European Trade Union Confederation response to the first stage of consultation with the social partners on possible future reviews of Directive 2004/37/EC

Introduction

In the view of the European Trade Union Confederation (ETUC), the current consultation on the revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) represents a positive opportunity to define the positions of the social partners on an issue fundamental to the development of prevention policies in Europe. This consultation should not in any way be used to delay the Commission's adoption of the third and fourth batches of proposals for revising the CMD. Nor should it be used to justify the Commission not taking action on its obligation to explore the possibility of extending the scope of the Directive to include reprotoxic substances by first quarter 2019 as agreed in the first amendment to the CMD[1]. The elements envisaged by the Commission with regard to the first two batches of proposals are covered by the preceding consultation which took place in 2004 and 2007. The Commission has rightly adopted the first two batches of proposals without further consultation of the social partners who significantly contributed to the debates both formally, via the work of the Advisory Committee on Health and Safety at Work, and informally via a number of conferences, publications and contacts with various EU institutions.

In this response, the ETUC would like to discuss crucial issues concerning the revision of the CMD, as well as a number of other issues going beyond this revision and which should help establish a comprehensive strategy for eliminating occupational cancers.

We share the Commission's finding that, in the field of preventing occupational cancers, EU policies up to now have not produced results as encouraging as those in other fields such as the prevention of work-related accidents. A variety of factors explain this finding. The risks arising from exposure to carcinogens and mutagens at work are not immediately visible. The costs of the associated health problems are not or hardly borne by the companies, instead being "outsourced" to the victims, their families and to national social security and healthcare systems. There is a major gap between the cancers recognised as occupational diseases in the various EU Member States and the number of cancers attributable to occupational exposure. The majority of cases are not vosible, i.e. problems interrupting or hindering production. Instead, it takes place within the ordinary production context. Absenteeism caused by occupational cancers does not create great burden for companies exposing their workers to such substances due to the long latency period between exposure and the outbreak of the disease. Most national data and all EU data on cancers contains very little information on patients' occupations. In the majority of Member States, no systematic data exists on exposure to carcinogens or mutagens. Whether such data pertains to the number of exposed workers, the substances to which they are exposed, levels of exposure and available prevention schemes, it is generally scarce, not very systematic and does not constitute a basis for defining adequately targeted strategies. Gender is rarely taken into account in the production of data and in the policies adopted. At EU level, most of the data available is over

[1] Agreement between the representatives of the European Parliament and the Council on the first amendment of the CMD on 11 July 2017

20 years' old, having been collected in 15 Member States at that time as part of the CAREX programme.

Inclusion of reprotoxic substances within the scope of the CMD

1. The most important issue with regard to the future evolution of the CMD is that of extending its scope to cover reprotoxic substances. It is unacceptable that the Commission's preparatory document makes absolutely no reference to this issue, even though the agreement reached on 11 July 2017 between the European Parliament and the Council introduced a new provision into the CMD, obliging the Commission to give its opinion on such an extension before the end of Q1 2019. For this deadline to be met, there is no time to be lost.

In the view of the ETUC, the CMD's scope must be extended to include reprotoxic substances. This is also the position of the European Parliament which voted in amendments regarding this issue with an overwhelming majority (some 85% of votes).

1.1 Certain characteristics are shared by carcinogens and mutagens on the one hand and reprotoxic substances on the other. It is these commonalities which justify the workplace prevention of these substances of very high concern being organised in a homogeneous and consistent manner. Whether carcinogens, mutagens or reprotoxic substances, their consequences are extremely serious for human health. They also share the characteristic of having consequences with long latency periods, i.e. the immediate visibility of the risks concerned is greatly reduced. The main interest in extending the scope of the CMD to reprotoxic substances involves organising prevention activities on the basis of the more systematic and tighter requirements set forth in this CMD compared to the vaguer and more general requirements applied to all chemical risks in the context of the Chemical Agents Directive (hereinafter "CAD"). The number of substances involved is considerable: 249 have been identified under the CLP regulation (Regulation (EU) No 1272/2008) as known or presumed reprotoxic substances. However, 134 of these are not subject to the stricter CMD as they are category 1A or 1B reprotoxics only (not also classified as carcinogens or mutagens). Insufficiently controlled, the risks are thought to affect 2 - 3 million workers in Europe. However, this is only an approximate figure, as little to no data on exposure to reprotoxic substances has been collected by Member States.

