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Consultation of the social partners on the protection of workers from risks related to exposure to carcinogens, mutagens and substances which are toxic for human reproduction

1. INTRODUCTION

The purpose of this document is to elicit the opinion of the social partners on the protection of the health and safety at work of workers from occupational carcinogens, mutagens and substances toxic for reproduction.

Occupational carcinogens are a major cause of concern not only because of the serious health effects on individual workers, but also because of the economic impact on businesses, and the social costs to European countries. Occupational cancer deaths arising from exposure to chemicals costs Member States around € 70 billion annually¹.

Around 32 million European workers are exposed to occupational carcinogens at levels that can be considered beyond safety. Moreover, between 35.000 and 45.000 cancer deaths per year in the EU are due to exposures occurring in the workplace. Most of these cancers are preventable. The most common exposures at the workplace are solar radiation, environmental tobacco smoke, crystalline silica, diesel exhaust, radon decay products and wood dust².

In men, it can be estimated that 13% of lung cancers, 9.5% of bladder cancers, 30% of sino nasal cancers and 8% of laryngeal cancers can be attributed to occupational exposures. In women these percentages are 3% for lung cancer, 9% for bladder cancer and 5% for sino nasal cancer³.

The World Health Organisation's International Agency for Research on Cancer (IARC) has classified environmental tobacco smoke as carcinogenic to humans⁴. Passive smoking in the workplace increases the risk of lung cancer by between 17%⁵ and 39%⁶. Passive smoking at work has also been associated with an increased risk of cardiovascular disease⁷ and respiratory symptoms⁸. In addition, passive smoking

¹ RPA: Assessment of the Impact of the New Chemicals Policy on Occupational Health. Final Report prepared for European Commission Environment Directorate-General, March 2003.

² Kogevinas M, Kauppinen T, Boffeta P, Saracci R: Estimation of the burden of occupational cancer in Europe. Study financed by "Europe Against Cancer". Contract SOC 96-200742 05F02. Final Report, March 1998.

³ See footnote 2.

⁴ <http://www.iarc.fr/pageroot/GENERAL/indexgen.html>

⁵ Boffetta P, Agudo A, et al: Multicenter case-control study of exposure to environmental tobacco smoke and lung cancer in Europe. Journal of the National Cancer Institute 1998; 90: 1440-1450.

⁶ Wells AJ: Lung cancer from passive smoking at work. Am J Pub Health 1998; 88: 1025-9.

⁷ Kawachi I and Colditz G A: Workplace exposure to passive smoking and risk of cardiovascular disease: summary of epidemiological studies. Environmental Health Perspectives 1999; 107(suppl. 6): 847-851.

at work is strongly associated with absence from work, consultation of doctors and use of medication thereby resulting in costs to employers, non-smoking employees and the health services⁹.

European workers are being exposed not only to occupational carcinogens and mutagens but also to reprotoxic substances. The present focus on cancer-causing chemicals in toxicity evaluations has overshadowed other important health endpoints, such as reproductive and developmental toxicity, that may occur at much lower levels of exposure¹⁰. A recent review of the effect of occupational exposures on male fertility has found that significant associations were reported between impaired semen parameters and chemical exposures to metals, pesticides, ethylene glycol ethers and estrogens¹¹.

Therefore, there is a need to strengthen prevention and to adopt better measures to protect the health of European workers from exposure to carcinogens, mutagens and reprotoxic substances. In this line, the Commission intends to propose the extension of the scope of the "Carcinogens and Mutagens Directive" to substances toxic for reproduction. In addition, it plans to propose the revision of occupational exposure limits values (OELVs) for carcinogens, listed in the Directive, and to establish OELVs for some carcinogens, mutagens and reproductive toxicants, not yet included in the Directive. Finally, it is suggested to introduce the possibility of indicative OELVs for carcinogens, mutagens and reprotoxic substances to simplify and better adapt the procedure to technical progress.

2. THE GENERAL CONTEXT

Community action on prevention of exposure to occupational carcinogens began long time ago. Thus, already in 1990, the Council adopted Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work (sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)¹². Further developments were Council Directive 97/42/EC¹³ amending for the first time Directive 90/394/EEC and Council Directive 99/38/EC¹⁴ amending for the second time Directive 90/394/EEC and extending it to mutagens.

