European Trade Union Confederation (ETUC)
Confédération européenne des syndicats (CES)

Second stage of consultation of the social partners on the protection of workers from risks related to exposure to carcinogens, mutagens and substances toxic for reproduction

ETUC RESPONSE

INTRODUCTION

The International Agency for Research on Cancer (IARC) most recent estimates claim 2.3 million new cases of cancer and over a million cancer deaths in the European Union in 2006. Some of these cancers are directly caused by working conditions. Others are the result of environmental exposures which, in many cases, are themselves related to firms' business activities. Even putting a conservative estimate of 8% on working conditions-related cancers (ILO, 2005), it is clear that with over 80 000 deaths per year, the work-related cancer mortality far outweighs the death rate from work accidents, and is probably the main cause of working conditions-related deaths in Europe.

The most common exposures to carcinogens at the workplace are solar radiation, environmental tobacco smoke, crystalline silica, diesel exhaust, radon decay products, wood dusts; aromatic and aliphatic compounds, halogenated derivatives, organic nitrogen compounds and some heavy metals.

The Carcinogens Directive 2004/37/EC[1] adopted in 1990 sets a hierarchy of obligations to employers in order to protect workers from risks related to exposure to carcinogens. The first of these measures is the obligation to eliminate or replace the carcinogen or mutagen with a substance which is not dangerous or is less so. Should such substitution prove technically impossible, the employer must ensure that the production or use of the carcinogen or mutagen takes place in a closed system. If this precaution cannot be taken, the employer must ensure that the worker's level of exposure is reduced to a level as low as is technically possible. The Directive also makes provision for the introduction, where possible, of occupational exposure limit values.

Nevertheless, the Carcinogens Directive has several drawbacks. It only covers substances meeting the criteria for classification as carcinogens and mutagens category 1 and 2 in accordance with Directive 67/548/EEC. The numerous reprotoxic substances used at the workplace are therefore out of the scope of the Directive. Moreover, in 17 years time only three carcinogens (benzene, vinyl chloride monomer and hardwood dusts) have been given a binding occupational exposure limits because of the cumbersome and time consuming procedure defined in the Directive.

Revision of the Carcinogens Directive was one of the big measures flagged up in the Commission's strategy on health and safety at work 2002 -2006. Before taking a Community initiative in this area, the Commission consults the social partners under article 138 of the EC Treaty. There are two compulsory phases in the procedure: the Commission first consult the social partners on the possible direction of Community action; then, it consults them on the content of the proposed measure.

[1] codified version of Directive 90/394/EEC

The first phase consultation was launched in April 2004 and ETUC after an internal consultation of its member organisations and the opinion adopted by its Executive Committee gave positive responses to the four questions put by the Commission[2].

In the view of ETUC, there is a need:

- to extend the scope the Carcinogens Directive (2004/37/EC) to reprotoxic substances;
- to revise the three existing binding occupational exposure limits values listed in the directive;
- to set exposure limits for additional substances not yet listed in the directive;
- to revise the current Community process of setting exposure limit values for carcinogens.

On 9th March 2007, three years after the first phase of the consultation, the Commission launched the second phase in order to obtain the opinion of the European social partners on the content of a possible Community proposal in this area.

After consultation of its member organisations, ETUC is pleased to respond hereunder to the questions put by the Commission for the second phase of the consultation.

QUESTIONS PUT BY THE COMMISSION FOR THE SECOND STAGE OF THE CONSULTATIONS WITH THE SOCIAL PARTNERS

Question 1: What is your opinion or, where appropriate, your recommendation on the objectives and content of the Commission planned proposal pursuant to Article 138(3) of the Treaty establishing the European Community?

ETUC welcomes the Commission planned initiative to strengthen prevention and adopt better measures to protect the health of European workers from exposure to carcinogens, mutagens and reprotoxic substances. The Commission intention of extending the Carcinogens Directive (2004/37/EC) to include substances toxic to reproduction is particularly appreciated. ETUC also welcomes the proposed revision of the binding occupational exposure limits values (BOELVs) for carcinogens listed in the Directive and the Commission's intention to establish BOELVs for additional carcinogens, mutagens and reprotoxic substances (CMRs) not yet included in the Directive.

Question 2: Should the scope of Directive 2004/37/EC be extended to include category 1 and 2 reprotoxic substances ?

