

European Trade Union Confederation response to the second stage of consultation with the social partners revisions of Directive 2004/37/EC

Key messages:

- The revision of the carcinogens and mutagens directive needs to address the fundamental needs and expectations from workers and citizens in the European Union.
- It must be part of a global strategy for elimination work related cancer in Europe. The ETUC urges the Commission to adopt a roadmap in 2018 with different initiatives at EU level. These initiatives should take into account all the occupational risks for women and men, including asbestos and solar UV radiation.
- The scope of application of the directive must be revised including reprotoxins by 2019. It should include different work activities with specific risk of cancer like hairdressing, painting or exposure to cytotoxic substances in the health services.
- 50 binding occupational exposure limits (BOEs) should be set in order to cover the majority of workplace exposures. The protection for workers exposed to Crystalline Silica should be improved.
- The process for setting BOELs needs to be more consistent and more transparent.

Introduction

The European Trade Union Confederation (ETUC) welcomes the revision of the Carcinogens and Mutagens Directive 2004/37/EC (CMD). After a long period of paralysis, real progress has been achieved with the final adoption of the text of the first revision in October 2017. We hope that the amendments voted by the European Parliament and by the Council of Ministers will improve the second revision during 2018. This important legislation of the European Union meets fundamental needs and expectations of workers and citizens. The recent trade union study on the costs of work related cancer shows that significant cost savings would be realized with better prevention, in particular for workers and their families, national health systems and social security systems¹.

¹ <http://www.etui.org/content/download/32928/305280/file/J907+Final+Report+9+Nov+2017-2.pdf>

We are surprised by the fact that most of the proposals made by the Commission do not consider any idea submitted by the social partners. We have the feeling that the documents for the second stage of the consultation were largely written before analysing the different responses. Those responses are mentioned in a purely descriptive way in the second section of the Consultation Document, but they are not considered as a substantial contribution for improving the EU strategy for eliminating work related cancer.

We consider that the Consultation Document² and the Analytical Document³ prepared by the Commission should have integrated more systematically the amendments adopted by the Parliament and the Council during the discussion of the first batch. Among those amendments, some recitals define important principles which should inform the on-going revision process. We mention only some of them:

- 1) Providing “a consistent level of protection from the risks related to carcinogens and mutagens” (see new recital 1 adopted with batch 1);
- 2) “The limit values set out in this Directive should be revised where necessary in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure-level measurements at the workplace. That information should, if possible, include data on residual risks to the health of workers and opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL) and of the ACSH. Information related to residual risk, made publicly available at Union level, is valuable for future work to limit risks from occupational exposure to carcinogens and mutagens, including by revising the limit values set out in this Directive. Transparency of such information should be further encouraged » (see new recital 6);
- 3) “Appropriate and consistent data collection by Member States from employers is necessary to ensure the safety and proper care of workers. The Member States are to provide the Commission with information for the purposes of its reports on the implementation of Directive 2004/37/EC. The Commission already supports best practice with regard to data collection in Member States and should propose, as appropriate, further improvements to the data collection required pursuant to Directive 2004/37/EC” (see new recital 8);
- 4) “This Directive strengthens the protection of workers' health and safety at their workplace. Member States should transpose this Directive into their national law. They should ensure that competent authorities have sufficient numbers of trained staff and other resources necessary to carry out their tasks related to the proper and effective implementation of this Directive, in accordance with national law or practice. Application of this Directive by employers would be facilitated if they had guidance, where relevant, to identify better ways to achieve compliance with this Directive” (see new recital 28).

² C(2017) 7466 final, 10 November 2017.

³ SWD(2017) 370 final, 10 November 2017.

We are also surprised by the vague wording of many sections of the Commission “Consultation document”. The Document states that “some agents and processes suggested by the workers’ organisations fall outside of the scope of the CMD and thus are not considered in this consultation paper”. We would like to know which agents and processes are considered in that sentence. If it is about asbestos or electromagnetic fields, the issue is obvious. We never asked the Commission to consider them in the revision of the CMD. If it is about cytotoxic drugs, rubber dust and fumes or leather dust, we are still convinced that they are relevant for the CMD and that their exclusion from the scope of application of the directive reflects a very narrow interpretation of the Annex I.

