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Opinion

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**Opinion on the approach and content of an envisaged proposal by
the Commission on the amendment of Directive 2004/37/EC on
Carcinogens and Mutagens at the workplace**

Adopted on 05/12/2012

Proposal of the Commission on the amendment of Directive 2004/37/EC¹ on carcinogens and mutagens

This opinion presents the view of the ACSH regarding the proposed amendment of directive 2004/37/EC on the protection of workers health and safety from risks arising from possible exposure to carcinogens or mutagens at the workplace.

The Commission services propose to introduce an amending directive which will introduce additional substances in Annex I, thereby bringing them within the scope of the directive and to introduce binding occupational exposure limit values for a number of substances in Annex III. At the same time the Articles on risk management and setting of occupational exposure limit values will be amended to better align them with current needs and the approach presented in the Chemical Agents Directive 98/24/EC².

In accordance with the Treaty on the Functioning of the EU, the Commission has carried out the mandatory two stages of consultation of the social partners at EU level. As a result of these consultations the Commission services have decided that the directive should be amended.

The Working Party on Chemicals has considered this issue and agrees with this approach.

General key issues

1. It is of utmost importance to have guidelines at EU level on the methodologies for deriving limit values in accordance with art. 16.

A number of approaches to developing occupational exposure limits (OELs) exist; they have been discussed in detail in the Working Party on Chemicals and they should form the basis for future discussions on developing an approach to preparing proposals, at EU level, for OELs for carcinogens.

The ACSH urges the working party on chemicals to come forward with a proposal on an approach to setting OELs in the coming two years.

2. The ACSH invites DG EMPL to work on the development of such guidelines, in co-operation with the Working Party on Chemicals, with the intention to bring forward proposals for limit values for additional substances for the next two years.

3. DG EMPL, in co-operation with the ACSH, is invited to develop guidance to better facilitate the practical implementation of the minimization obligation according to Article 5 of the directive.

¹ OJ L 229, 29.6.2004, p. 23.

² OJ L 131, 5.5.1998, p. 11.

It should be clarified that the risk minimization requirement of Art 5 applies even in the case where there is an OEL and exposure should be minimized below the limit value in accordance with the general requirements of the directive. The Employers Interest Group indicate that this requirement should reflect the feasibility of the OEL.

4. It is noted that OELs are one factor determining risk management measures (RMMs) and all approaches to establish risk management need to be taken into account to ensure effective workplace chemical risk management.

Most of the limit values proposed reflect feasibility issues and some additional measurement methodology challenges. Consequently, some of the OELs are less protective than others and, therefore, there is a need to review these values in the near future. In the meantime, additional risk management measures may be implemented to control risk at work.

Concluding General Remark

The working party on chemicals has discussed these issues in great detail in each of its meetings since June 2010. This amendment of CMD is a first step in creating a modern and effective legal framework for the effective risk management of occupational carcinogens and mutagens. Further work will be required to prepare for a more substantial revision of the directive and to bring forward proposals for more OELs under Annex III and, where appropriate, to include additional substances in Annex I.

The ACSH gives a positive opinion on the approach proposed by the Commission Services and adopts this Opinion at the meeting of 5th December 2012.

Specific comments from the Workers' Interest Group on the general issues

In the discussions of the Working Party on Chemicals, it emerged that there is no guidance on the methodology for deriving limit values in accordance with art. 16. As part of the ad-hoc utilized methods for deriving the limit values proposed for inclusion in Annex III, cost-benefit analysis has been employed in a way which is not taking into account the EU Charter of Fundamental Rights, in particular human dignity (art. 1), right to life (art. 2), and right to the integrity of the person (art.3).

The Workers' Interest Group calls on the Commission to initiate the development of such a guidance which is in conformity with the abovementioned Fundamental Rights, and to include the Advisory Committee on Safety and Health and its Working Party on Chemicals in that development as a whole.

In these discussions it further emerged that, due to deficits in the enforcement of the minimization obligation according to art. 5(3), there is a considerable discrepancy between Member States in the progress on the lowering of exposure levels.

This situation is in contradiction to art. 1 (1) of Dir. 89/391/EEC, which encourages improvements in the safety and health of workers at work and it does not conform to the social dimension of the internal market as underlined in recital 16 of Dir. 2004/37/EC.