1.2 In all other fields of EU legislation, carcinogens (C), mutagens (M) and reprotoxic (R) substances come under the same legal regime, being defined as CMR substances and belonging to the category of "substances of very high concern" (SVHCs), for which specific and homogeneous legal rules have been defined. This approach – proportionate to the seriousness of the dangers intrinsically linked to the toxicological properties of these substances – is the one used for instance in REACH and in more specific regulations concerning pesticides, cosmetics or biocides. There is no reason for applying a different standard when the health and safety of workers is involved. This alignment with REACH and the other EU legislations on chemicals where C, M and R are treated the same could be seen as a regulatory simplification. It would also improve the synergies between all these legislations.

1.3 The provisions set forth in Directive 92/85 of 19 October 1992 on pregnant workers are insufficient for ensuring effective protection in the field of reproductive health when faced with

occupational exposure to chemical substances. These provisions only apply to pregnant workers, and the prevention measures only apply once women have notified their employers of their pregnancy. In practice, such notification rarely occurs before the 10th week of pregnancy. According to a French survey carried out in 2015, 50% of pregnant employees notified their employers of their pregnancy in the 3rd month and 32% in the 2nd month or less, while 17% waited until the 4th, 5th or 6th month. The harmful effects of reprotoxic substances on foetal development is particularly dangerous in the first weeks of pregnancy. On the other hand, the risks associated with occupational exposure to reprotoxic substances do not just involve pregnant women. They just as much affect men and non-pregnant women. Contrary to the other EU directives on health at work, Directive 92/85 does not provide for any consultation of workers' representatives in assessing risks and prevention measures. This boosts the tendency to consider the protection of pregnant workers as a question concerning individuals in an abnormal situation and not as a collective health issue in all companies. Limiting the specific regulation/legislation on workplace reproductive risks to provisions concerning pregnant workers has two negative aspects: a) it hinders the primary and collective prevention of such risks; and b) there is a risk of discrimination insofar as employers may exclude women from certain activities involving exposure to reprotoxic substances. The right approach for ensuring effective protection of reproductive health for men and women exposed to chemicals at work is therefore the inclusion of reprotoxic substances in the scope of the CMD.

1.4 That's why several Member States have extended the scope of their national regulations on carcinogens to reprotoxic substances (Austria, Belgium, Czech Republic, Germany, France, Finland). No data exists pointing to such an extension resulting in disproportionate or unrealisable provisions. On the contrary, the small amount of data available suggests that they contribute to more systematic prevention, better targeting workplace reproductive risks. This was exactly one of the conclusions of the study carried out for the Commission in 2013 by the consulting consortium RPA-Milieu[2].

1.5 Extending the CMD's scope to reprotoxic substances would also allow the setting of occupational exposure limits (OELs) for a number of these substances. At the request of the ETUC, the European Trade Union Institute compiled a list of 66 substances in 2016 for which it was deemed relevant to define such limits[3]. There is currently just one binding OEL in the EU legislation governing such substances – for metallic lead and its compounds. The limit is set at 150 µg/m^3 [4]. Even at the time of its adoption in 1982, this left extremely high residual

[2] RPA et Milieu, *Final Report for the analysis at EU-level of health, socioeconomic and environmental impacts in connection with possible amendment to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens and mutagens at work to extend the scope to include category 1A and 1B reprotoxic substances*, Contract number: VC/2010/0400, February 2013, see in particular p. 328.

[3] http://www.etui.org/Publications2/Reports/Reprotoxins-that-should-be-subject-to-limit-values-for-workers-exposure

[4] At the same time, a binding biological PbB level was adopted for individual workers: 70 µg Pb/100 ml blood. This level is totally inadequate to ensure effective health protection, as has not been revised for 35 years.

risks. At the time, it was presented as a provisional compromise associated with legal constraints then in force. The Commission undertook to revise it five years after the directive's adoption. This undertaking was not honoured. 36 years' later, the OEL of 150 µg/m³ remains in force. By way of example, the OEL in Denmark was set to 50 µg/m³ in 2007. On the other hand, in the context of the CAD, indicative limits have been defined for 11 reprotoxic substances. Extending the CMD's scope would allow these indicative limits to be transposed into binding OELs in Annex III of the CMD. Looking at the national provisions of individual Member States, we note major disparities for both reprotoxic substances and for carcinogens and mutagens. This alone justifies EU action.