In its communication "Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006¹⁵", the Commission announced its intention to propose extending the scope of the directive on "carcinogenic agents". The Commission pointed out the need of adapting existing directives to changes in scientific knowledge, technical progress and the world of work.

⁸ Lam T H, Ho L M et al: Environmental tobacco smoke exposure among police officers in Hong Kong. *Journal of the American Medical Association* 2000; 284: 756-763.

⁹ McGhee S M, Adab P, et al: Passive smoking at work: the short term cost. *Journal of Epidemiology and Community Health* 2000; 54: 673-676.

¹⁰ McElgunn B: Reproductive and developmental hazards in the workplace. *Clin Excell Nurse Pract* 1998 May; 2 (3): 140-5.

¹¹ Sheiner EK, Sheiner E, Hammel RD, Potashnik G, Carel R: Effect of occupational exposures on male fertility: literature review. *Ind. Health*. 2003 Apr; 41 (2): 55-62.

¹² OJ L 196, 26.7.1990, p. 1.

¹³ OJ L 179, 8.7.1997, p. 4.

¹⁴ OJ L 138, 1.6.1999, p. 66.

¹⁵ COM(2002) 118 final.

In this respect, the Council, in its "resolution on a new Community strategy on health and safety at work (2002-2006)", called on the Commission to submit to it any proposal needed for achieving the objectives set out in the new strategy and in particular those needed to consolidate, simplify and rationalise the existing legal framework and adapt it to technical progress, so that existing legislation can be better enforced¹⁶.

In this context, the "resolution of the European Parliament on the Commission communication: Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006" welcomed the commitment taken by the Commission to extending the scope of the "Carcinogenic Agents Directive", but warned that a more comprehensive approach was required; legislation should set exposure limits on priority dangerous substances, demanded that substitutes be used wherever possible and workers' interests were reflected in environmental, commercial and other initiatives on chemical products¹⁷.

The Nice European Council approved the European Social Agenda¹⁸, which identifies as a priority for action to adapt existing standards on health and safety at work.

The proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemical Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} {SEC(2003 1171)}¹⁹, presented by the Commission, proposed an authorisation for substances of very high concern. This group includes substances that are carcinogenic, mutagenic or toxic to reproduction; persistent organic pollutants; substances which are persistent, bioaccumulative and toxic; substances which are very persistent and very bioaccumulative; and endocrine disrupters.

On an international level, and with reference specifically to tobacco smoke, the Community and its Member States are finalising the signature and ratification of the Framework Convention on Tobacco Control, the first global treaty of its kind. Protection from exposure to tobacco smoke is the subject of Article 8 and Parties to the Treaty shall provide for "protection from exposure to tobacco smoke in indoor workplaces" by the adoption of "effective legislation, executive, administrative and/or other measures"²⁰.

In the context of Article 138(2) of the Treaty, the Commission thus proposes to consult the social partners on further Community initiatives aimed to further improve the protection of workers by extending the scope of the "Carcinogens Directive" to reproductive toxicants, by revising the OELVs for the carcinogens listed in the Directive, by establishing OELVs for some substances not yet included in the Directive, and by introducing the possibility of indicative OELVs for carcinogens, mutagens and substances toxic for reproduction.

¹⁶ OJ C 161, 5.7.2002, p. 1.

¹⁷ A5-0310/2002 final.

¹⁸ <http://ue.eu.int/en/Info/eurocouncil/index.htm>

¹⁹ COM(2003) 644 final.

²⁰ <http://www.who.int/features/2003/08/en/>

3. PROTECTION OF THE HEALTH AND SAFETY OF WORKERS FROM CARCINOGENS AT NATIONAL LEVEL

All Member States have communicated to the European Commission the provisions of national laws adopted to implement Council Directive 90/394/EEC and Council Directive 97/42/EC. The deadline for bringing into force the laws, regulations and administrative provisions necessary to comply with Directive 99/38/EC was April 2003.

The Commission submitted a questionnaire on national legislation on OELVs for carcinogens to the members of the National Expert Working Group on Occupational Exposure Limits²¹ in March 2003. The following conclusions can be drawn from the replies of Member States to this questionnaire and/or a review of national legislation²²:

- There is a marked difference in the number of OELVs for carcinogens, regulated under national legislation, between the Member States. The figure varies between three and one hundred.
- Austria, Belgium, Denmark, France²³, Germany²⁴, Ireland, Spain, Finland, the Netherlands²⁵, Sweden²⁶ and the UK include a bigger number of OELVs for carcinogens in their legislation.