Therefore Member States are invited to monitor exposure levels in accordance with art. 3 (2) in a comprehensive way and to report the results to the Commission and the Advisory Committee on Safety and Health on a regular basis.

In these discussions it further emerged that some of the limit values proposed for inclusion in Annex III either correspond to considerably high risks for contracting cancer or are not protective for non-malignant health effects.

In particular for those substances which are specifically addressed under II. (below), the further lowering of their limit values should have a high priority and the respective review process should be initiated by the Commission within five years.

Furthermore, the urgently needed guidance on the methodology for deriving limit values addressed above should include recommendations on protection both against high risks of individual workers of contracting cancer and against non-malignant health effects.

Finally, the Workers' Interest Group reiterates the opinion that the scope of Directive 2004/37/EC should be extended to include substances meeting the criteria for classification as toxic for reproduction category 1A or 1B in accordance with the CLP Regulation.

With a view that the actions recommended above to remedy the observed deficits will be addressed without delay, the Workers' Interest Group supports the positive opinion of the ACSH as stated below.

Specific key issues to be addressed

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The views on each of the component parts of the possible amendment of Directive 2004/37/EC are presented below:

I. Respirable Crystalline Silica (RCS)

General remarks

It is agreed that for RCS a binding OEL at 0.1 mg/m³ 8 hour time weighted average (8hr TWA), measured as respirable dust, is justified. The value should be reviewed within 3-5 years. However, it is recognized that there are different legal possibilities to adopt such a binding OEL namely the Chemical Agents Directive (CAD) or the Carcinogens or Mutagens Directive (CMD).

If the OEL is to be adopted under CMD then it will also be necessary to include process generated RCS in Annex I of CMD to give legal certainty to the inclusion of RCS in the scope of the directive.

Specific comments from the Employers Interest Group on RCS

The employers take note of the fact that there is no scientific consensus on the question if RCS is a direct carcinogen or only acts in a secondary stage on pre-existing silicosis lesions. Moreover, EU legislation offers no possibility to distinguish the mechanism and potency.

It is the Commission's responsibility to define a regulatory framework that is effective in terms of prevention and to choose appropriate instruments taking into account scientific information as well as technical and economical aspects. This is to be done in full respect of the articles 151 and 153 of the Treaty, taking into account preserving the competitiveness of the economy

It is also the responsibility of the Commission to ensure coherence between the different regulations dealing with chemical substances such as Reach, CLP, the ecoconception of products and the health and safety regulations. At this moment, the pieces of the puzzle do not fit together. The EU legislative framework as we know it today is not adapted.

Several members of the employers group were able to give examples of substances, managed under the CAD, requiring stricter measures than foreseen by the CMD. Other examples show substances, currently classified as carcinogens, for which measures as substitution or closed processing are not always technically feasible or not the most effective risk management measures. Any decision on RCS therefore must be taken with extreme precaution. A serious impact assessment at EU level of the policy options for RCS seems indispensable.

Bearing that in mind and knowing that such an in depth revision of the legislative framework would take years, the employers urge the Commission to opt for a pragmatic solution. The principles of substitution and the closed process approach (priority in the hierarchy of measures under the CMD) cause huge problems for industries and processes where exposure to RCS might occur. Classification under annex I of the CMD would also be detrimental to the prevention approaches and good practices are already implemented by the professionals in the field, including good practice guides and social partner agreements. Therefore the pragmatic solution we propose is to approach RCS via the CAD with a binding limit value of 0,1 mg/m³. That approach is likely to yield the best results in terms of prevention, protection and efficiency. As accompanying policy measures the employers ask for more support and efforts in collecting and disseminating good practices, particularly for those branches of industry that still struggle to find preventive measures adapted to their seize and needs.

Finally, the employers call upon the Commission to ensure better coordination between national institutes dealing with limit values, measuring and measuring methods. A more harmonised approach towards measuring (methods) is necessary to avoid an unlevel playing field for industries throughout Europe.

