EUROPEAN COMMISSION
DG Employment, Social Affairs and Inclusion

Employment and Social Legislation, Social Dialogue
Health, Safety and Hygiene at Work

The Advisory Committee on Safety and Health at Work

Supplementary Opinion No. 2

Supplementary opinion No. 2 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

Supplementary opinion No. 2

Doc. 2016/13

Adopted on 28/11/2013

Proposal of the Commission on the amendment of Directive 2004/37/EC[1] on carcinogens and mutagens

This supplementary opinion No. 2 presents the view of the Advisory Committee on Safety and Health (ACSH) regarding certain aspects of 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. It supplements Opinion (Doc. 2011/12) adopted on 5th December 2012 and Supplementary Opinion (Doc. 727/13) adopted on 30th May 2013.

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/EC (CAD)[2]. The Working Party on Chemicals has considered whether the scope of the Chemicals and Mutagens Directive (CMD) should be extended to include substances which are toxic to reproductive health.

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.

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. As indicated in the first Opinion, of 5th December 2012, 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 supplementary opinion at the meeting of 28.11.2013.

1 OJ L 229, 29.6.2004, p. 23.
2 OJ L 131, 5.5.1998, p. 11.

Specific key issues to be addressed

The views on each of the component parts of the possible amendment of Directive 2004/37/EC are presented below; this complements the views expressed in the first Opinion (Doc. 2011/12) and in the first supplemental Opinion (Doc 727/13).

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

(a) Rubber process fume and dust

General remarks

In its recent monograph 100F, IARC concluded that “there is sufficient evidence in humans for the carcinogenicity of occupational exposure in the rubber-manufacturing industry” (group 1). This conclusion is mainly based on a systematic review published in 1998 of epidemiological studies on cancer in the rubber-manufacturing industry. “No data on experimental animals with relevance to the rubber-manufacturing industry were available to the (IARC) Working Group.”

Since then, industry has undertaken considerable efforts to reduce and / or replace carcinogenic substances used and / or generated in the rubber-manufacturing industry.

However, rubber fumes and dusts generated during various industrial processes have a complex and / or unknown compositions. In addition, there is uncertainty whether and to what extent these rubber fumes and dusts may still contain carcinogens.

It was also not in the remit of the IOM study report to identify specific carcinogenic substances currently still contained in rubber dust and fumes.

Therefore, work should be carried out to identify and evaluate the scientific aspects with the view to determine the appropriate way to include these carcinogenic substances not already and specifically covered by the CMD.

In all cases, it should be recalled that Article 3(2) of Directive 2004/37/EC stipulates, that "In the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken."

This opinion should be reviewed within 3 years, taking into account any existing and new scientific publications (e.g. the RAPRA report 2011) and any new information available on the composition of rubber fumes and dusts.

Specific comments from the Employers Interest Group

The rubber industry has historically, over the last 50 years, been applying a substance by substance approach, which is the only scientifically-sound approach, for making improvements to the workplaces.

Extensive industrial hygiene monitoring programs form the basis of this approach, generating exposure data for many chemicals of known or suspected concern. Examples exist of targeted reductions in chemical exposures in the rubber industry in the past decades, including benzene, nitrosamines and poly-aromatic hydrocarbons, amongst others. Additionally, technological advances in the rubber industry manufacturing process have been made to reduce worker exposures, including the use of closed systems, increased ventilation and its efficiencies and automation to reduce the need for worker to contact chemicals, rubber mixes or parts.

Therefore Employers recommends to:

- Continue the robust enforcement and implementation of EU health and safety legislations that identify substances of concern and associated exposure and risks, and to drive the establishing of substance by substance OELs, and substitution actions based on established worker risks.

- Support the development and creation of internationally recognized standard test methods for the qualitative and quantitative assessment of the chemical species in rubber fumes, thus facilitating industry's ability to pro-actively identify and eliminate potentially existing risks associated to individual hazardous components and originating raw materials. The qualitative test method has been published on June 2013 under the name ISO TS 17796 "Qualitative analysis of rubber fumes". The method has been proposed by the industry, developed by the ISO Technical Committee 45, and validated unanimously by the experts the 21 countries members of the ISO working group. The industry is going to promote this test method to monitor its use and to manage elimination of hazardous product when possible. In the same time the industry develops a set of quantitative methods, which enable industry to evaluate in order to reduce exposure of hazardous substances as long as elimination is not possible.