1.6 There is currently no EU legislative provision specifically protecting workers against the effects of endocrine disruptors. Without completely solving this problem, extending the CMD's scope to reprotoxic substances would nevertheless lead to certain endocrine disruptors also being covered (for instance phthalates and bisphenol A).

Consistent and transparent criteria for setting OELs: an approach ensuring equivalent protection levels for all workers

2.1 As regards OELs setting, it is crucial to define criteria providing greater transparency and consistency in the legislation. The OELs proposed by the Commission in the first two batches of proposals will not fulfil such criteria. Certain OELs are in contradiction to Article 168 TFEU which stipulates that "a high level of health protection shall be ensured in the definition and implementation of all Union policies and activities". Certain OELs leave a considerable residual risk. The most glaring case involves chromium VI, for which the limit initially proposed by the Commission corresponded to a residual risk of one case of lung cancer among 10 exposed workers. The document submitted to this consultation of the social partners steers clear of this issue, despite it not being new. 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 [5] for carcinogenic, mutagenic and reprotoxic substances must be included in any future initiative." This issue remains exceedingly relevant. It has not been resolved. This constitutes the main obstacle towards establishing consistent legal rules on OELs. The absence of any solution is leading to arbitrary decisions where each OEL is defined on a fuzzy basis, a not very transparent mix of economic, technical and health criteria. In practice, what we have today is a cost-benefit approach offering enormous margins of uncertainty and manipulation possibilities which are inherent to the complexity of the issue and the very fragmentary availability of data.

2.2 For the ETUC, health-based OEL should be set whenever possible. In the case of such an OEL being proved technically not feasible, transition periods could be defined.

[5] In the Commission's document, this is the abbreviation for "binding occupational exposure limits values" They correspond to the "occupational exposure limits" (OELs) set forth in Annex III of the CMD.

2.3 Numerous CMR substances are likely to produce harmful effects whatever their level of exposure. For these substances, the lower the level of exposure, the lower the probability of harmful effects. On the basis of the experience gained in several Member States[6], we are of the opinion that each OEL should be set in a way ensuring that the residual risk of cancer is lower than four cases per thousand exposed workers[7]. This limit should be considered as a binding threshold with no exceptions. Even so, this would still constitute a risk very much higher than that generally used as a basis in public health legislation in various fields. Risk should therefore be reduced to the extent technically feasible. When in one of the Member States, a lower OEL has already been adopted, it should be considered as a strong argument supporting the technical feasibility of that OEL and it should constitute the reference for EU initiative. The target should be that OELs are defined in such a way as not to allow a residual risk of four cases of cancer per 100,000 workers to be exceeded. When the residual risks are between these two levels, we are of the opinion that the following specific provisions will need to be implemented to minimise them:

2.3.1 The CMD must contain a specific obligation to adopt a plan for minimising exposure for all cases where exposure exceeds the residual risk levels of 4 cases of cancer per 100,000 workers.

2.3.2 The Member States and the Commission must encourage sectoral initiatives facilitating the implementation of such plans and must give priority to finding safer substitutes for the CMRs.

2.3.3 The OELs adopted in Annex III of the CMD should fulfil transparency principles, indicating the respective associated residual risk of cancer. This information is important, as it will stimulate research into preventive solutions aimed at eliminating or reducing exposure to CMRs.

2.3.4 The CMD should stipulate that the OELs set forth in Annex III be subject to a revision once every five years.

2.3.5 The medium-term objective of this whole process should be to define homogeneous and consistent levels of health protection in all EU policies, whether they regard food hygiene, the quality of water, road safety, consumer protection or the protection of workers. Reducing social health inequalities implies that workplaces be considered on the same level as living spaces, with no toleration of a level of risk higher than in other contexts.

2.3.6 With a view to completing this revision, there is a need to arrange a cooperation between

[6] We refer here especially to M.E.J. Pronk, *Overview of methodologies for the derivation of Occupational Exposure Limits for non-threshold carcinogens in the EU*, RIVM, 2014.