Specific comments from the Governmental Interest Group on RCS

The Government Interest Group does not have a single position. One view is that a binding limit for RCS is best established in the Chemical Agents Directive (CAD) on the basis that preventing silicosis substantially prevents cancer and that a binding limit under CAD has pragmatic advantages for a substance that is widely distributed on earth. However, this would have to be done quickly and in the same timescale as the proposed amendments to the Carcinogens and Mutagens Directive (CMD). Another view is that as exposure to RCS can lead to cancer, a binding limit should be established under CMD.

Specific comments from the Workers Interest Group on RCS

RCS is recognized by the International Agency for Research on Cancer (IARC) as an occupational carcinogen (IARC group I, carcinogenic to humans) and, as it is not scientifically proven that silicosis is the necessary precondition for the development of lung cancer in workers exposed to RCS, the Workers' Interest Group is of the opinion that the binding OEL for RCS should be adopted under the CMD.

In the discussions of the Working Party on Chemicals it emerged that for the time being a concentration value of 0.05 mg/m³ does not yet seem to be technically feasible across all industries in Europe. Given the fact that, according to the SCOEL sum document 94 (November 2003), p. 8, concentrations even at 0.05 mg/m³ will lead to silicosis (with a probability of at least 5 %) and to lung cancer, a further exposure reduction below the proposed binding OEL of 0.1 mg/m³ is paramount. Since exposure reduction below a binding OEL is requested only by the CMD, but not by the CAD, the adoption of the proposed binding OEL solely by the CMD will legally guarantee the obligation of further exposure reduction to prevent silicosis and lung cancer.

In addition, the Workers' Interest Group doubts that it is legally possible for the Commission to propose a binding OEL for RCS under the CAD in the framework of the revision of the CMD. The specific question raised in the second phase of the social partner consultation in 2007 was about whether or not BOEL for more substances should be included in the CMD (and not in CAD). Should a BOEL for RCS be proposed under the CAD, this would require a new consultation of the social partners, impose considerable delays (minimum 5 years) in the adoption of the BOEL at EU level and trigger a high number of avoidable cases of silicosis and lung cancers in exposed workers.

Therefore, the Workers' Interest Group considers both the inclusion of RCS in Annex I and the introduction of the binding OEL for RCS in Annex III of the CMD as the only way to achieve the faster limitation of the exposure to RCS and, at the same time, to establish the necessary legal obligation of a further exposure reduction.

II. Annex I: List of substances, preparations and processes, linked to Article 2(a)(iii).

General remarks

The current proposal does not foresee the inclusion of additional substances in Annex I. However, if the OEL for RCS is to be adopted under the CMD it will be necessary to include RCS (including process generated RCS) in this Annex to bring legal certainty to its inclusion in the scope of the directive.

Supplementary opinions may be prepared for any substances (mainly process generated substances) that are to be discussed at future meetings of the Working Party on Chemicals.

Specific comments from the Employers Interest Group

See comments above

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

III. Annex III: Limit values and other directly related provisions, linked to Article 16.

(a) Hardwood dust

General remarks

An 8hr TWA of 3 mg/m³, measured as inhalable dust, with a review period of between 3-5 years is proposed.

It is recognized that better guidance on measurement methodologies is required to take account of mixed exposure to both hard and soft wood dusts.

Specific comments from the Employers Interest Group

The employers' delegation opposes the proposal to reduce the Occupational Exposure Limit value for Hardwood dust from 5mg/m³ to 3mg/m³. This proposal does not take into account the fact that certain hand-held machines, which are not replaceable as substitutes are not available on the market, do not allow for exposure limits below 5 mg/m³, although all technical and organisational measures have been taken. For that reason some countries (e.g. Germany and Austria work with negative list of certain handheld machinery).

It is to be noted that the SHEcan study on hardwood dust (consultant study commissioned by EC) only investigated the situation in one country and then extrapolated the results to the European level. This is not an appropriate methodology to measure economic impact: not only the structure and nature of the industry tends to differ but also the used measuring methods can lead to significant differences in evaluations. Limit values of different countries cannot be compared without taking into account other elements of the prevention and protection system. An on paper more stringent (lower) limit value in one country may result in less protection compared to a country with a higher limit value, when measuring methods and accompanying measures are taken into account.

