

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

UNICE reply

Introduction

In its consultation document, the Commission argues that a high number of the working population are exposed to carcinogens at the workplace. It states that the most common exposures at the workplace are solar radiation, environmental tobacco smoke, crystalline silica, diesel exhaust, radon decay products and wood dust. It highlights moreover that workers are also exposed to reprotoxic substances. The Commission therefore sees a need to consult the social partners on the possibility to revise the Carcinogens Directive¹ and extend its scope. More concretely, the Commission announces that it intends to look further into:

- proposing an extension of the scope of the current Directive to substances toxic for reproduction;
- proposing the revision of the occupational exposure limit values (OELVs) for carcinogens currently included in the Directive;
- establishing OELVs for some carcinogens, mutagens and reprotoxic substances not yet included in the Directive;
- introducing the possibility of indicative OELVs for carcinogens, mutagens and reprotoxic substances to simplify procedures and enable better adaptation to progress.

In the light of the above, it invites the social partners 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?

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.

¹ Council Directive 90/394/EC on the protection of workers from the risks related to exposure to carcinogens at work, Official Journal L 196, 26 July 1990.

Vigorous efforts have been undertaken to prevent the exposure of workers to unsafe levels of carcinogens and prevent occupational cancer. The long latency periods for cancer mean that these efforts are not yet always widely reflected in statistics for occupational diseases which rather reflect exposures of the past.

In its introduction, the Commission bases its argument for revising the Carcinogens Directive on flawed, unproven and misleading statements and data, which do not do justice to the seriousness with which this topic should be treated. UNICE invites the Commission to avoid using single sources that lack scientific rigour and credibility

UNICE stresses the fact that there are different initiatives that have been taken or are currently being developed on chemical agents at EU level and that much more attention needs to be paid to the way they might interact or conflict (particularly the Chemical Agents Directive², the Carcinogens Directive and REACH). It is important not to seek to move an issue forward on so many fronts that priorities are blurred and inconsistencies are generated.

Before taking any steps towards revising the Carcinogens Directive, the Commission should assess the implementation and impact of the current Directive. Moreover, any proposals for revision of the current Directive must build on new sound scientific evidence, which would justify change, as well as take into account socio-economic impacts and feasibility factors.

Specific comments

On the possible extension of the scope of the directive to solar radiation, environmental tobacco smoke, diesel exhaust, crystalline silica, radon decay products and wood dust

Exposure to solar radiation, environmental tobacco smoke (passive smoking), crystalline silica and radon decay products can have a carcinogenic potential, but this does not mean automatically that these exposure situations must therefore be dealt with as a priority issue or would qualify for consideration under the Carcinogens Directive.

It needs to be noted that cancers which develop after exposure to crystalline silica most often affect persons who already have pulmonary silicoses and are observed after exposure to high levels of dust. In addition, it is important to remember that, when IARC classified crystalline silica as a “group 1 human carcinogen” in 1997, it took the precaution of mentioning that it had noticed that the carcinogenicity of silica for humans is not found in all the circumstances of industrial exposure studied. Moreover, at EU level, crystalline silica has so far not been classified as a group 1 or 2 human carcinogen. Equally, diesel engine exhaust, which has been classified by IARC in group 2A, has not been classified as a group 1 or 2 human carcinogen at EU level. Giving priority to this substance in the Carcinogens Directive therefore seems unjustified.

Moreover, possible exposure situations to the above-mentioned agents, particularly solar radiation environmental tobacco smoke, diesel engine exhausts and radon decay products, are far from being exclusively limited to the workplace, which may generally lead to uncertainties with regard to determining the origin, whether occupational or not, of a health problem. Moreover, only very specific professions may be concerned by sometimes higher occupational exposure situations with regard to one or the other agent. UNICE believes that these agents call for different approaches than the one provided by the Carcinogens Directive or the legislative route. A particular focus should be put on practical guidance and enhanced sectoral prevention efforts.

² Directive 98/24/EC, Official Journal L 131, 5 May 1998

Considering solar radiation and environmental tobacco smoke in particular under the Carcinogens Directive seems absurd, as these agents are not substances used or generated in industrial processes. Moreover, several provisions of the directive, such as Articles 4, 5 and 6 prescribing the substitution of substances or the use of closed systems in cases where substitution is not possible, clearly demonstrate that the directive has not been developed in order to deal with such exposures.