In some Member States, such as France, Denmark, Germany, the Netherlands, Sweden and the UK, OELVs for carcinogens are based on a scientific health risk assessment and take into consideration technical, socio-economic and measurement concerns. In other Member States, OELVs are the result of a critical evaluation of the exposure limits established by the first group of Member States and the American Conference of Governmental Industrial Hygienists (ACGIH).

Regarding environmental tobacco smoke, the legal situation differs widely across the Member States²⁷. A number of Member States have restrictions on smoking in the workplace and impose varying degrees of obligations on employers in this regard. Other Member States restrict smoking in public places. Several Member States are planning to adopt new laws in the near future.

²¹ The role of the National Experts Working Group on OELVs is defined in the document "Establishment of Occupational Exposure Levels in the European Community", 5/5191/94 EN, of 27.01.94, adopted by the Advisory Committee on Safety, Hygiene and Health Protection at Work on 5.07.94.

²² http://europe.osha.eu.int/good_practice/risks/ds/oel/members.stm

²³ INRS: Valeurs limites d'exposition professionnelle aux agents chimiques en France. Cahiers de notes documentaires – Hygiene et securite du travail. Numero 174, 1er trimestre 1999, reimpression 2003.

²⁴ Deutsche Forschungsgemeinschaft: List of MAK and BAT Values 2002. Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area. Report No. 38. Wiley-Vch. Weinheim.

²⁵ Ministerie van Sociale Zaken en Werkgelegenheid: Nationale MAC-lijst 2002. Sdu Uitgevers. Den Haag, 2001.

²⁶ Swedish Work Environment Authority: Occupational exposure limit values and measures against air contaminants. Statute Book of the Swedish National Board of Occupational Safety and Health. AFS 2000: 3.

²⁷ http://www.smokeatwork.org/summary_index.htm; <http://www.euro.who.int/Document/E80607.pdf>

4. PROTECTION OF HEALTH AND SAFETY OF WORKERS FROM CARCINOGENS AND MUTAGENS AT COMMUNITY LEVEL

Community action in this area is possible under Article 137 of the EC Treaty.

In this respect, Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)²⁸ as amended by Directives 97/42/EC²⁹ and 1999/38/EC³⁰ has as main objective to protect workers' health and safety against risks specifically arising or likely to arise from exposure to carcinogens and mutagens at work. To this end it lays down minimum requirements concerning carcinogens and mutagens, including limit values.

The Directive establishes that if there is a risk of exposure to carcinogens or mutagens, the nature, degree and duration of the exposure and the risk to the workers' health and safety must be determined in order to assess the risks and to take to appropriate precautionary measures.

According to the Directive, it is the duty of the employer to reduce the use of a carcinogen or mutagen by replacing it with a substance, preparation or process which is less dangerous or not dangerous. If it is not technically possible to carry out such substitution, the employer must ensure that the carcinogen is manufactured and used in a closed system. Where neither of these precautions is possible, the employer must reduce the level of exposure to a carcinogen or mutagen to as low a level as is technically possible.

Furthermore, the Directive list a number of measures to which the employer must adhere when a carcinogen or mutagen is used:

- (a) limitation of the quantities of a carcinogen or mutagen at the place of work;
- (b) keeping as low as possible the number of workers exposed or likely to be exposed;
- (c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;
- (d) evacuation of carcinogens and mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
- (e) use of existing appropriate procedures for the measurement of carcinogens and mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
- (f) application of suitable working procedures and methods;

²⁸ See footnote 12.

²⁹ See footnote 13.

³⁰ See footnote 14.

- (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
- (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
- (i) information for workers;
- (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens and mutagens;
- (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
- (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;
- (m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

The employers shall, when requested, make available to the competent authority appropriate information on:

- (a) the activities and/or industrial processes carried out, including the reasons for which carcinogens and mutagens are used;
- (b) the quantities of substances or preparations manufactured or used which contain carcinogens or mutagens;
- (c) the number of workers exposed;
- (d) the preventive measures taken;
- (e) the type of protective equipment used;
- (f) the nature and degree of exposure;
- (g) the cases of replacement.