The employers also wish to highlight some health issues. Some recently published studies published tend to disagree to some of the studies mentioned in the SHEcan report:

- Study Tulane university (US) : exposures to 6.97 – 2.92 or 1.16mg/m³ showed no statistically significant adverse effects on lung function
- Aarhus university Hospital (DK): This study among workers exposed to low levels of wood dust does not support an association between acute and chronic decline in lung function.

Finally, we bring to your attention that a project on prevention of exposure to wood dusts between the social partners in the sector (CEI-Bois as employer organization and EFBWW as workers organization) was successfully finished (in 2012) and gave rise to a brochure on best practices to reduce exposure to wood dusts. This approach is very likely to yield better results in prevention and protection than a reduction of the limit value.

Specific comments from the Governmental Interest Group

The Government Interest Group notes that, in practice, a limit for hardwood dust also applies to softwood dust as the two cannot be readily distinguished. The Government Interest Group does not have a single position on the level at which a binding limit should be set. One view is that 3 mg/m³ is presently the limit of feasibility, particularly for small and medium sized enterprises (SMEs), and a binding limit at this level still presents significant challenges for compliance. However there is also a view that the limit should be set at 1 mg/m³ to further reduce the contribution hardwood dust makes to occupational cancer.

Specific comments from the Workers Interest Group

In view of current limit values of 2 mg/m³ or below in the majority of Member States examined in the impact assessment and as addressed in the discussions of the Working Party on Chemicals, the Workers' Interest Group favours a binding OEL of 2 mg/m³ (inhalable dust) for the time being.

Given the fact that, according to the SCOEL sum document 102 (December 2003), p. 16, concentrations above 0.5 mg/m³ total dust will induce pulmonary effects and, thus, should be avoided, a further exposure reduction below the proposed binding OEL should be striven for urgently with a review period of a maximum of three years.

(b) Trichloroethylene

General remarks

An 8hr TWA of 10 ppm is proposed.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(c) Hydrazine

An 8hr TWA of 0.013 mg/m³ is proposed. This should be complemented with a footnote to state that as an analytical method is not fully validated for the time being, for achieving a binding OEL level at 0.013 mg/m³, further validations by industry are expected before being able to implement this value.

Specific comments from the Employers Interest Group

This OEL is not feasible for all processes in the industry across the EU. There also does not seem to be an important health benefit for introducing an OEL (see IOM report).

An IOM study carried in 2011, addresses the health and socio-economic aspects of control of hydrazine exposures (IOM Research Project: P937/15; May 2011). For hydrazine, the authors concluded that "There are no important health benefits from introducing a limit at either 0.013 or 0.13 mg/m³, mainly because exposures are predicted to continue to decrease over the next 20 years and the additional impact of any limit is judged to be negligible.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(d) Acrylamide

An 8hr TWA within the range 70-100 $\mu\text{g}/\text{m}^3$ is proposed with a review period of 3 years.

Specific comments from the Employers Interest Group

The Employers group indicates there are technical feasibility concerns regarding an effective implementation of a BOEL between 70 and 100 $\mu\text{g}/\text{m}^3$ for some facilities.

Specific comments from the Governmental Interest Group

None at this stage.

Specific comments from the Workers Interest Group

None

(e) Chromium VI

An 8hr TWA of 25 $\mu\text{g}/\text{m}^3$ is proposed. An adequate review period for further reduction to 1-10 $\mu\text{g}/\text{m}^3$ still has to be determined.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None at this stage.

Specific comments from the Workers Interest Group

In the discussions of the Working Party on Chemicals it emerged that even a binding OEL of 25 $\mu\text{g}/\text{m}^3$ would still correspond to a high cancer risk. Based on the SCOEL sum document 86 (December 2004), p. 1, concentrations at 25 $\mu\text{g}/\text{m}^3$ would correspond to risks between 2 and 14 excess lung cancer cases per 1,000 exposed workers. To limit excess risks at or below 4 additional lung cancer cases per 1,000 exposed workers, in accordance with the upper risk limits agreed on in both the Netherlands and Germany, the exposure would need to be limited to a concentration value in the range between 1 and 10 $\mu\text{g}/\text{m}^3$, also taking into account recent scientific reviews not yet included in the SCOEL document.

Therefore, a further exposure reduction below the proposed binding OEL is paramount.

(f) Epichlorohydrin

An 8hr TWA of 1.9 mg/m³ is proposed.

