

Health and Safety Executive Board		Paper No: HSE/08/82	
Meeting Date:	26 November 2008	FOI Status:	Partially closed (Paragraphs 21 and 22 and Annex 2)
Type of paper:	Below the line	Exemptions:	35(1)(a) Formulation of Government policy
Trim reference:	2008/508669		
<b>EUROPEAN COMMISSION'S 3<sup>rd</sup> DIRECTIVE ON INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES</b>			

### Purpose of this paper

1. To advise the Board of developments concerning the European Commission's proposals for a 3<sup>rd</sup> Indicative Occupational Exposure Limit Values (IOELV) Directive, and to seek the Board's agreement to the proposed United Kingdom voting position.

### Background

2. Ministerial agreement will need to be sought in advance of a vote of Member States. The vote is expected to take place towards the end of the year or early next year.

3. The European Commission's draft 3<sup>rd</sup> Indicative Occupational Exposure Limit Values (IOELV) Directive is approaching a vote of Member State representatives, prior to its formal adoption by the Commission.

4. The legal basis for IOELV directives is the Chemical Agents Directive (98/24/EC). This Council directive provides a European Commission (Comitology) procedure to introduce indicative, health-based occupational exposure limits (permissible concentrations of a particular substance in the air) for individual substances, on the advice of its Scientific Committee for Occupational Exposure Limits (SCOEL) and the Advisory Committee on Safety and Health at Work. The process of setting IOELVs does not take into account socio-economic factors.

5. Two previous IOELV directives have already been adopted and implemented by Member States. The 1<sup>st</sup> IOELV Directive (2000/39/EC) was adopted in June 2000 and contained IOELVs for 63 substances; the 2<sup>nd</sup> IOELV Directive (2006/15/EC) was adopted in February 2006 and contained IOELVs for a further 33 substances.

6. IOELV directives require Member States to introduce national occupational exposure limits for the substances listed in the Annex to the directive, taking into account the level of the IOELV. In Great Britain our policy is to establish Workplace Exposure Limits (WELs) at the level of the IOELV, unless a more stringent limit has already been agreed by the social partners and HSE. There is nevertheless the option to establish a GB limit that is numerically higher than the IOELV, although we would need robust justification.

7. Implementation of IOELV Directives in Great Britain is achieved when the Board agrees new and revised WELs, and when they are subsequently published in the HSE publication ***EH40 Workplace Exposure Limits***. Proposals for new and revised WELs will be subject to a full three-month consultation exercise among interested parties.

### Argument

8. The text of the draft 3<sup>rd</sup> IOELV Directive is attached at Annex 1. It contains

IOELVs for 20 substances:

Bisphenol A	Formaldehyde	Methylisocyanate
Carbon disulphide	Hydrogen sulphide	Methyl methacrylate
N, N-Dimethylformamide	Mercury and divalent	N-Methyl-2-pyrrolidone
1,4-Dioxane	inorganic compounds	Phenol
2-Ethoxyethanol	2-Methoxyethanol	Sulphuric acid (mist)
2-Ethoxyethyl acetate	2-Methoxyethyl acetate	Tertiary-butyl-methyl ether
Ethylacrylate	Methylacrylate	Vinyl acetate

9. Of these 20, three substances have IOELVs that equate to or are higher than the existing GB WELs – hydrogen sulphide, methyl methacrylate and tertiary-butyl-methyl ether. We therefore anticipate no changes to the existing position as regards these three substances.

10. For six of the substances – bisphenol A, mercury and compounds, methylacrylate, methylisocyanate, sulphuric acid (mist) and vinyl acetate, there is currently no existing GB WEL, although methylisocyanate is covered under a generic WEL for all isocyanates. Additionally, for phenol, a short-term exposure limit is required where one does not currently exist.

11. For the remaining 10 substances, the existing GB WEL is higher than the IOELV, and it is therefore proposed (subject to the 3-month consultation period referred to above) that the WEL be reduced in line with the level of the IOELV.