The Analytical Document does not provide sufficient information on many issues. It does not contain gender disaggregated data. It does not indicate which substances (apart from the nine chemicals already in the pipeline for batch 3 and batch 4) are envisaged for future developments in order to reach the objective of 50 binding occupational exposure limits (BOELs) by 2020. It does not explain the criteria for selecting the 9 agents under consideration. It reflects a poor level of cooperation with Member States, where the processes for setting BOELs for carcinogens, mutagens and reprotoxic substances CMRs are more developed.

We won’t repeat all the points already developed in our response for the first stage. We ask the Commission to consider the response for the first stage as a part of our response for the second stage since most of the issues raised by ETUC in September are still pending and should be addressed in future initiatives by the Commission.

1. Scope of application of the directive and annex I

The ETUC insists on including reprotoxins in the scope of application of the directive. This issue was largely explained in the first section of our response to the first stage of consultation.

The revision of annex I is crucial for defining correctly the scope of application of the directive. Annex I is based on the fact that substances are classified only if they are put on the market. When a process is exposing workers to a cancer risk, those process-generated exposures do not necessarily meet the conditions for being classified under the Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

In our view, the wording of the directive must be understood taking into account the objectives it pursues and its context. The central objective of the CMD is to protect workers against the risk of occupational cancer. The role of annex I is to fill any potential gap between a narrow scope of application depending exclusively on the criteria laid down by the CLP Regulation and the reality of work activities involving a risk of occupational cancer. For this purpose, Annex I includes “substance, mixture and process”. Part of the added value of a specific workers’ protection legislation is to cover situations which cannot be adequately regulated by market rules because they adopt a substance based approach and do not consider work activities as such. There is a large body of scientific evidence indicating that specific work activities must be considered

carcinogenic since they imply multiple and complex exposure to carcinogens. In that perspective, the findings of the International Agency for Research on Cancer (IARC) should be taken into account as an important part of the context of the directive. Some monographs of the IARC identify specific work activities like painting, firefighting, hairdressing, rubber manufacturing, aluminium production, iron and steel founding, printing processes, etc... as exposing workers to the risk of occupational cancer. Other monographs deal with complex process-generated chemicals like mists from strong inorganic acids or coal-tar distillation. If we want to elaborate a “time proof” legislation protecting effectively workers against CMRs, annex I must be heavily revised to take account of all the work activities with a risk of occupational cancer.

In order to make more explicit that approach and avoid any legal uncertainty, we consider that an amendment should be introduced in article 2 of the directive and in the title of annex I. Paragraph 2, a, iii and the title of annex I should add the word “occupational exposure” after “substance, mixture and process”. The new wording would therefore be “substance, mixture, process or occupational exposure”. The introduction of the wording “occupational exposure” would strengthen the link between the CMD, and EU activities based on it, and the IARC systematic programme at international level. “Occupational exposure” would be defined as “specific work activity with an occupational exposure to a complex mixture with carcinogenic, mutagenic or reprotoxic effects on the humans”. Such a revision should be introduced with the batch 3 in 2018. The roadmap of Commission should include a list of “occupational exposures” which are envisaged for annex I and precise deadlines about their inclusion. A first list could be based on the IARC monographs. Other data (like findings from NOCCA⁴) should be used.