Specific comments from the Employers Interest Group

It should be noted that the risk to sustain a cancer at this OEL is extremely low and is irrelevant in comparison with existing health risks in daily life. Additional RMMs are not appropriate to reduce the health risk.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(g) Refractory ceramic fibres

It is agreed that an OEL is necessary. However there is difference of view on the exact numerical value that would be appropriate. The Workers Interest Group request a value of 0.1 f/ml whereas the Employers Interest Group request a value of 0.3 f/ml, both values as 8hr TWA.

Specific comments from the Employers Interest Group

Employers advise to follow the recommendation of SCOEL (SUM DOC 165; Sept 2011) stating the mechanism for lung cancer is a secondary one, with a threshold. The cancer is derived from inflammation that may be prevented by exposure under 0.3 f/ml. Also, other non carcinogen respiratory effects are prevented under this value. The recommendation may be summarized by the following statements, extracted from the SCOEL text:

“...the studies indicate that the exposures since the late 1980s neither had deleterious impact on the lung function, nor diagnosed pleural plaques or mesothelioma. These exposures ranged from approximately 1 fibre/ml to below the limit of detection (Rice et al 1997).

Assuming a 45 years exposure the average cumulative exposures of 147.9 and 184.8 fmo/ml, respectively, result in an average fiber concentrations of 0.27 and 0.34 f/ml. Considering these values as no observed adverse effect levels SCOEL proposes an OEL of 0.3f/ml. From the available information it is concluded that the genotoxic effects observed in the different

studies are secondary so that RCFs are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported.”

However the employers group would like to stress that industries have been working on a 0.5 f/ml exposure limit for many years – a protective level established in many EU Member States’ workplace regulations and have developed programs to help driving exposures down to and in various cases below this level. A further reduction of exposures is technically difficult and will in many cases ultimately lead to the mandatory use of respiratory protection.

Specific comments from the Governmental Interest Group

The Government Interest Group does not have a single position, and some members are still developing their positions on refractory ceramic fibres. One view is that 0.3 f/ml is appropriate, as SCOEL considered this to be a no observed effect level, and on the basis of feasibility. Another view prefers a limit of 0.1 f/ml in line with the exposure limit for asbestos fibres.

Specific comments from the Workers Interest Group

The Workers’ Interest Group disagrees with the view expressed in the SCOEL sum document 165 (September 2011), p. 17, that refractory ceramic fibres should be considered as genotoxic carcinogens with a practical threshold. Instead, the group refers to the considerations detailed in the scientific explanations given for the exposure risk relationship on aluminosilicate fibres derived in Germany (cf. http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/910/910-Aluminiumsilikat-Fasern.pdf?__blob=publicationFile&v=2), according to which aluminosilicate fibres exhibit a carcinogenic potency comparable to asbestos.

Therefore, the Workers’ Interest Group favours a binding OEL of 0.1 f/ml which corresponds to an additional cancer risk of 4 per 1,000 exposed workers, in accordance with the upper risk limits agreed on in both the Netherlands and Germany.

(h) 1,2-Dibromoethane

At its meeting of November 2012, the working party Chemicals decided that a discussion on this substance should be continued at its meetings during 2013.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None at this stage.

Specific comments from the Workers Interest Group

None

(i) MDA

An 8hr TWA of 80 $\mu\text{g}/\text{m}^3$ with a skin notation is proposed.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

IV. Article 5: Prevention and reduction of exposure and Article 16: Limit values

General remarks

A number of minor changes to the wording of these and other Articles could be proposed. These should be policy neutral with the intention to provide improved clarity of meaning to the existing policy intention. The Working Party on Chemicals has discussed these issues and identified possible changes; at the same time it is agreed that there is a need to revisit these issues during the next phase of the amendment of this directive.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

The Government Interest Group considers that the requirements of CMD continue to be important, and agrees that some clarifications maintaining the existing policy intention are desirable and should be introduced in the first phase of the review and amendment of CMD. However, a broader revision of CMD is also urgent.

In addition one view is that the link with Article 58(2) of REACH should be substantiated by including clear and precise provisions in CMD on when exemption from authorisation under REACH is justified.

Specific comments from the Workers Interest Group

None