The employer shall also ensure that workers and/or workers' representatives receive sufficient and appropriate training on the basis of all available information concerning the potential risks to health, the precautions to be taken to prevent exposure, etc. In particular, the employer shall inform workers of installations and related containers containing carcinogens or mutagens, ensure that all containers, packages and installations containing carcinogens or mutagens are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Reinforced health surveillance is foreseen and the practical recommendations for the health surveillance are given in annex II.

Annex III sets limit values on the basis of the available information, including scientific and technical data. At present, Annex III includes only limit values for benzene, vinyl chloride monomer and inhalable hardwood dust.

Directive 83/477/EEC³¹ on the protection of workers from the risks related to exposure to asbestos at work, as amended by Directive 2003/18/EC³², provides a limit value for asbestos.

Regarding substances toxic to reproduction, Council Directive 92/85/EEC³³ on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding provides protection for the pregnant woman and the unborn child.

This Directive imposes a number of obligations on employers. These include:

- Assessment of any risks to safety or health and any possible effect on the pregnancy or on breastfeeding for workers; and
- Taking the necessary measures to ensure that exposure of workers to any such risks is avoided (applying protective measures or moving the worker to another job or granting leave in accordance to national legislation and/or national practice to protect the worker's health).

Annex I incorporates a non-exhaustive list of agents, processes and working conditions for which the employer needs to assess the nature, degree and duration of exposure for pregnant or breastfeeding workers in the establishment of concern. The chemical agents included in Annex I are:

- a) substances labelled R40, R45, R46 and R47³⁴ under Directive 67/548/EEC in so far as they not yet appear in Annex II of the Directive;
- b) chemical agents in Annex I to Directive 90/394/EEC;
- c) mercury and mercury derivatives;
- d) antimitotic drugs;
- e) carbon monoxide; and
- f) chemical agents of known and dangerous percutaneous absorption.

Annex II describes the agents and working conditions to which exposure is prohibited. Pregnant and breastfeeding workers are under no circumstances to be obliged to perform duties if a risk has been established from exposure to lead and lead derivatives in so far as these agents are capable of being absorbed by the body.

Council Directive 98/24/EC³⁵ on the protection of the health and safety of workers from the risks related to chemical agents at work provides a binding Occupational

³¹ OJ L 263, 24.9.83, p. 25.

³² OJ L 97, 15.4.03, p. 48.

³³ OJ L 348, 28.11.92, p. 1.

³⁴ Note that R47 has been replaced by R60 and R61.

Exposure Limits Value for inorganic lead and its compounds. Lead has been classified toxic for reproduction for humans.

Regarding environmental tobacco smoke, several health and safety at work Community directives have already established restrictions on smoking at work. This is the case of Directive 89/654/EEC³⁵ that mentions that measures must be introduced for the protection of non-smokers against discomfort caused by tobacco smoke, in rest areas and rest rooms. In addition, Directive 90/394/EEC³⁷ provides for the use of "non smoking" signs in areas where workers are exposed or likely to be exposed to carcinogens. Directive 83/477/EEC³⁸, on the protection of workers from the risks related to exposure to asbestos at work, establishes the obligation to constitute areas where there should be no smoking. Moreover, Directive 92/85/EEC³⁹ lists carbon monoxide as one of the chemical agents for which the employer should assess the nature, degree and duration of exposure of pregnant workers and workers who have recently given birth or are breastfeeding. This shall be followed by further action by the employer to ensure that the exposure of these workers to such risk is avoided.

The Health and Safety Framework Directive 89/391/EEC⁴⁰ establishes as an obligation on the employer to be in possession of an assessment of the risks to safety and health at work, including those facing groups of workers exposed to particular risks. Therefore, passive smoking should be considered in the risk assessment and appropriate preventive measures implemented, if necessary.

Several health and safety at work directives include provisions on ventilation and sufficient fresh air in enclosed workplaces. This is the case of Directives 89/654/EEC⁴¹, 92/57/EEC⁴², 92/91/EEC⁴³ and 92/104/EEC⁴⁴.

