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The Advisory Committee on Safety and Health at Work

Supplementary Opinion

Supplementary 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

Supplementary opinion

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

This supplementary opinion 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.

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 30 May 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)

I. Possible extension of the scope of Directive 2004/37/EC to include substances toxic to reproductive health

General remarks

It is agreed that exposure to reprotoxic substances at the workplace needs to be effectively controlled and that this is a priority issue. However, at this stage, it is not yet possible to agree on the most appropriate approach at EU level. This is because of divergent views on the concept, purpose and scope of CAD and CMD, including how to regulate substances for which a scientific threshold can be established.

Notwithstanding these divergent views the ACSH encourages the Commission services, together with the WPC: 1) to identify priority reprotoxic substances for evaluation by SCOEL and to bring forward proposals for OELs as quickly as possible to further improve the protection of worker health; and 2) to develop guidance to help employers and workers. The guidance should address both fertility and developmental aspects of reprotoxic substances.

In addition, as a large percentage of exposures to reprotoxic substances are to inorganic lead and lead compounds, and as the existing EU binding occupational and biological limits for these substances are known to be not sufficiently protective of health, these limits should be reviewed and amended as soon as possible.

Specific comments from the Employers Interest Group

The Carcinogens Directive has been specifically conceived for dealing with carcinogens for which no safe exposure level can be derived. For this reason there is a main focus on substitution, closed systems and bringing exposure levels to a level as low as is technically achievable.

For reprotoxic substances a "safe" exposure limit can be set in many cases. More generally, mechanisms and procedures for dealing effectively with reprotoxic substances will differ fundamentally from those employed to deal with carcinogens and mutagens. Therefore, the Chemical Agents Directive, and not the Carcinogens Directive, provides for the correct legislative frame to operate in and to ensure that the exposure to these types of substances can be addressed if deemed appropriate.

Reprotoxic substances currently clearly fall under the scope of the Chemical Agents Directive.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

It is the strong view of the Workers Interest Group 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.

The main reasons are as follow:

1) The current situation where workers are protected from the risks of reprotoxic substances by the Chemical Agents Directive (98/24/EC) is far from satisfactory. The nature, the severity and the irreversibility of the health effects resulting from exposure to substances toxic to reproduction are of particular concern for workers of both sexes in a wide range of industrial sectors, including the agricultural, mining, manufacturing, health and service sectors. Therefore, such health effects have to be prevented and levels of protection of workers have to be raised by applying the more stringent provisions of the Carcinogens Directive.

2) Expanding the Carcinogens Directive to include substances that are toxic to reproduction would improve prevention for workers of both sexes in general and for pregnant workers in particular. It should be recalled that one of the faults in the legislation on the protection of pregnant workers (Directive 92/85/EEC) is that the health and safety measures only have to be implemented once the worker reports to her employer that she is pregnant (often around the 10th week of pregnancy). However, there are major risks of birth defects caused by exposure to a substance toxic to development during the first few weeks of pregnancy.

3) Many substances toxic to reproduction are currently produced and marketed in the EU. According to the health, socio-economic and environmental impact study ordered by the European Commission, there are 105 reprotoxic category 1A and 1B substances that fall outside the scope of the Carcinogens Directive (they are reprotoxic substances only and they are not also classified as C and/or M). These are the reprotoxic substances with a harmonised classification under the CLP regulation. However, in order to have a comprehensive view on the number of reprotoxic substances currently present on the EU market and to which workers are potentially exposed, one should also take into account the substances that are self-classified as R1A or R1B by companies under the CLP regulation. A search on the

Classification & Labelling Inventory available on the ECHA website shows that these substances amount at 1416.

4) Including substances toxic for reproduction in the scope of the Carcinogens Directive would be in coherency with the REACH requirements for substances of very high concern which include, inter alia; category 1 and 2 reprotoxic substances (R) in addition to category 1 and 2 carcinogens (C) and mutagens (M). This can be seen as a regulatory simplification and it would also increase the synergies between the two pieces of legislation.

5) If substances toxic for reproduction are not brought into the scope of Directive 2004/37/EC, this means that they will only be covered by the provisions of the Chemical Agents Directive (CAD). As not all the reprotoxic substances are threshold substances, this will leave all the non-threshold reprotoxic substances insufficiently addressed under the EU OSH legislation.