12. This text of the draft Directive has been agreed by the European Commission's tripartite Advisory Committee on Safety and Health at Work, following detailed discussion of the content within the forum of the Working Party on Chemicals, a sub-committee of the Advisory Committee.

### ***Areas of contention***

13. Within the European Commission's Working Party on Chemicals, there was general agreement on the Commission's proposals for 17 of the 20 substances listed in the draft Directive. However, three substances have been the subject of lengthy discussion at Working Party meetings – carbon disulphide, formaldehyde and mercury and its divalent inorganic compounds.

#### *Carbon disulphide*

14. The Employers side have argued that no health problems have been encountered at workplace concentrations of 10 ppm (proposed IOELV is 5 ppm). HSE's toxicologists' opinion is that a WEL set at 5ppm is appropriate.

#### *Formaldehyde*

15. Industry has lobbied HSE concerning the Commission's proposal for an IOELV for formaldehyde set at 0.2 ppm (8-hour time-weighted average (TWA)) and 0.4 ppm (Short-term Exposure Limit (STEL)). The principal opponents of such a limit are the wood panel industry who claim that, in relation to any health effects, the additional expenditure in order to comply with this limit would be excessive. This industry claims that setting an 8-hour TWA limit at 0.2 ppm rather than at 0.3 ppm or 0.5 ppm has significant financial implications. Although comfortable with a limit as proposed, HSE's toxicologists have acknowledged that an equally good case could be made for an 8-hour TWA limit set at 0.3 ppm which, it seems, would be

acceptable to industry. Officials are also concerned that the health effect of eye irritancy on which the limit is set includes subjective aspects of annoyance and personal perception. There is some human data which suggests a no-effect level at around 0.5 ppm, and it is not clear why SCOEL has recommended 0.2 ppm. HSE officials believe, nevertheless, that the existing GB WEL for formaldehyde of 2 ppm (both 8-hour TWA and STEL) is outdated and needs to be reduced.

16. Perhaps the best solution would be for the limit for formaldehyde to be removed from the draft 3<sup>rd</sup> IOELV Directive and for a binding limit, taking into account socio-economic factors, to be established in due course. Nevertheless, if the adopted Directive contains an IOELV of 0.2 ppm (8-hour TWA) for formaldehyde, HSE would have the option to set a slightly higher WEL if that was supported in public consultation and the Board considered it to be appropriate.

### Mercury

17. The SCOEL recommendation for mercury and its divalent inorganic compounds is for an IOELV set at 0.02 mg.m<sup>-3</sup> (20 µg/m<sup>3</sup>) (8-hour TWA). Industry have disputed this figure claiming that it lacks a robust scientific basis. All parties agree that biological monitoring is a more appropriate means of protection against the harmful effects of mercury, than monitoring of workplace atmospheres, and SCOEL has recommended permissible concentrations of mercury in blood and urine. The European Commission has signalled that it is prepared to introduce a biological limit value although this requires a different (and longer) process than setting an IOELV.

18. Officials believe that, in the absence of biological limit values, the SCOEL-recommended airborne limit is appropriate. It is very similar to the former HSC-approved Occupational Exposure Standard that was withdrawn, for reasons of a lack of scientific justification, in 2005. They are content with SCOEL's consideration of the existing data.

### **Next steps**

19. The European Commission will now prepare a proposal and invite Member States to vote. This vote is expected towards the very end of 2008 or in early 2009. Assuming a qualified majority vote (QMV) in favour, the Directive will then be adopted by the European Commission with an 18-month implementation period for Member States to bring in domestic measures to comply.

20. ➔

21. ←

### **Consultation**

22. A full consultation exercise of interested parties will be conducted once the Directive is adopted, proposing that the IOELVs be transposed into GB WELs, except where the GB limit is already more stringent. It is planned to consult the Advisory Committee on Toxic Substances prior to submitting the draft Consultation Document to the Board.