We implore the Commission to be more consistent with the basic principle sustaining that legislation: it is fundamentally a hazard based legislation. This means that legal standards have been designed taking into account the intrinsic properties of determined substances and processes. At that stage, other considerations like socio-economic analysis provided by an impact assessment are completely irrelevant. The adaptation of the scope of application has to be based exclusively on scientific findings about the potential harm of substances and processes. It is a typically hazard-based provision. What matters is that some processes-generated substances are causing cancer. The causal relation must be considered according to the weight of evidence used across EU legislation. Substances and processes are included when they are known to have carcinogenic potential for humans or they are presumed to have carcinogenic potential for humans. A very similar approach is used by the IARC when it classifies substances or processes as “carcinogenic for humans” or “probably carcinogenic for humans”. We do not accept the Commission view that when proposing new processes for annex I, it

⁴ E Pukkala, J I Martinsen, E Lynge, H K Gunnarsdottir, P Sparén, L Tryggvadottir, E Weiderpass, K Kjaerheim,

Occupation and cancer – follow-up of 15 million people in five Nordic countries, Acta Oncologica, 48- 5, 646-790, 2009.

should be taken into “account an analysis of social, economic and environmental impacts”⁵. If socio-economic considerations might be relevant for adapting annex III, it is not the case for annex I.

We urge the Commission to consider the revision of Annex I independently from the possibility of setting BOELs in annex III. We don’t understand why the documents for the second stage of consultation do not mention at all the important issue of cytotoxic treatments.

2. Revision of Annex III

We agree with the selection of five chemicals for annex III in the third batch and with the first candidate list of four substances for the fourth batch. We consider them only as a minimal list which must be extended to reach the objective of setting 50 BOELs for 2020. The trade union list has been elaborated on the basis of a clear prioritisation criteria. We ask the Commission to consider these chemicals as a priority⁶. Obviously, if during the legislative process, some of those chemicals can be included in the second revision through amendments voted by the European Parliament and the Council of Ministers, we would welcome such developments. It would save lives.

The Commission has the responsibility to avoid any potential bottlenecks in the expertise process contributing to the setting of OELs. We have already expressed our opinions in the current debate on the respective roles of SCOEL and RAC. We share the views of the Dutch Ministry of Employment in its letter to the Commission of 13 October 2017 that “transferring tasks without adequate measures to ensure the quality and quantity of work and work processes may lead to lesser and less relevant Occupational Exposure Limits being proposed”. In our view, several basic principles should be guaranteed. Any committee involved in scientific expertise for the preparation of BOELs should include independent and recognized experts in all the relevant scientific fields related to workers’ protection against chemical risks. There should be a balanced geographical distribution of the members of the committee. The consultation process with the different stakeholders (principally trade unions and employers’ organisations) should be organised with sufficient time and full information. The current role of the Advisory Committee for Health and Safety should be maintained and guaranteed. A fruitful cooperation with national bodies involved in setting OELs should also be sustained.

2.1 define a methodology for setting BOELs for non-threshold CMRs

We regret that the analytical document does not propose any consistent methodology for setting BOELs for non-threshold CMRs. It is a simple list of chemicals with some information on their health impact and their use in Europe. There is a need for defining more precise criteria based on the experience of several Member States as outlined in the second section of our response for the first stage of consultation. We won’t repeat

⁵ Consultation Document, page 6. We agree that a socio-economic impact is taken into account for proposing BOELs. Our opposition is about the revision of annex I.

⁶ <http://www.etui.org/Publications2/Reports/Reprotoxins-that-should-be-subject-to-limit-values-for-workers-exposure>

our arguments here. They have been extensively developed in the second section of the ETUC response for the first stage of consultation. These must be taken into account as the debate on this important question cannot be permanently procrastinated.

In the document introducing the second stage of the consultation (2007) of the social partners on revising the CMD, the Commission wrote: "Nevertheless, scientific, technical and socio-economic data alone will not be sufficient to enable binding limit values to be set for carcinogenic, mutagenic and reprotoxic substances. What is also needed is an appropriate definition by the political authority of the level of risk that can be accepted by society. **The Commission is of the opinion that these criteria for setting BOELVs for carcinogenic, mutagenic and reprotoxic substances must be included in any future initiative**" (our emphasis). Ten years later, this important issue remains unresolved. This constitutes the main obstacle towards establishing consistent legal rules on OELs.