Moreover:

a) if a reprotoxic substance exhibits a threshold but no OEL has been derived, there is no indication to the employer on the exposure level that should not be exceeded - and under the current situation, i.e. within the scope of the CAD, no minimization obligation applies that might help to bring the exposure level down and, perhaps, below the effect threshold;
b) if a reprotoxic substance exhibits a threshold and an OEL has been derived, but at the workplace the OEL is exceeded, within the scope of the Carcinogens Directive stronger pressure for lowering the exposure concentration is provided than within the scope of the CAD.

6) Many substances toxic for reproduction are also identified as endocrine disrupting chemicals[3]. In that case, as there is no safe exposure level for endocrine disruptors, the health-based OELs that might be derived for threshold reprotoxic substances would be useless to protect workers from endocrine disruptors' adverse effects. Having all substances toxic for reproduction included in the scope of Directive 2004/37 will automatically ensure that the more stringent provisions of the Carcinogens Directive also apply to many endocrine disruptors.

7) Six EU countries (Austria, Czech Republic, Finland, France, Germany, The Netherlands) have already widened the Carcinogens Directive's scope to substances toxic to reproduction when implementing it into national law.

8) The findings of the health, socio-economic and environmental impact study ordered by the European Commission are that:

[3] http://ec.europa.eu/environment/endocrine/documents/sec_2011_1001_en.pdf

a) The quantitative approach regarding the costs and benefits assessment of extending the scope of the Carcinogens Directive to reprotoxic substances is currently not possible due to high uncertainties and severe data limitations.

b) However, the qualitative assessment undertaken of the impacts in two Member States that have extended the scope in their national legislation (France and Germany) clearly shows evidence that this has led to benefits in terms of a reduction in workers' exposure to reprotoxic substances.

The Workers' Interest Group is convinced that, if the scope of the Carcinogens Directive is extended to reprotoxic substance, workers in all EU countries would also benefit from a better protection.

Finally, it is worth mentioning that the European Parliament in its report adopted[4] in December 2011 is also calling for an enlargement of the scope of 2004/37/EC to include substances toxic for reproduction.

[4]http://www.europarl.europa.eu/sidesSearch/search.do?type=REPORT&language=EN&term=7&author=96868

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

(a) Diesel engine exhaust emissions (DEEE)

General remarks

An entry in Annex 1 is proposed; this should cover the emissions from older types of diesel engines for which the emissions are considered to be carcinogenic. Such engines have emissions that have a chemical composition and particulate spectrum size which are different to newer types of diesel engines. For newer types of engines further investigations on scientific and the technical aspects needs to be carried out prior to taking a decision as regards their possible future inclusion in Annex I.

The principle of including DEEE in Annex III is agreed subject to taking into account the following criteria: 1. a binding limit value of no higher than 100µg/m^3 8hr TWA measured as elemental carbon; 2. feasibility in certain employment sectors, in particular mining and construction; and 3. in certain workplaces the environmental background levels needs to be taken into account.

It may be necessary to allow more time for certain sectors to comply with a future binding limit value.

Specific comments from the Employers Interest Group

When speaking about old and new diesel engines, a clear definition should be added to distinguish these engines.

Epidemiological studies taken into account by IARC to classify DEEE are mainly based on past-exposure from old diesel engines which cannot be extrapolated to new ones which are quite different in terms of particles and chemical concentration and composition. In addition, additional emission control devices (particle filter) have been generalised on new vehicles.

Situation of certain sectors (mining and construction) should be taken into account as the duration of use of certain vehicles can be very long (several decades for some of them). It is necessary to allow more time for certain sectors to comply with a future binding limit value till normal replacement of old equipment by new ones. As uses of diesel engine can be very close to non-professional sources (motorway…), the background level resulting from the environmental pollution should be taken into consideration when implementing and checking exposure limit value and considering the real carcinogenic components in DEEE. In some other case, emission may occur when trucks from another company leave goods. In many cases the employer knows little about what kind of engine is used in the trucks that visit the company which makes it hard to estimate the exposure and take measure according to the CMD directive.

In addition, Employers wonder how DEEE following relevant criteria to be considered as carcinogen will be practically assessed in particular in SME using old heavy equipment which cannot be easily replaced. As composition of DEEE extremely varies depending on several

factors (type of engine, fuel and lubricant, maintenance, emission control devices…), qualitative and quantitative assessment may be difficult to perform.