More generally, passive smoking is a public health issue that has been addressed in many Member States in a way that also provides for satisfactory solutions at the workplace. UNICE therefore sees no need for action at EU level. Generally, where national legislation, agreements between social partners or individual company policies do not yet address this issue, employers suggest that practical solutions are found at appropriate levels.

UNICE recalls that hardwood dust is included in the scope of the directive, but stresses that this has led to substantial implementation and practical application problems in several countries, because the requirements of the directive had to be interpreted to some extent in order for the provisions to be workable at all.

On the possible extension of the scope of the directive to reprotoxic substances

UNICE is opposed the inclusion of substances toxic to reproduction in the scope of this Directive for the following reasons:

- 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 and UNICE refutes the Commission’s statement on page 9 where it argues that “regarding substances toxic to reproduction, Community legislation does not cover specifically male workers or female workers outside pregnancy, breastfeeding or having recently given birth”.
- There may however be a need for additional emphasis on the coverage and proper application of the Chemical Agents Directive and for this purpose practical guidance documents, incorporating a part on reprotoxic substances, may be helpful.

On the possible revision of the current limit values set out in the Carcinogens Directive and the introduction of additional new binding OELVs

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

Secondly, in this context, UNICE would like to recall the ACSH employer group’s list of priority substances for OEL-setting dated November 2002, which is based on the work done by the national expert working group (NEWG). UNICE invites the Commission to take due

account of it in any further thinking about extending the scope of the current Directive and proposing the setting of other binding OELVs on carcinogens and mutagens.

On the possible introduction of indicative OELVs (IOELVs) under the scope of the Carcinogens Directive

Currently, the OELVs set under the Carcinogens Directive are binding. Employers fully oppose considerations to introduce indicative OELVs under the Carcinogens Directive for the following reasons:

- overall highly unsatisfactory experiences with IOELV-setting procedures currently in place;
- heterogeneous handling of IOELVs at national level and resulting distortions of competition;
- only the establishment of BOELVs takes into account science, socio-economic impact, technical feasibility and analytical measurability and thus is more likely to lead to the setting of safe, but workable limit values.

These arguments make BOELVs the preferred route to deal with carcinogens and mutagens.

UNICE believes generally that OELV-setting is most appropriately undertaken at the Community level, as it contributes to harmonising the level of protection regarding workers' health and safety in the EU. However, 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. However, employers and industry are ready to further reflect with the Commission to simplify but improve the BOELV-setting procedure, provided that socio-economic impact assessments, the consideration of feasibility factors and of stakeholder input into the discussion are guaranteed pillars of such a procedure. In this context, UNICE would also like to recall that work on this question is currently going on within one of the ACSH working parties.

Conclusion

Reply to question 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?)

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 sound new scientific evidence and must take account of socio-economic and feasibility factors.

UNICE stresses that the inclusion of solar radiation, environmental tobacco smoke, crystalline silica, diesel exhaust and radon decay products in the scope of the directive is not pertinent and does not point in the right direction in terms of how these issues could be most appropriately addressed.

UNICE believes that these agents call for different approaches than those provided for by the Carcinogens Directive or the legislative route. A particular focus should be put on practical guidance documents and enhanced sectoral prevention efforts.

Finally, UNICE 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.

Reply to question 2:

(If so, should this initiative be taken at Community level?)

UNICE believes generally that OELV-setting with regard to carcinogens and mutagens is most appropriately undertaken at the Community level provided there is sound scientific evidence to justify considering OELV-setting. The setting of OELVs at EU level generally contributes to harmonising the level of protection regarding workers' health and safety in the EU and fosters a level playing field for companies.

UNICE suggests that there may be a need for the practical guidance that is currently elaborated at Community level to further facilitate implementation of the Chemical Agents Directive, to incorporate a part on reprotoxic substances.

Reply to question 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?)

UNICE is opposed to enabling the setting of indicative OELVs under the Carcinogens Directive. The setting of binding limit values remains the preferred route to deal with carcinogens and mutagens within its framework.