2.2 lack of transparency of annex III

We would like to express our concern about the lack of transparency of annex III.

In our view, each BOEL should provide consistent and homogeneous information and be structured in 10 sections. Six of those sections are already used in Annex III. Four new sections would provide essential information for the different stakeholders. Our proposal takes into account the new recitals adopted during the legislative process of batch 1 and the experience of several Member States.

1. Name of the agent (as is already the case);
2. EC number (where it is relevant, as is already the case)
3. CAS number (where it is relevant, as is already the case);
4. Binding limit value calculated for 8 hours and, where relevant, for short term (as is already the case);
5. Transitional measures (where relevant, as is already the case);
6. Date of adoption of that limit value (new column);
7. Date of review for that limit value (new column);
8. Residual risk from that limit value as it was evaluated when the limit value was adopted for a non-threshold substance (new column);
9. Skin notation (where it is relevant, as is already the case in part B of Annex III);
10. Measurement methodology (new column).

Introducing those changes would bring positive outcomes.

- a) Information on residual risk would increase the awareness of the need to avoid exposure or to minimise it when it is not technically possible to avoid it;
- b) The date of review would increase the predictability of legislative developments among the different stakeholders;
- c) The definition of measurement methodology would contribute to a consistent application and enforcement of the CMD across Europe and would grant an equal level of protection for workers exposed to the substances with a BOEL. This issue is already considered as an integral part of an EU legislative provision in the case of asbestos (see article 7 of Directive 2009/148 of 30 November 2009). Taking

into account the latest technical expertise, the measurement methodology should help employers and competent authorities to overcome the problem of variability and to use a relatively small number of measurements to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations exceeding the BOELs;

- d) The date of review should be calculated in principle 5 years after the date of entry into force of the BOEL. It would increase the foresight of legislative changes and facilitate the planning of the different phases for the adoption of BOELs (expertise including cooperation with the Member States, consultation of the Advisory Committee for Health and Safety, impact assessment, etc...)

2.3 improving the protection of workers exposed to crystalline silica

With more than 5 million workers exposed in the European Union, crystalline silica is a carcinogen for which a review of the recently adopted BOEL is particularly important. We do not believe that new evidence is needed. Existing evidence is easily sufficient to start the work and prepare a new BOEL. There is a common position between ETUC, IndustriAll and the European Federation of Building and Woodworkers which was adopted on 1st March 2017. That common position considers that a BOEL of 0,05 mg/m³ must be introduced in annex III with a transition period during which Member States could apply the BOEL of 0,1 mg/m³. In any case, by 2027, the BOEL of 0,05 mg/m³ should be applied and by 2022 the transition period should be reviewed and possibly shortened in the light of an assessment of workers' exposure in the EU and existing best practices in the various sectors of industry.

3. Enforcement

We consider that the issue of enforcement should be addressed by the Commission. If enforcement is fundamentally a responsibility of each Member State, the experience in other fields of legislation indicates that minimal standards could be defined by the EU legislation in order to guarantee a consistent level of application of the directive. It is already the case in different directives in the field of environmental protection⁷.

4. For a strategic EU roadmap in 2018

The European Commission should adopt in 2018 a strategic roadmap for eliminating work-related cancer. Such a roadmap should clarify the further development of the CMD. It should provide a list of the future agents which will be considered for annex III with

⁷ See, for instance, Directive 2012/18/EU of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC; Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

deadlines. It should set criteria for the setting of BOELs at EU level for non-threshold chemicals.