- Take into account the improvements to workers' protection made by industry over the last 30+ years through a more accurate and transparent assessment of recent and future epidemiology studies.

- Take into account that three years is a challenging timeframe for the review of the opinion considering the timing associated with the acquisition of new data and standardization activities.

In conclusion, according to the arguments and recommendations above, Employers ask to not include rubber process dust and fume in the annex I or III of the Directive. (2004/37 EC) on Carcinogens and Mutagens.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

Rubber fumes and dusts generated during various industrial processes have complex and / or unknown compositions. According to a recent report (RAPRA report 2011) commissioned by the European Tyre & Rubber manufacturers' association (ETRMA), many studies are showing that rubber process fume and dust are containing carcinogens. In particular, the following carcinogens have been identified: N-nitrosamines, polycyclic aromatic hydrocarbons (PAHs), butadiene, acrylonitrile, benzene. Their presence and their respective concentration are depending on specific parameters, such as the recipe of the rubber mixture and the operating conditions of the production process.

Despite the reduction and / or replacement of carcinogenic substances used and / or generated in the rubber-manufacturing industry, which has been undertaken by industry in recent years, it cannot be guaranteed that even in state-of-the-art processes such fumes and dusts will be free of carcinogens. Therefore, the Workers' Interest Group is of the opinion that rubber fume and dust must be included in Annex I of the CMD; however, certain processes, to be described by specific parameters, might be exempted if it can be shown by the manufacturer that the fumes and dusts generated in that process are free of carcinogens. For fumes and dusts generated in all other rubber production processes, it is the duty of employers to assess whether or not those fumes and dusts contain carcinogens, and to act according to the outcome of that assessment.

Given the evidence provided in the RAPRA report 2011, it should be concluded that generic rubber process fumes and dusts are within the scope of the CMD. Unless the employer has shown in his risk assessment that fume and dust generated in any such process considered by him are free of carcinogens, the obligations of the CMD have to be applied currently. With a view to resolve any ambiguities amongst employers about their legal obligations, the Workers' Interest Group strongly advocates the inclusion of rubber process fume and dust in Annex I of the CMD,

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

(a) 1,3 Butadiene

General remarks

An 8h TWA of 1 ppm (= 2,25 mg/m^3) is proposed. No STEL or skin notation was considered necessary.

A revision shall be conducted in 3 years.

Specific comments from the Employers Interest Group

An OEL of 1 ppm may be technically feasible in most of the facilities producing or using 1,3 Butadiene. But, there are significant additional costs for reducing from 1 to 0.5 ppm the level of exposure at workplace. This does not appear adequately reflected in the IOM report (2011),

which is due to the reliance on local exhaust ventilation and personal protective equipment to reduce exposures assumed in the IOM study. Costs to industry for reducing the OEL from 1 to 0.5 ppm were estimated as 123 million Euro in 2005. Although the TNO report (2005) requires updating to reflect today's industry, investment costs for making reductions below 1 ppm may still be deemed relevant as the same control options would be used.

Companies often operate with action limits below a national OEL. This is sometimes also part of requirements under national legislation, such as for determining monitoring measurements needed. Therefore there are wider practical implications of meeting a level that is below 1 ppm.

When looking at the risk estimates, there may be little potential for overall societal benefits evident, e.g. when compared to loss of economic competition for EU industry and consequences of unemployment.

In that context, Employers consider that a three years review is not appropriate.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(b) Bromoethylene / Vinyl bromide

General remarks

An 8h TWA of 1 ppm (= 4.37 mg/m^3) is proposed following the SCOEL recommendation for vinyl chloride, the carcinogenic effect of which are similar to vinyl bromide.

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) 4,4-methylene bis 2-chloroaniline (MOCA)

General remarks

The establishment of an airborne limit value is not useful to protect workers. MOCA is a genotoxic carcinogen without an identifiable threshold limit for health effects and it has a

high potential for dermal absorption. Therefore a biological limit value is considered to be the best available option.

The numerical value of 5 umol total MOCA in urine/ mol creatinine for a possible binding biological OEL is acceptable provided a suitable analytical method is available.