[7] The calculations are based on 40 years of occupational exposure, with standardised working time (8 hours a day, 5 days a week, 48 weeks a year).

the expert committees working on OELs in the context of the EU institutions and the committees involved in such work in the individual Member States. A multi-annual plan would allow work to be divided up between these bodies. It should be based on priority criteria taking particular account of the number of workers exposed, the level of the residual risk associated with the OELs, the existence in at least one Member State of an OEL providing a higher level of protection, and the existence of data produced in particular in the context of implementing REACH. Priority lists have already been drawn up by the ETUC and RIVM, the Dutch public health institute. They are more or less convergent, and could serve as the basis for establishing an EU list. Publishing a multi-annual plan containing the complete list and the deadlines by which the OELs are to be defined would greatly heighten the predictability of future legislative developments.

2.3.7 Many CMRs have adverse health effects going beyond cancer and reproductive risks. When determining OELs, account should also be taken of these other risks. In certain cases, this will involve setting a lower OEL than one not taking account of the cancer or reproduction risks. By way of example, the OEL for beryllium must also take account of sensitisation effects, the OEL for diesel engine exhaust emissions must take account of the risk of non-cancer respiratory diseases and cardiovascular diseases, etc. Similarly, when multiple risks exist in the field of reproductive health (for instance, infertility, congenital malformations and childhood cancers), all of these risks should be taken into account.

2.3.8 For all activities related to OELs setting, it is crucial to make better use of the data collected during the implementation of REACH.

2.3.9 The delays which have built up in the definition of OELs have so far prevented an essential issue to be discussed: the determination of harmonised measurement methods. For many OELs, measurement practices diverge from one country to the next. In certain Member States for example, the national authorities tend to prescribe precise methods, while in others the importance of this issue is underestimated.

2.4 We consider that providing an independent scientific expertise for the EU legislative process is a crucial issue for the development of the CMD. Taking into account the experience of the work with SCOEL recommendations, the Advisory Committee has recently underlined that "The SCOEL members have unmatched expertise in occupational hygiene, toxicology, routes of workplace exposure, epidemiology and workplace measurement techniques, together with experience of process generated substances which are outside the scope of REACH but are highly relevant for OSH. As well as assessing the scientific evidence itself, the SCOEL also runs a public consultation aiming to ensure that all scientifically relevant information is taken into account when forming a recommendation. The Commission must guarantee the respect of conflict of interests' rules." We are also concerned that the ACHS soon will run out of proposals due to the fact that the Commission has not issued mandates to the SCOEL for a sufficient number of substances.

Taking account of multiple exposures

2.5 Many workers are subject to multiple exposures. It is crucial that prevention plans based on the various data which employers are required to collect pursuant to CMD Article 6 take account of this question. In any event, when a worker is subject to multiple exposures in one activity and OELs exist for at least two of these exposures, the effect of the chemical agents must be considered as cumulative under the following formula $\Sigma\ C_i/LV_i \leq 1$ in which Ci represents the concentration of agent i, while LV_i is the limit value (OEL) of agent i. This formula is not applicable when scientific data allows a better exposure assessment.

2.6 It will never be possible to have OELs for all CMRs, and their measurement in workplaces with a wide range of exposure situations (for example in the construction sector, in handling and cleaning work, in transportation, etc.) will not allow all CMR risks to be mapped exactly, taking account of spatial and temporal variations. We consider it important to include both in the CMD and CAD a general provision on the continual reduction of workers' exposure to dust and fumes.

Improving the quality of impact assessments

2.7 The Commission's impact assessments for the 1st and 2nd batches of proposals systematically underestimated the expected benefits of the considered policy options, failing to include the reduction of pathologies other than cancer. This is the main difference observed between the impact assessment for the OEL on crystalline silica adopted by the United States (0.05 mg/m³)[8] and that adopted by the European Union (0.1 mg/m³). The difference is considerable. According to the assessment made by the OSHA in the United States, the choice of an OEL of 0.05 mg/m³ instead of 0.1 mg/m³ will lead to a reduction of lung cancer deaths in the order of 62 people a year and an overall reduction of mortality in the order of 644 people a year when one includes deaths caused by respiratory diseases and non-cancerous kidney diseases. Justifying the proposed BOEL, the European Commission's assessment is limited solely to lung cancers without this choice being truly transparent. Indeed, the table on page 65 of this assessment refers solely to the "total number of attributable deaths".