In addition, Council recommendation on the prevention of smoking and on initiatives to improve tobacco control⁴⁵ provides that Member States implement legislation and/or other effective measures to protect from exposure to environmental tobacco smoke in indoor workplaces. Moreover, the World Health Organisation Framework Convention on Tobacco Control, signed by the European Commission on 16 June 2003, establishes that countries shall adopt and implement effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces⁴⁶. In this line, the Senior Labour Inspectors Committee will organise a thematic day on passive smoking at the workplace in Dublin during the Irish Presidency. It is foreseen that examples of good practice and existing national legislation in the Member States will be presented and debated.

³⁵ OJ L 131, 5.5.98, p. 11.
³⁶ OJ L 393, 30.12.89, p.1.
³⁷ OJ L 196, 26.7.90, p.1.
³⁸ OJ L 263, 24.9.83, p.25.
³⁹ OJ L 348, 28.11.92, p.1.
⁴⁰ OJ L 183, 29.6.89, p.1.
⁴¹ OJ L 393, 30.12.89, p.1.
⁴² OJ L 245, 26.8.92, p.6.
⁴³ OJ L 348, 28.11.92, p.9
⁴⁴ OJ L 404, 31.12.92, p.10.
⁴⁵ OJ L 22, 25.1.2003, p. 31.
⁴⁶ <http://www.who.int/features/2003/08/en/>

5. THE IMPORTANCE OF COMMUNITY ACTION AND A POSSIBLE APPROACH AT COMMUNITY LEVEL

Thus although Community legislation on the protection of the health and safety of workers applies to carcinogens there is a high percentage of European workers still exposed at levels that can be considered beyond safety⁴⁷.

Regarding substances toxic to reproduction, Community legislation does not cover specifically male workers or female workers outside pregnancy, breastfeeding or having recently given birth.

Occupational cancer has enormous costs for companies and the whole society. 2000 figures estimate that one occupational cancer death cost Member States an average of €2.14 million⁴⁸. This includes only medical care, lost output and human costs. The costs of the overall occupational cancer deaths arising from exposure to chemicals would be around €70 billion annually.

There are recognisable differences both between countries and also within countries, between sectors, in relation to occupational carcinogens, mutagens and reproductive toxicants and the practical action taken to address them.

At present, Directive 90/394/EEC includes limit values only for three carcinogens. So, some Member States only avail of OELVs for a few carcinogens. On the other hand, other Member States have listed a considerable number of OELVs for carcinogens in their national legislation. This has resulted in a great variety of protection levels within the European Union.

Moreover, the current process of setting OELVs for carcinogens is cumbersome, time consuming and it cannot react quickly enough to new scientific data that would advise a review of the value. OELVs may be adopted by the Council and transposed by Member States many years after the production of the scientific review that justifies the value.

In the light of the subsidiarity principle, the gaps in Community law and national legislation in this area show that action at Community level should be considered with a view to:

- extending Directive 90/394/EEC to substances toxic to reproduction, for male workers, female workers outside pregnancy, breastfeeding or having recently given birth
- establishing OELVs for carcinogens and substances toxic to reproduction not yet listed in the Directive.
- revising OELVs for carcinogens listed in the Directive.
- introducing the possibility to adopt indicative OELVs for carcinogens, mutagens and reproductive toxicants to simplify and better adapt the procedure to technical progress.

⁴⁷ See footnote 2.

⁴⁸ See footnote 1.

The Commission would propose OELVs for carcinogens, mutagens and reprotoxic substances, on the basis of number of exposed workers, type of exposure, scientific knowledge, technical progress, socio-economic impact and the existing national OELVs. In addition, the Commission would propose revised limit values, if appropriate, for the three substances already included in Annex III of Directive 90/394/EEC, taking into account changes in scientific knowledge, technical progress and the world of work. Hence, an initiative in this field would be proportionate and respect the principle of subsidiarity.

6. TOPICS FOR CONSULTATION

In the light of the above, the social partners are invited to answer the following questions:

- (1) Do you consider it advisable to take an initiative in this area? In particular, do you think that the absence of measures in this area has an adverse impact on the protection of the safety and health of workers?
- (2) If so, should this initiative be taken at Community level?
- (3) If so, do you share the Commission's view as to how the Community should approach the problem, namely by initially encouraging Member States to take the necessary measures on a voluntary basis, or do you consider that a binding instrument is called for from the outset?