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ADVISORY COMMITTEE ON TOXIC SUBSTANCES

THE PROCESS OF DEVELOPING AND IMPLEMENTING INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES (IOELVs)

A Paper by Richard Pedersen – HSE

Issue

1. Background information on process followed for developing and implementing indicative occupational exposure limit values (IOELVs).

Timing

2. Routine.

Recommendation

3. ACTS is asked to note the contents of the paper.

Background

4. At the last ACTS meeting held on 9 July, certain members asked for more information on the process whereby IOELVs are determined and then implemented into domestic legislation.

IOELVs

5. IOELVs are established by the European Commission under Article 3 of the Chemical Agents Directive (98/24/EC). This Directive, sets out general principles for assessing and preventing risks at work from the use of chemical agents, and includes the legal framework for IOELVs, binding occupational exposure limit values (BOELVs) and binding biological limit values.
6. Article 3 states:

“1. The Commission shall evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data.

2. On the basis of the evaluation described in paragraph 1, the Commission after first consulting the Committee on Safety Hygiene and Health protection at Work, shall propose European objectives in the form of indicative occupational exposure limit values, to be set at Community level.

These limit values shall be established or revised, taking into account the availability of measurement techniques, in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC. Member States shall keep workers' and employers' organisation informed of indicative occupational exposure limit values set at Community level.

3. For any chemical agent for which an indicative occupational exposure limit value is established at Community level, Member States shall establish a national exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice."

7. IOELVs are health-based limits which conventionally are established only for substances for which it is possible to establish a threshold or a no-effect level, considered to be protective of health. A thorough assessment of the available scientific information is essential as a first step. This is undertaken by the European Commission's Scientific Committee for Occupational Exposure Limits (SCOEL).

SCOEL

8. SCOEL usually meets four times a year. Presently, SCOEL has 20 members, drawn from a number of EU Member States. There are currently two UK-based members, both of which are members of ACTS (Professor Hay and Professor Levy).

9. Some of SCOEL's work programme is driven by conclusions reached in Risk Reduction Strategies prepared for individual substances under the now defunct Existing Substances Regulation (Reg. 93/793) (now taken into REACH). SCOEL's assessments are conveyed to DG Employment and Social Affairs who decides whether to take forward the establishment of an IOELV.

10. ACTS Members may find it useful to look at the relevant European Commission website http://ec.europa.eu/employment_social/health_safety/scoel_en.htm for further information on the role of SCOEL and the derivation of IOELVs.

11. Our website above sets out a 10 point list of key stages in the development of OELs.

- 1 Establishment by DG Employment of a list of priority substances for which OELs should be developed.
- 2 Submission of the priority list to SCOEL.
- 3 Evaluation by SCOEL of the published scientific data on the toxicology of the chemical.
- 4 Preparation by SCOEL of a draft recommendation summary document (SCOEL/SUM).
- 5 Six-month consultation period during which the contact points may provide comments on the SCOEL/SUM document.
- 6 Consideration by SCOEL of comments and new data followed by amendment, if necessary, of the recommendation.
- 7 Publication by the Commission of the final recommendation of SCOEL.
- 8 Development by the Commission of a proposal for a directive based on the SCOEL recommendation.
- 9 Consultation of the Advisory Committee on Safety and Health at Work on the Commission's proposal.
- 10 Adoption of the Commission's final proposal either through adaptation to technical progress procedure (IOELVs) or by the Council and European Parliament route (BOELVs).

12. Under Point 5, comments are sought on the science underpinning the recommendation for an OEL. SCOEL is particularly anxious to hear of any additional toxicology studies of which it may not be aware, and to seek views on the availability of appropriate measurement techniques. Input on matters of achievability or socio-economic impact is not sought and is not considered by SCOEL.
13. HSE, International Chemicals Unit (ICU) is a point of contact for dissemination of the draft SCOEL/SUMs. ICU circulates the documents to a contact list which includes all members of ACTS and WATCH. HSE toxicologists and other scientific experts consider the documents and HSE submits comments if we have concerns about the scientific basis of the proposed limit. In line with the tripartite process followed at EU level, we suggest that other recipients of the documents submit their own comments likewise, although we believe that little has been put forward in the past.
14. Currently 6 draft SCOEL/SUMs are subject to the 6-month consultation, with a deadline for comments of 15 January 2009. These are for:
- | | |
|----------------------------------|---|
| Acrylamide | Hydrogen peroxide |
| 2,6-Dimethylaniline (o-xylidene) | Tetrachloroethylene (Perchloroethylene) |
| Edetic acid (EDTA) | Trichloroethylene |
15. As part of stages 8 and 9 above, the recommendations of SCOEL are considered by the Working Party on Chemicals in the Workplace, a subgroup of the Advisory Committee for Safety and Health at Work. This sub-group has 12 members, 4 from each of the employer, employee and Government interests. Members are appointed in a personal capacity, and speak on behalf of their "constituency". Presently one representative from the employer and one representative of the Government interest groups are UK based (the Government representative is the Head of ICU, who currently also chairs the Working Party).
16. The Working Party considers, amongst other matters, the appropriateness of the inclusion of SCOEL-recommended limits for an IOELV Directive. It does not debate the level at which an individual limit should be set. However, if there are questions over the scientific basis used by SCOEL in recommending a limit, the Working Party can ask that the substance is referred back to SCOEL for further consideration.
17. When the European Commission considers it has sufficient agreed SCOEL recommendations, it prepares a draft Commission Directive setting out proposed new IOELVs. This is transmitted to the Advisory Committee on Safety and Health at Work with an opinion from the Working Party (or, if necessary, with differing views from the Employer, Worker or Government interest groups). The Advisory Committee gives its opinion on the proposal, if necessary establishing its view by means of a vote.
18. If the Advisory Committee has an agreed position in favour of the proposal the Commission invites all Member states to vote on the proposed IOELV Directive. If the Commission's proposal receives a qualified majority, the Commission adopts the Directive and it is published in the *Official Journal of the European Union*. Member States then have a fixed timescale (typically 18 months) to implement the Directive in their national legislation.