2.8 Greater transparency would mean that the impact assessments published by the Commission take account not just of the selected policy options but also those rejected and the reasons for such decisions. In practice, the Commission works on a case-by-case basis. In its impact assessment of the 1st batch of proposals, there is no analysis on the different policy options about reprotoxic substances, despite this issue being at the centre of the discussions on the future of the CMD since 2004 and despite the Commission having commissioned a 400-page study on the issue. In other cases, the Commission provides certain explanations (e.g. with regard to diesel engine exhaust emissions). In our view, any policy option which has been the subject of preparatory work should be explained, with the Commission stating the reasons for not ultimately adopting it. This should certainly be the case when diverging opinions have arisen during the consultation of the social partners or during the discussions within the Advisory Committee for Health and Safety. This would also be necessary when external

[8] https://www.regulations.gov/document?D=OSHA-2010-0034-4247

experts are commissioned to conduct preparatory impact studies.

2.9 When one of the Member States has already set an OEL that is lower than the OEL proposed by the Commission, there should be a requirement in the Impact Assessment to justify the non-adoption of the stricter OEL.

2.10 New entries for the annex I should not be submitted to an impact assessment. The decision-making process is exclusively based on the weight of evidence about the intrinsic toxicological properties of substances generated by a process. The approach must be the same than for harmonized classification in the framework of CLP regulation No 1272/2008.

Establishing priority criteria to achieve the target of 50 OELs by 2020

3.1. The ETUC insists that the target of 50 substances in Annex III has to be achieved by 2020. After 2020, the process of setting OELs for CMR's should continue on a dynamic way in order to include most of the substances at the workplace. The criteria we have proposed in the preceding paragraphs are intended to facilitate the adoption of OELs. In addition, the number of OELs for CMRs already defined in at least one Member State is much higher than this total. The more systematic use of data gathered by national bodies would also facilitate the adoption of OELs. The whole body of data gathered in the context of implementing REACH also points to quantitative and qualitative benefits when setting OELs for Annex III. In our view, the three fundamental criteria for determining priorities are as follows: (1) the number of exposed workers in the European Union; (2) the magnitude of the health risks associated with the current level of exposure of these workers; (3) the existence of relevant data for determining OELs for these substances and in particular the existence of an OEL in at least one Member State. The first two criteria take precedence over the third one. With regard to the first two criteria, in our view it is a good idea to take account of the most prevalent exposures among men and among women, as these are not necessarily the same due to both the gendered division of labour and the respective risks. For instance, taking account of occupational exposures linked to breast cancer could possibly lead to priorities which would not appear in a non-gender-based analysis. This criterion also applies to the determination of the relevant process generated substances for Annex I.

3.2 We support the inclusion of 8 substances in batches 3 and 4 as it is proposed by the Commission in the Consultation document. We consider that batch 4 should be expanded in order to reach the target of 50 BOELs in 2020. We attach in annex a list of substances which might be included in batch 4.

Revising Annex I

4. It is of crucial importance to expand Annex I by including processes concerning the main current exposure situations in the European Union. While the inclusion of crystalline silica represents in itself a major step forward, there remains a lot to do to achieve this target. The priority criteria are as follows: (1) the number of exposed workers; (2) the magnitude of the negative health effects, and (3) the existence of relevant scientific research. In this respect, it is important to include in Annex I all processes for which International Agency for Research on Cancer (IARC) monographs are available. By way of example, exposures caused by the combustion of various materials during

firefighting or the multiple exposures of painters to carcinogens should be included in Annex I[9]. The differing situations of men and women must also be taken into account when applying criteria (1) and (2). For instance, the exposure of healthcare workers to hazardous drugs constitutes a major risk for women workers with regard to both cancers and reproductive health. In our view, such exposure must be included in Annex I of the 3rd batch of proposals with the following entry : "Work involving exposure to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs"Apart from diesel engine exhaust emissions, in our view rubber dust and fumes as well as leather dust should also be included in the Commission's third batch of proposals.

Crystalline silica

5. The compromise reached between the European Parliament and the Council on crystalline silica requires the Commission to re-examine the OEL defined for this substance. In our opinion, the Commission must immediately start preparatory work for adopting an OEL conforming with article 168 of TFEU requiring a high level of human health protection in the definition and implementation of all Union policies and activities. The new OEL for crystalline silica should be set at 50 µg/m³. Considering the large quantity of exposed workers, it should be one of the priorities in the coming months.