ETUC confirms that the scope of Directive 2004/37/EC should be extended to include substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC. The main reasons are:

1) 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. Therefore, such health effects have to be prevented and levels of protection of workers have to be raised by applying

[2] http://hesa.etui-rehs.org/uk/dossiers/files/20-Res-ConsultCancerRep-gb.pdf

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) Including reprotoxic substances in the scope of the Carcinogens Directive would be in line with the REACH requirements for substances of very high concern which include, *inter alia*; category 1 and 2 reprotoxicants (R) in addition to category 1 and 2 carcinogens (C) and mutagens (M). This would also increase the synergies between the two pieces of legislation.

In addition, ETUC would like to stress that substances meeting the criteria for classification as CMR category 1 and 2 in accordance with Directive 67/548/EEC cover not only CMR category 1 and 2 substances actually included in annex I of Directive 67/548/EEC but also more broadly any substance or agent that meets these classification criteria. This means that substances which for some reason have not been included in the Community classification, but are nevertheless known CMRs can be brought by Member states within the Directive's scope.

Question 3: Should the binding occupational exposure limit values (BOELVs) for the three substances included in Annex III to Directive 2004/37/EC be updated ?

ETUC is of the opinion that the BOELVs set for the three carcinogenic substances currently listed in the directive (benzene, vinyl chloride monomer and hardwood dusts) must be updated to take into account the latest technical and health-related data. This should also be the case for all other limit values set at Community level either indicative or binding.
In particular, there is also a need to revise the BOEL for lead and its derivatives under Directive 98/24/EC which is outdated. Norway has for example adopted a value which is more stringent than the Community limit value.

Question 4: Should binding limit values for more substances be included in Directive 2004/37/EC ?

ETUC is of the opinion that additional BOELVs for carcinogens, mutagens and reproductive toxicants not yet included in the Directive are necessary to ensure equivalent protection for all workers of both sexes in the European Union. In the view of ETUC, the inclusion of BOELVs for additional substances in the Directive must only be an adjunct to the principles defined in Directive 2004/37/EC, namely the principle of substitution and the hierarchy of protective and preventive measures accompanying the implementation of the ALARA[3] principle.

[3] ALARA: as low as reasonably achievable

In that framework, ETUC calls on the Commission to both recognise that respirable crystalline silica from occupational sources is a carcinogen for human and to adopt an occupational exposure limit for it at Community level. It should indeed be recalled that in Europe up to 4 million workers are exposed to crystalline silica dusts at the workplace. IARC has classified crystalline silica inhaled from occupational sources in the group of substances carcinogenic to humans in 1996 and the EU's Scientific Committee for Occupational Exposure Limits (SCOEL) has recommended an OEL for crystalline silica in 2002. Most of EU countries have also their own statutory OEL for crystalline silica which differs from country to country. As a consequence not all European workers have an equivalent protection from risks related to exposure to crystalline silica.
In April 2006, an autonomous inter-sectoral agreement has been signed by 15 EU employers' organisations and two European industry unions with the aim to minimise exposure to respirable crystalline silica at work by applying Good Practices.
Since the agreement does not cover all the workers who are exposed to crystalline silica dust[4], ETUC asks the Commission to bring in legislation on crystalline silica to ensure that the principle of equivalent protection for all EU workers provided for in the framework directive 89/391 is carried out. Should future Community legislation on respirable crystalline silica be proposed, ETUC is convinced that it would generate synergies with the autonomous agreement and bring in new signatories.

In addition, ETUC calls on the Commission to include dust from soft wood under the scope of the Directive. From our point of view, scientific evidence of the carcinogenic properties of soft wood dust is already existing for a long time and there is no reason for the Directive to cover wood dust from hard wood only.

Question 5: What should be the criteria or the process for setting binding occupational exposure limit values for carcinogenic, mutagenic and reprotoxic substances ?

In the view of ETUC the setting of occupational exposure limit values (OELVs) for carcinogenic, mutagenic and reprotoxic (CMR) substances should be based on the following principles:

1. Occupational exposure limit values for CMR substances should be a supplemental regulatory instrument for a secondary aim, that is minimization of exposure, which sets in if, and only if, the primary aim of avoiding exposure completely cannot be achieved.
2. Since ETUC is of the opinion that limit values for CMR substances should have a different regulatory function compared to OELVs for non-carcinogens, for the former a different term to “OELV” should be used.
3. If limit values for carcinogens are derived at Community level, such limits should be binding ones.
4. Limit values for CMR substances should consist of two components: an exposure level and an associated level of quantitative risk
5. The risk level that determines the limit values for CMR substances should be so low that the derived limit values are considerably below the technical-based OELVs for the respective substances; only under this precondition can the risk-based limit value achieve its intended function as a driver for further exposure reduction.

