BUSINESSEUROPE

POSITION PAPER

15 June 2007

SECOND-STAGE CONSULTATION OF THE SOCIAL PARTNERS ON THE PROTECTION OF WORKERS FROM RISKS RELATED TO EXPOSURE AT WORK TO CARCINOGENS, MUTAGENS AND SUBSTANCES TOXIC FOR REPRODUCTION

INTRODUCTION

In its consultation document, the Commission highlights that it

- sees a need to amend Directive 2004/37/EC to bring it in line with new developments in scientific knowledge and technology;
- intends to propose an extension of the scope of the Directive to include substances toxic for reproduction;
- wishes to propose a revision of the binding occupational exposure limit values (BOELVs) for carcinogens already listed in the Directive and establish BOELVs for carcinogens, mutagens and reprotoxic substances not yet included in the Directive;
- wishes to develop clearer criteria for BOELV-setting.

In the light of the above, the Commission invites the social partners to inform it of their positions on the measures which might be envisaged such as:

1) extending the scope of Directive 2004/37/EC to include category 1 and 2 reprotoxic substances,
2) updating binding limit values for substances included in Annex III to Directive 2004/37/EC or,
3) introducing binding limit values for more substances in Directive 2004/37/EC,
4) introducing objective criteria for setting binding occupational exposure limit values for carcinogenic, mutagenic and reprotoxic substances, explaining what these criteria should be and indicating what should be the process for setting new limit values,
5) training and information requirements (e.g. how existing measures could be implemented more effectively, examples of best practice, ways to improve coordination and sharing of information).

Moreover, social partners are asked to inform the Commission about their wish to launch a negotiation procedure in accordance with Articles 138 and 139 of the Treaty.

GENERAL COMMENTS

European employers attach high importance to the protection of workers' health and safety and agree that the effective protection of workers from occupational cancer deserves continuous attention.

Building on its reply to the first-stage consultation, BUSINESSEUROPE highlights the following.

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Reply to question 1:

BUSINESSEUROPE is opposed to the inclusion of category 1 and 2 substances toxic for reproduction in the scope of Directive 2004/37/EC for the following reasons:

The Carcinogens Directive has been specifically conceived for dealing with carcinogens and mutagens, especially those for which a threshold of effect cannot be set, and 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, it is scientifically proven that it is usually possible to identify levels at which exposure does not have an effect. An exposure limit can thus generally be set. Moreover, it is important to note that mechanisms and procedures for dealing effectively with reprotoxic substances differ fundamentally from those employed to deal with carcinogens and mutagens. Reprotoxic substances currently fall under the scope of the Chemical Agents Directive, which provides the correct legislative frame within which to operate, in order to ensure that the exposure to these types of substances can be addressed appropriately, via risk assessment, exposure measurements, setting of limit values, control measures, and training and health surveillance.

There may however be a need for further practical guidance documents on the Chemical Agents Directive, including also a focus on reprotoxic substances.

Reply to questions 2 and 3:

A possible revision of current limit values and/or the introduction of new binding OELVs can only be justified on the grounds of an evaluation of the current directive and new sound scientific evidence. Apart from that, socio-economic impact and technical feasibility factors also need to be fully taken into account in any reflections about the revision of BOELVs.

At the same time, it is important to note that the context has changed now that REACH has entered into force.

REACH requires that manufacturers and importers register category 1 and 2 carcinogens, mutagens and reprotoxic substances (CMRs) of a volume higher than 1 tonne a year and perform a Chemical Safety Assessment covering the complete life cycle of the substance, and consequently exposure of workers. These substances will have to be registered before end-2010 and will be subject to an authorisation process.

Besides registration, REACH requires that category 1 and 2 CMRs undergo an authorisation process after inclusion in annex XIV. Derived No Effect Levels (DNELs) will be set for substances used in a volume of more than 10 tonnes a year and which have a threshold of effect. Derived Minimum Effect Levels (DMELs) are proposed for carcinogens and mutagens for which a threshold of effect cannot be established. DNELs and DMELs for CMRs are currently under discussion. Their relationship and interaction with existing occupational exposure limit values also needs to be further discussed and clarified.

Consequently, REACH will reinforce existing measures and require additional risk management and exposure prevention measures at workplace level.

Furthermore, a specific authorisation procedure will be implemented for substances of very high concern, including category 1 and 2 CMRs, with the objective of substitution.

In the light of this, a revision of the Carcinogens Directive seems premature. It would be more appropriate to look into the issue again after the implementation of REACH, with a view to assessing whether additional action would be justified.

Reply to question 4:

Employer organisations and industry have on different occasions expressed their dissatisfaction with opaque and unsatisfactory OELV-setting procedures at EU level, for IOELVs as well as BOELVs.

Employers and industry are ready to reflect further with the Commission on how to simplify and improve the BOELV-setting procedure for carcinogens and mutagens, even though such a process seems premature for the reasons mentioned above.

Socio-economic impact assessments, the consideration of feasibility factors and of stakeholder input must be considered as guaranteed pillars of a BOELV-setting procedure. Building on its 2006 seminar on OELV-setting for carcinogens, ACSH could also further look into this issue.

Reply to question 5:

Training and information activities targeting workers are a key aspect of prevention policies. The current directive contains detailed provisions on information and training, which are appropriate. BUSINESSEUROPE could however see benefit in the compilation of a compendium of good practice.

CONCLUSION

BUSINESSEUROPE is not in favour of extending the scope of the Carcinogens Directive to reprotoxic substances. These already fall under the scope of the Chemical Agents Directive and can be most appropriately dealt with in that frame. However, further practical guidance to facilitate implementation of the Chemical Agents Directive and incorporating a part on reprotoxic substances could be envisaged.

Any initiative to propose a revision of OELVs for substances currently included under the Carcinogens Directive or to set new OELVs for carcinogens or mutagens within its frame can only be justified on the grounds of an evaluation of the current directive and sound new scientific evidence and must, moreover, take account of socio-economic and feasibility factors.

At the same time, with REACH now in force, category 1 and 2 CMRs will undergo a registration and authorisation process. Consequently, appropriate and additional risk management and exposure prevention measures for CMRs will have to be implemented at the workplace. Considering a revision of the Carcinogens Directive therefore seems premature. It would be more appropriate to look into the issue again after the implementation of REACH, with a view to assessing whether additional action would be justified.

BUSINESSEUROPE does not wish to initiate negotiations in accordance with Articles 138 and 139 of the Treaty.

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