However, it should be noted that Article 5(4) of Directive 2004/37/EC stipulates that "Exposure shall not exceed the limit value of a carcinogen as set out in Annex III". This means that demonstrating compliance with a biological limit value becomes mandatory. This can lead to legal, ethical and medical confidentiality issues as well as matters of national law at individual MS level.

Consequently the use of BLVs, in particular in the framework of the CMD, needs to be discussed and agreed and the Commission will explore the possibilities on how best to address this issue.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(d) Ethylene oxide

General remarks

An 8h TWA of 1 ppm (= 1.83 mg/m^3) is proposed. All countries except the UK mentioned in the IOM report have already established a limit value of 1 ppm. According to the SCOEL recommendation for the substance, a skin notation is warranted.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(e) 1,2-Epoxypropane

General remarks

An 8h TWA of 1 ppm (= 2.41 mg/m^3) is proposed, which corresponds to the value also proposed by SCOEL in its recommendation.

Specific comments from the Employers Interest Group

During routine production and manufacturing practices involving 1,2-Epoxypropane in facilities, the workers' exposures have been monitored and are kept well below the current OEL of 2 ppm. This is due to current engineering and administrative controls. Nevertheless, a potential for higher exposures does remain during maintenance and loading operations. In these cases, 1 ppm threshold can only be achieved with breathing personal protective equipment.

Employers consider that this issue should be taken into consideration when implementing the BOEL.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(f) 2-Nitropropane

General remarks

An 8h TWA of 5 ppm (= 18.25 mg/m^3) is proposed, which should be reviewed after certain period to be determined according to the level of priority for this substance.

Specific comments from the Employers Interest Group

Employer's representatives consider 2-Nitropropane is not a high priority substance regarding the tonnage placed on the market for non-intermediate uses and the number of workers potentially exposed.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

The Workers Interest Group notes that registration data for 2-nitropropane available on ECHA's website show that this carcinogen is produced in the tonnage band up to 10 000 tonnes/year. The substance has a full registration dossier which indicates non-intermediate uses (used in laboratories and in coatings). The guidance on safe use proposed by the

registrant reads: *"Ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, use only in enclosed systems or with local exhaust ventilation. Exhaust systems should be designed to move the air away from the source of vapor/aerosol generation and people working at this point. Lethal concentrations may exist in areas with poor ventilation. »* . Therefore, the Workers interest group considers that a binding occupational limit value is urgently needed to protect EU workers from the risks of exposure to this substance

(g) Hexachlorobenzene

General remarks

No OEL is proposed due to the fact that the substance has already been prohibited globally under the Stockholm Convention and the Protocol on Persistent Organic Pollutants under the UN Convention on Long-Range Transboundary Air Pollution.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(h) 1,2-Dichloroethane

General remarks

An 8h TWA of 2 ppm (= 8.14 mg/m^3) is proposed.

However it should be recognized that there is a lack of robust and up to date scientific data (especially concerning the mode of action).

For technical reasons, a 2 ppm OEL may be difficult to achieve for some activities, especially in the case of multipurpose facilities using the substance in batch processes not operating continuously. Additional time may be requested for implementing the OEL at 2 ppm.

Specific comments from the Employers Interest Group

Most of the plants in Europe use best available technology/techniques. As an example closed pumps (canned or magnetic driven) are used where possible, seal types have been optimized, gasket types have been optimized etc. It would be difficult to find additional technical improvements that would (substantially) reduce 1,2-Dichloroethane levels in the plants during normal operation. Such substantial reduction would require a very high level of containment

(f.i. double walled equipment, containment etc.), which is in our view not technically and certainly not economically feasible.

For facilities producing 1,2-Dichloroethane or using it as intermediate, the critical issue is exposure during maintenance activities or shutdowns. Due to its much lower steam pressure than VCM it is much more difficult to achieve the required levels. Flushing procedures have been optimized during the years and therefore taking more time is the only option to reduce 1,2-Dichloroethane levels during decommissioning and shutdowns. Especially the time necessary before entering columns/equipment will remain critical. We cannot think of any technical improvements in this shut-down preparation phase. As already highlighted, longer flushing has a direct impact on plant availability factor, and hence on economics.

For fine and specialty chemical uses of 1,2-Dichloroethane as process and extracting solvent, 2 ppm OEL may be difficult to achieve for some activities, especially in the case of multipurpose facilities using the substance in batch processes not operating continuously. Additional time is requested for implementing the OEL at 2 ppm.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None