[4] The Building workers' federation refused to sign the agreement, meaning that it will not apply to over 2 million workers in that sector.

6. The dose-risk relations for individual CMRs, which are needed to translate the general target risk into substance-specific limit values, have to be derived by SCOEL according to a sound scientific methodology. For each CMR substance, the derivation has to be made transparent in a scientific documentation publicly available.
7. To avoid any confusion about the proposed regulatory nature of limit values for CMR substances, those limit values should be published in a list separate from the one for OELVs for non-CMR substances.

Question 6: How existing measures on training and information requirements could be implemented more effectively ? What are the ways to improve coordination and sharing of information ?

ETUC is convinced that REACH, the recently adopted reform of EU legislation on marketing and use of chemicals will be an opportunity to improve the effectiveness of the existing EU legislation for the protection of workers exposed to chemicals (mainly Chemical Agents Directive 98/24/EC and Carcinigens Directive 2004/37/EC). The data generated by REACH should foster a better knowledge of the properties of chemical substances, their effects on human health and ways of reducing and minimising risk during their use. It should also greatly improve the transmission of such data along the entire length of the supply chain, thanks to better quality labeling and safety data sheets. In addition, the authorisation and restrictions procedures provided for in REACH should promote the substitution of the most harmful substances by less hazardous ones. REACH will therefore enhance the EU directives on worker protection in various ways, and will promote their implementation by employers in the workplace.

However, as the guidelines to help industry comply with REACH requirements are still under construction, ETUC recommends that the Commission makes sure that the guidelines for the authorisation procedure and the chemical safety report under REACH are fully in line with the provisions provided for in the workers protection legislation and in particular the hierarchy of risk management measures defined in Directive 98/24/EC and Directive 2004/37/EC.

In addition, as REACH shall apply without prejudice to the Carcinogens Directive, ETUC calls on the Commission to find out the best synergies between the two pieces of legislation and clarify the relationships between the occupational exposure limits (OELVs) in the worker protection legislation and the derived no-effect levels (DNELs) under REACH.

Based on the data generated by REACH, ETUC also recommends that the Commission sets up a strategy to improve coordination and sharing of information at EU level as regards as the availability of safer alternatives to chemicals of very high concern. The Commission should also coordinate the collection of exposure data to CMR substances at the workplace in order to monitor the evolution of workers' exposure to CMRs and set priorities for legislative actions.

Of course, the REACH reform will not be sufficient in itself to solve all the problems of occupational diseases related to exposure to CMR substances. Even when data exist and are properly communicated, they still have to be put to effective use by recipients in the workplace.

For this reason, other measures will likewise be required in order to improve the effectiveness of the legislation on worker protection: stepping up their representation in the various branches of industry, intensifying the social dialogue at national and European level, providing training for workers and employers about chemical risks, and redoubling checks on compliance with the legislation in the workplace.

Question 7: Could you inform the Commission whether you wish to launch the negotiation procedure on the basis of the proposals described in the second phase consultation document pursuant to Articles 138(4) and 139 of the Treaty and, if so, to specify whether you wish to adopt an overall approach or focus on particular features.

ETUC informs the Commission that our organisation doesn't want to launch a negotiation procedure pursuant to Article 138(4) and 139 of the Treaty. However, ETUC calls on the Commission to propose an amended text of Directive 2004/37/EC on the basis of the proposals described in the second phase consultation document in order to:

- extend the scope the Carcinogens Directive (2004/37/EC) to reprotoxic substances;
- revise the three existing binding occupational exposure limits values listed in the directive;
- set exposure limits for additional substances not yet listed in the directive;
- revise the current Community process of setting exposure limit values for carcinogens.

On the two last points we urge the Commission to take into account the principles proposed by ETUC in drawing the revised Community process of setting exposure limit values for carcinogens and to propose a limit value for respirable crystalline silica at work as a priority.

Finally, given the very long latent period between exposure and the appearance of diseases, ETUC calls on the Commission to revise Article 14 of Directive 2004/37/EC to ensure that workers are entitled to medical checks at regular interval for at least 40 years following the end of exposure to the CMR substances.

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