### **Costs and Benefits**

23. An Impact Assessment is currently being prepared to assess the likely costs to industry of the proposed new and revised WELs. We anticipate that the highest

estimates of cost will come from industries using formaldehyde, in particular the wood panel industry.

**Action**

24. That the Board:

- a. notes the position on the draft 3<sup>rd</sup> IOELV Directive;
- b. agrees the proposed UK voting line; and
- c. agrees that the attached letter (Annex 2) be sent by the Chair to Lord McKenzie, seeking his agreement to the voting line.

**Paper Clearance**

25. This paper was produced by Richard Pedersen and Robin Foster, and was cleared by the SMT.

Draft

**COMMISSION DIRECTIVE ../.../EC**

**Establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC<sup>1</sup> and amending Directive 2000/39/EC<sup>2</sup>**  
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,  
Having regard to Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, and in particular Article 3(2) thereof,  
Having regard to the opinion of the Advisory Committee on Safety and Health at Work,

Whereas:

- (1) Pursuant to Directive 98/24/EC, the Commission is to propose European objectives in the form of indicative occupational exposure limit values (IOELVs) for the protection of workers from chemical risks, to be set at Community level.
- (2) In carrying out this task, the Commission is assisted by the Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL) set up by Commission Decision 95/320/EC<sup>3</sup> as amended by Commission Decision 2006/275/EC<sup>4</sup>.
- (3) Indicative occupational exposure limit values are health-based, non-binding values, derived from the most recent scientific data available and taking into account the availability of measurement techniques. They set threshold levels of exposure below which, in general, no detrimental effects are expected for any given substance after short term or daily exposure over a working life time. They are European objectives to assist the employers in determining and assessing risks, e.g. in accordance with Article 4 of Directive 98/24/EC.
- (4) For any chemical agent for which indicative occupational exposure limit values are established at Community level, Member States are required to establish a national occupational exposure limit value taking into account the Community limit value, but may determine its nature in accordance with national legislation and practice.

---

<sup>1</sup> OJ L131, 5.5.1998, p. 11

<sup>2</sup> OJ L 142, 16.6.2000, p.45

<sup>3</sup> OJ L188, 9.8.1995, p.14

<sup>4</sup> OJ L101, 10.4.2006, p. 4

- (5) Indicative occupational exposure limit values should be regarded as an important part of the overall approach to ensuring the protection of the health of workers at the workplace against the risks arising from hazardous chemicals.
- (6) Results of the risk assessments and risk reduction strategies developed in the framework of Council Regulation (EEC) 793/93<sup>5</sup> on the evaluation and control of the risks of existing substances provide for the establishment or revision of OEL for a number of substances.
- (7) A first and a second list of indicative occupational exposure limit values were established by Commission Directives 2000/39/EC and 2006/15/EC<sup>6</sup> under Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to exposure to chemical agents at work.
- (8) Directive 91/322/EEC as amended by Directive 2006/15/EC contains IOELVs for 10 substances and remains in force.
- (9) In accordance with Article 3 of Directive 98/24/EC, SCOEL has assessed (20) substances, which are listed in the Annex to the present Directive. One of these substances, phenol, was already listed in the Annex of Directive 2000/39/EC. SCOEL has reviewed the IOELV in the light of the recent scientific data and recommended the establishment of a short time exposure level (STEL) to complement the existing time weighted average (TWA) IOELV. Therefore, this substance, now listed in the Annex of the present Directive, should be deleted from the Annex to Directive 2000/39/EC.
- (10) Whereas mercury is a substance with potential serious cumulative health effects, health surveillance including biological monitoring in accordance with articles 3 and 10 of Directive 98/24/EC on chemical agents should complement the IOELV.
- (11) It is also necessary to establish short-term exposure limit values for certain substances to take account of effects arising from short-term exposure.
- (12) For some substances, it is necessary to take into account the possibility of penetration through the skin in order to ensure the best possible level of protection.
- (13) This Directive should constitute a practical step towards the achievement of the social dimension of the internal market.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Committee instituted by Article 17 of Council Directive 89/391/EEC<sup>7</sup> of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.