The roadmap should also consider other legislative initiatives like the revision of the asbestos directive and the revision of the optical radiation directive. Those two revisions must be considered as a priority since a strengthened prevention of asbestos-related cancer and skin cancer would significantly reduce the global burden of work-related cancers. Other legislative instruments in the field of workers protection must be revised. They have been identified in the ETUC response from September 2017 (see section 7). In the case of asbestos, the European Parliament has adopted a resolution on 14 March 2013⁸ with a list of initiatives which should be carried out at EU level. In the case of skin cancer, effective prevention measures can be simple and would strongly reduce the burden of work-related cancer. We fully agree with the findings of the Consensus report on skin cancer⁹ published in April 2016. One of the main issues raised by the report is the need to revise the optical radiation directive to include solar UV radiation. Since 2014, the German accident social insurance system has carried out dosimetric assessments of outdoor workers¹⁰. Exposures of up to 5 SED/day are common, compared to a tolerable risk of 1,3 SED/day. For instance, dockworkers' yearly exposure has been measured to be 222 SED, whilst masons/bricklayers have on average an exposure of 435 SED per year. No other occupational carcinogen has such high risk (exceeded threshold-level by 5 times).

The roadmap should take into account progress in scientific knowledge. In particular, we want to mention the need to adopt specific rules for occupational exposures to endocrine disruptors. Those exposures not only affect the health of the exposed workers but also the health of their offspring. The roadmap should deal with the needs of preventing risks from nanomaterials. Other issues have been identified in our response for the first stage of consultation (see point 8 of that response).

The roadmap should integrate a gender perspective. Workplace exposures and their negative health impact can be different for men and women. The gender dimension of preventing work related cancer has been neglected both in legislation and in workplace interventions. Most of the occupational exposures playing a role in breast cancer are not

⁸ See <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0093+0+DOC+XML+V0//EN>.

⁹ SM John et alii, *Recognizing non-melanoma skin cancer, including actinic keratosis, as an occupational disease - A Call to Action*, *Journal of the European Academy of Dermatology and Venereology*, 30, suppl. 3, 38-45.

¹⁰ See findings from GENESIS-UV: <http://www.dguv.de/ifa/fachinfos/strahlung/genesis-uv/aktuelle-ergebnisse/index-2.jsp>.

considered a priority for preventative action while breast cancer is with lung cancer among the main causes of death from cancer for women in Europe¹¹.

The roadmap should combine legislative initiatives with non-legislative action. It should also be aimed at mainstreaming work-related cancer prevention across different EU policies. The collection of relevant data at EU level and an adequate support for research in the different relevant fields would be an important contribution to better prevention and a regular evaluation of the effectiveness of policies. In public health, cancer statistics at EU level should integrate information on occupations by gender and by cancer sites using the experience of NOCCA (the Nordic Occupational Cancer project). NOCCA has proven to be a driver for innovative research.

In our view, the future of OSH legislation on chemical risks should be built on a three-level approach:

- *a first block of general obligations as they are defined in the Chemical Agents Directive which needs also some amendments like a general obligation of minimising the exposure to dust and vapour (see ETUC response from September 2017, point 2.6);

- * a second block of stricter obligations as they are defined in the CMD for all the substances of very high concern in an occupational context. In that perspective, the first step should be to include reprotoxicants in 2019. If we consider the five scenarios envisaged by the Commission for the impact assessment study¹², we support scenario 2: inclusion of reprotoxic 1A and 1B chemicals in the scope of the CMD with the full application of the existing CMD requirements¹³. Other categories of substances should be introduced in the scope of application of those stricter provisions on the basis of their intrinsic toxicological properties. The approach could be quite similar to the application of article 57f in REACH. It should consider, among priorities, the seriousness, the irreversibility and the delay of hazardous effects. Among the substances which meet those conditions, endocrine disruptors, sensitizers, immunotoxic and neurotoxic substances should be considered as a priority during the period 2020-2025. Rather than a case-by-case approach, the preference should go to defining criteria of identification for a category of substances. From that point of view, we consider that the criteria proposed in 2016-2017 by the Commission for the identification of endocrine disruptors in pesticides and biocides are not based on consistent principles of regulatory toxicology. They should reflect the precautionary principle and

¹¹ According to EUCAN statistics, 90.665 women died from breast cancer in 2012 in the European Union while 81.442 died from lung cancer. According to the ETUI study on the costs of work related cancers, more than 35.000 cases of breast cancer can be attributed to a list of 25 workplace exposures every year in the European Union. Most of them are affecting women (see: <http://www.etui.org/fr/content/download/32929/305287/file/J907+Final+Report+9+Nov+2017-2.pdf>)

¹² European Commission, Call for tenders, n° VT/2017/37, p. 13.

