additional costs of compliance with an OEL of 19mg/m^3 (5ppm). | 8 hour TWA 5ppm (19mg.m^-3).  
Carc  
Significant differences in spp sensitivity  
Positive DNA repair synthesis in rat in vitro and in vivo but other genotox generally negative  
Chronic exposure to 100ppm (0.013g/kg) for 18 months induced liver changes |
| 4,4-methylenedianilene (MDA) | No recent document available | IARC 2b  
EU cat 2 carcinogen  
REACH candidate substance of high concern  
By analogy with other aromatic amines, presumed it may cause bladder cancer.  
Considers possible OEL of 0.8mg/m³ (0.1ppm) or 0.08mg/m³ (0.01ppm).  
In 2010 exposure estimated at most 0.14mg/m³ in manufacture in chemical industry and 0.07mg/m³ in other sectors.  
Data inadequate for proper risk estimate or health impact assessment.  
Believed the impact would be 8 hour TWA 0.01ppm (0.08mg.m⁻³).  
Notation Carc, skin  
NOEL in rat and mouse 100ppm in drinking water (repeated dose – but no timescale given).  
In vitro genotox. Little information in vivo.  
Possibility that rat and mouse thyroid (rat and mouse) and liver tumours (mouse) may have been caused by non-genotoxic mechanism.  
Epping Jaundice incident indicates liver damage in humans following ingestion of about 3mg/kg MDA. Single | including hepatocellular carcinomas in some male rats.  
A NOAEL of about 25ppm in a rat 22 month study.  
Slightly retarded fetal development in rats. |
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<th>low for setting either OEL would be low due to current low estimated inhalation exposures.</th>
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<td>Cost of reducing dermal exposures aggregated over 2010-2069 estimated as €1400m-29000m due to large number of workplaces possibly affected.</td>
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<td>Recommends collection of further MDA exposure data using biological and personal exposure monitoring due to potentially large numbers exposed and significant uncertainty about skin exposures.</td>
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<td>exposure has resulted in one or two cases of myocardial effects and retinal damage.</td>
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<td>Observation of possible excess in mortality from bladder cancer.</td>
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<td>Dermal absorption a significant route of exposure.</td>
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