---

<sup>5</sup> OJ L84, 5.4.1993, p. 1

<sup>6</sup> OJ L38, 9.2.2006, p. 36

<sup>7</sup> OJ L183, 29.6.1989, p. 1

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

In implementation of Directive 98/24/EC, a third list of Community indicative occupational exposure limit values is hereby established for the chemical agents listed in the Annex.

*Article 2*

Member States shall establish national occupational exposure limit values for the chemical agents listed in the Annex, taking into account the Community values.

*Article 3*

In the Annex to Directive 2000/39/EC the reference to phenol is deleted.

*Article 4*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 18 months after the entry into force at the latest.

They shall forthwith communicate to the Commission the text of those provisions and a correlation table between the provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

*Article 5*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 6*

This Directive is addressed to the Member States.

**ANNEX 1 Indicative Occupational Exposure Limit Values (IOELVs)**

CAS <sup>(1)</sup>	NAME OF AGENT	LIMIT VALUES				Notation <sup>(2)</sup>
		8 hours <sup>(3)</sup>		Short term <sup>(4)</sup>		
		mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	mg/m <sup>3</sup>	ppm	
50-00-0	Formaldehyde	-	0.2	-	0.4	-
68-12-2	N,N Dimethylformamide	15	5	30	10	skin
75-15-0	Carbon Disulphide	15	5	-	-	skin
80-05-7	Bisphenol A (inhalable dust)	10	-	-	-	-
80-62-6	Methyl Methacrylate	-	50	-	100	-
96-33-3	Methylacrylate	18	5	36	10	-
108-05-4	Vinyl Acetate	17.6	5	35.2	10	-
108-95-2	Phenol	8	2	16	4	skin
109-86-4	2-Methoxyethanol	-	1	-	-	skin
110-49-6	2-Methoxyethyl acetate	-	1	-	-	skin
110-80-5	2-Ethoxy ethanol	8	2	-	-	skin
111-15-9	2-Ethoxyethyl acetate	11	2	-	-	skin
123-91-1	1,4 Dioxane	73	20	-	-	-
140-88-5	Ethylacrylate	21	5	42	10	-
624-83-9	Methylisocyanate	-	-	-	0.02	-
872-50-4	n-Methyl-2-pyrrolidone	40	10	80	20	skin
1634-04-4	Tertiary-butyl-methyl ether	1835	50	367	100	-

7439-97-6	Mercury and divalent inorganic mercury compounds (measured as mercury) <sup>(7)</sup>	0.02	-	-	-	-
7664-93-9	Sulphuric Acid (mist) <sup>(8)</sup>	0.05	-	-	-	-
7783-06-4	Hydrogen Sulphide	7	5	14	10	-

(<sup>1</sup>) CAS: Chemical Abstract Service Registry Number

(<sup>2</sup>) A skin notation assigned to the occupational exposure limit value indicates the possibility of significant uptake through the skin

(<sup>3</sup>) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA)

(<sup>4</sup>) Short term exposure level (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified

(<sup>5</sup>) mg/m<sup>3</sup>: milligrams per cubic metre of air at 20° C and 101,3 KPa

(<sup>6</sup>) ppm: parts per million by volume in air (ml/m<sup>3</sup>)

(<sup>7</sup>) During exposure monitoring for Mercury and its divalent inorganic compound, account should be taken of relevant biological monitoring techniques that complement the IOELV.

(<sup>8</sup>) When selecting an appropriate exposure monitoring method, account should be taken of potential limitations and interferences that may arise in the presence of other sulphur compounds.

Done at Brussels, [...]

*For the Commission*  
**Member of the Commission**  
**[...]**

→ ← ANNEX 2 CLOSED