¹³ As soon as reprotoxic substances will be included in the scope of application of the CMD, the BOEL for inorganic lead and its compounds should be revised.

consider, on the basis of scientific evidence, three categories of endocrine disruptors: known for their effect on humans, presumed for those effects or suspected of them.

*a third block of specific prohibitions. There is a legal incongruity in the present situation. Specific prohibitions are contained in annex III of the Chemical Agents Directive 98/24 while they are related to carcinogens. Historically, it comes from the fact that the CAD has included the provisions of several former directives. One of them, the Directive 88/364/EEC of 9 June 1988 banned certain specific agents or work activities. Unfortunately, in 30 years, asbestos was the only other carcinogen to have been banned by workers protection legislation (see article 5 of Directive 2009/148 of 30 November 2009). More specific prohibitions of work activities which expose workers to certain CMR should be considered in the future without prejudice of other EU provisions on the marketing and use of those CMRs.

We are open to the idea of merging CAD and CMD in a new general directive where the present provisions of CAD would be applied to all workplace hazardous chemical agents and stricter CMD provisions would be applied to workplace 'very high concern' agents (CMRs + other categories meeting the above-mentioned criteria). In that case, annex III of the CAD would become an annex of the new Directive.

We are ready to contribute to the preparation of a roadmap with more detailed proposals. We are convinced that it would contribute to reinforcing the consistency of EU action over the long-term. Every stakeholder is convinced that the elimination of work related cancers needs a continuous process involving many different actions and that it should be based on a global strategy.

5. Creating dynamic synergy with market regulation

More coordination with market regulation and its implementation would also significantly increase the effectiveness of a EU strategy against work-related cancer. Both fields of legislation (workers protection and market regulation) are important. They should not be considered as mutually exclusive options.

Better coordination would be beneficial for all. In the authorisation process, when there is a safer alternative for workplace CMRs, that element should justify denying an authorisation for a substance. This has not previously been the case. For instance, authorisation has been granted in November 2016 for lead chromate pigments used for road marking and painting machinery while safer alternatives are available. Since then, around 380 companies have notified their ongoing use of the pigments. In the case of the revision of the CMD, for different substances the limit-values proposed by the Commission do not take into account sufficiently data provided by the registration process in REACH.

The adequacy of testing methods for a correct classification of substances is a basic condition for the good application of both market regulation and workers protection legislation. For instance, several studies indicate that tests required by the REACH do not include a specific analysis of toxic effects on the development of mammary

glands¹⁴. This is a serious gap impeding the identification of all substances that may contribute to the high prevalence of breast cancers.

In the other direction, BOELs proposed by the Commission for the revision of the CMD are not taking into account sufficiently data provided by REACH like DNELs and information on workplace exposure levels.

6. Social dialogue

The ETUC informs the Commission that we do not want to launch a negotiation procedure pursuant to Article 155 of the Treaty for the adoption of batch 3 and batch 4 and we urge the Commission to make immediate progress on this. However, this will not rule out discussing issues together with employers and seeking to find convergent positions on certain questions, as was the case with formaldehyde. We insist that social dialogue – whether sectoral or cross industry – plays an important role in implementing a strategy targeting occupational cancers. The European agreement in the hairdressing sector is obviously one example of this. The Commission's unacceptable delay in implementing this agreement via a directive is however not an encouraging sign for social dialogue on such issues.

¹⁴ See different references in Gray J, Evans N, Taylor B, Rizzo J, Walker M., *State of the evidence: the connection between breast cancer and the environment*, *Int J Occup Environ Health*, 2009;15(1):43-78.