There is a problem to measure diesel exhaust. There is no available approved analytical for the time being. There is a matter of opinion if elementary carbon is the best indicator for diesel exhaust and if it gives a mirror of the risk. It's not clear which compound in diesel exhaust causes the risk for cancer. In addition, measurement of elementary carbon is difficult and expensive. There are just a few laboratories in Europe which have equipment for analysis.

Independently of which indicator will be used for diesel exhaust measurement, a standardized method for measuring and analyzing the substance should available.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

Regarding the future binding limit value, it should be taken into account that the carcinogenicity of diesel engine exhaust emissions (DEEE) can be triggered by two different mechanisms, a genotoxic one without an effect threshold, and a second one based on inflammation reactions for which a threshold seems to be likely. Therefore, any binding OEL for DEEE should be lower than that threshold to be protective of the inflammation-based mechanism.

(b) Used engine oils

General remarks

An entry in Annex I of CMD is proposed. The entry should refer to used engine oils, and specify that the entry covers engine oils that have been used in internal combustion engines, including automobile and motor cycle engines, diesel rail engines, marine engines, diesel aero engines, and engines in portable machinery such as chain saws and lawn mowers.

The route of exposure of concern is skin.

Specific comments from the Employers Interest Group

None

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) 1,2 Dibromoethane/ethylene dibromide

General remarks

An 8h TWA of 0.1 ppm (= 0.8 mg/m^3) is proposed. This does not present a difficulty because the predicted costs of compliance are low. Also the health impact will be low. The limit is proposed because of pragmatic reasons.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

The opinion of the workers group is that this binding limit value should be reviewed at a future date. Based on data provided by the Dutch Health Council, and based on data provided by the manufacturers as part of their REACH registration, a much lower value is required to protect workers' health. The reduction of the proposed value should be striven for within a review period of not more than three years.

(b) Benzo(a)pyrene

General remarks

Based on the information contained in the study report, there is insufficient added health benefit in proposing an OEL of 2 µg/m^3 8 hrs TWA. However, an OEL for PAHs is important and work should be carried out to evaluate the scientific aspects with the view to proposing an OEL at some time in the future.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

In view of the risk-based values derived in the Netherlands and in Germany of 0.55 µg/m³ and 0.7 µg/m³, respectively, any proposed binding limit value should not exceed those values.

Given the high number of workers exposed to benzo(a)pyrene, such a value should be derived within less than three years.

(c) Vinyl chloride monomer

General remarks

An OEL of 1 ppm 8 hrs TWA is proposed. This is supported by the state of the art.

Specific comments from the Employers Interest Group

According to a survey done to prepare the REACH registration dossier of vinyl chloride monomer (VCM), in the majority of EU plants 90 % of the workers' exposure measurements are already below 2 ppm. Complying with 1 ppm would be more difficult, because in about 1/4 of plants 10 % of the workers' exposure measurements are close to, or above 1 ppm. These plants would have to carry out equipment modifications, which would require an adaptation period.

The plants which already comply would probably not have to invest. However, if a plant has to upgrade its equipment in order to ensure that 90 % of its exposure measurements are below 1 ppm, investments could be required to upgrade exposure control equipment and production equipment, sampling, decommissioning, loading and unloading of trucks, railcars or ships. The investments to achieve 1 ppm could be up to 2.5 million € per VCM or PVC plant.

Exposure during maintenance activities or shutdowns is the most critical issue. Stricter personal protection and longer purging time/ more ventilation are two possible ways of reducing exposure. The latter would merely result in additional production loss and increased (maintenance) costs. This is difficult to quantify, but the effect could be several days of production loss per year. These costs could easily accumulate to 250-500 k€ per year per plant, depending on capacity. Maintenance costs would also increase because additional measures (related to health) would have to be taken and more (preventive) maintenance would be required (repair of small leakages of valves, pump seals, flanges, gaskets etc.). An order of magnitude could be 50-100 k€/year per plant.

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None

(d) o-toluidine

General remarks

An OEL of 0.1 ppm 8 hrs TWA with a skin notation is proposed. It is recommended that a biological limit value is developed in order to complement the proposed OEL.

Specific comments from the Employers Interest Group

None

Specific comments from the Governmental Interest Group

None

Specific comments from the Workers Interest Group

None