19. Since 1998 the European Commission has established and adopted two lists of IOELVs. The 1st IOELV Directive (2000/39/EC) contained limits for 63 substances and was adopted on 8 June 2000. The 2nd IOELV Directive (2006/15/EC) contained limits for a further 33 substances and was adopted on 7 February 2006.
20. A draft 3rd IOELV Directive is currently in preparation with a potential further 20 substances. In line with the procedure above, the recommendations from SCOEL for each substance were discussed in the Working Party on Chemicals. In this case, the opinion which went forward from the Working Party included separate opinions from employer, worker and government interest groups on three substances (formaldehyde, carbon disulphide and mercury and divalent mercury compounds). Advisory Committee members were asked to vote individually on these three substances, as well as on the other substances in the Commission's proposal. The overall result was a majority view that all 20 substances should be in the proposed Directive with the values recommended by SCOEL. The proposed Directive as it presently stands is at Annex 1. We anticipate that Member States will be invited to vote on the proposal within the next 3 months.

IMPLEMENTATION OF DIRECTIVES IN GREAT BRITAIN

21. IOELV Directives are implemented in Great Britain by establishing Workplace Exposure Limits (WELs) under COSHH for the substances in question. WELs, taking into account the IOELVs are approved by the HSE Board and subsequently published in ***EH40 Workplace Exposure Limits***. All 96 substances for which IOELVs were set in the 1st and 2nd IOELV Directives have WELs in ***EH40 Workplace Exposure Limits***.
22. The process for establishing WELs, taking into account the corresponding IOELVs, is well-established. Once a final proposal for a Directive appears, HSE prepares to consult on its implementation. A draft Consultation Document is submitted to ACTS for its consideration, and subject to its agreement, to the HSE Board. The Consultation Document will include a preliminary Impact Assessment of the new and revised limits, and will point out where it is expected that compliance costs will be the highest.
23. Typically, consultation lasts three months during which specific views are sought from relevant stakeholders including trade associations representing the industries where the substances in question are either manufactured or used, trade unions, individual companies known to be manufacturers or users of the substances, and other Government Departments and public bodies. All Consultation Documents are placed on the HSE website in order to achieve maximum access.
24. On receipt of comments HSE will prepare its implementation plans. Generally speaking this will entail the establishment of new and revised WEL entries for ***EH40***, in line with the IOELVs in the Directive. However, in cases where the existing WEL is more stringent than the IOELV it is usual for that limit to remain in place. There is also scope for HSE to propose that the WEL should be higher than the IOELV. This situation occurred in a number of instances during the implementation of the 1st IOELV Directive, because WATCH reviews for the same substances were available. In those cases it was considered that it was more appropriate to go with the assessment made by WATCH than by SCOEL.

25. HSE's recommendations for new and revised WELs are submitted to ACTS for agreement, with any justification of why the proposed WEL differs from the IOELV. Subject to ACTS agreement, they are then put to the HSE Board for approval. Once approved the limits are included in a revised version of **EH40** on the HSE website, and, if appropriate in a new hard copy version.

Action

26. Members are requested to note the information provided.

Contact

Richard Pedersen, HSE.

Draft

COMMISSION DIRECTIVE ../.../EC

Establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC¹ and amending Directive 2000/39/EC²
(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/EC³ as amended by Commission Decision 2006/275/EC⁴.
- (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.
- (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.

¹ OJ L131, 5.5.1998, p. 11

² OJ L 142, 16.6.2000, p.45

³ OJ L188, 9.8.1995, p.14

⁴ OJ L101, 10.4.2006, p. 4

- (6) Results of the risk assessments and risk reduction strategies developed in the framework of Council Regulation (EEC) 793/93⁵ 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/EC⁶ 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/EEC⁷ of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.

⁵ OJ L84, 5.4.1993, p. 1

⁶ OJ L38, 9.2.2006, p. 36

⁷ 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(1)	NAME OF AGENT	LIMIT VALUES				Notation(2)
		8 hours(3)		Short term(4)		
		mg/m ³ (5)	ppm(6)	mg/m ³	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) ⁽⁷⁾	0.02	-	-	-	-
7664-93-9	Sulphuric Acid (mist) ⁽⁸⁾	0.05	-	-	-	-
7783-06-4	Hydrogen Sulphide	7	5	14	10	-

⁽¹⁾ CAS: Chemical Abstract Service Registry Number

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

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

⁽⁴⁾ 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

⁽⁵⁾ mg/m³: milligrams per cubic metre of air at 20° C and 101,3 KPa

⁽⁶⁾ ppm: parts per million by volume in air (ml/m³)

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

⁽⁸⁾ 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

[...]