Diesel engine exhaust emissions

6. We are surprised to find no mention of diesel engine exhaust emissions in the document submitted to the social partners for consultation. In the impact assessment presented by the Commission for the second batch of proposals, it did however indicate that its decision not to include diesel engine exhaust emissions both in Annex I and Annex III was provisional and would be reviewed. In the same impact assessment, the Commission stated that the absence of a legislative initiative would lead to 230,000 deaths over the coming 60 years. This order of magnitude is very much underestimated, given that it is based solely on deaths caused by lung cancer. When taking account of the other adverse health effects of diesel engine exhaust emissions, the number of avoidable deaths is much higher.

> 6.1 The Commission's observations stated in its impact assessment of the second batch of proposals regarding the difficulty of finding a satisfactory legal formulation are irrelevant in the CMD context. In practice, workers are exposed to diesel engines corresponding to widely varying emission standards. The composition of diesel engine exhaust emissions is not solely dependent on emissions standards applied for their construction, but also varies because several other factors, including maintenance, filter systems, combustion temperature, etc. The goal of the directive is not to define specific rules governing the design of diesel engines, their possible replacement or other measures determined by market rules. It would therefore be a good idea to start out from the scientific finding that diesel engine exhaust emissions are carcinogenic.

[9]Such activities are handled in monograph no. 98 published by the IARC in 2010.

6.2 Affirmation of the Scientific Committee on Occupational Exposure Limits (SCOEL) opinion, according to which "exhausts of these new technology diesel engines may not be considered carcinogenic"[10], is not based on consistent evidence. The sole source cited in the bibliography refers to the report compiled by the Boston-based Health Effects Institute. This report refers solely to vehicles meeting the latest standards in force in the United States. The laboratory conditions of this toxicological study are very much different to the real-life working conditions of workers currently exposed to diesel engine exhaust emissions both in the United States and in the European Union. This report is thus not a relevant document for justifying the SCOEL's affirmation.

6.3 In our view, the Commission must include diesel engine exhaust emissions as soon as possible in Annex I and in Annex III. The OEL in Annex III should be of 50 µg/m³ calculated on the basis of the concentration of elemental carbon and irrespective of whether the exhaust emissions are from old or new technology diesel engines. Such an OEL has been recently adopted in Germany for diesel engine exhaust emissions. In addition, a provision should be added in the CMD to reduce this OEL to 15 µg/m³ by 2025 in order to take into account epidemiological data. As mentioned by the SCOEL: "although toxicological data supports a threshold (possibly at 0.02 mg DEP/m3 or below, corresponding 0.015 mg EC/m3), epidemiological data suggests significant cancer risks already at and below these exposure levels[11]". ETUC will support any amendment of the European Parliament or the Council allowing these targets to be reached in the second batch.

Other relevant legislation regarding the protection of workers

7. Apart from the revision of the CMD, it would be a good idea to adapt other EU legislation to establish a coherent strategy for fighting occupational cancers.

7.1 Exposure to asbestos remains a priority issue in Europe due to the high number of buildings and equipment containing asbestos. The OEL defined in Directive 2009/148 does not provide a satisfactory level of protection for exposed workers. It would therefore be good to revise this OEL and to define a more effective European strategy on asbestos. Taking into account the development of scientific research, France and the Netherlands have recently revised their national OEL on asbestos with a national BOEL of 0,002 fibers/m³ in the Netherlands and 0,01 fibers/m³ in France against the 0,1 fibers/m³ in the EU directive.

7.2 Directive 2006/25 on the exposure of workers to risks arising from physical agents (artificial optical radiation) excludes solar radiation from its scope of application. However, solar radiation is a major cause of occupational cancers and involves a high percentage of workers. We demand that the Directive's scope of application be revised to include solar radiation (as originally proposed by the Commission). Its exclusion is the result of an amendment adopted by the European Parliament in September 2005.

[10] *SCOEL/OPIN/403 Diesel Engine Exhaust page 10 (December 2016).*
[11] *SCOEL/OPIN/403 Diesel Engine Exhaust page 10.*

7.3 In the context of the ongoing revision of Directive 2000/54 on biological agents, account needs to be taken of occupational exposure to biological agents which can lead to cancers or reproductive disorders.

7.4 Directive 2013/35 on electromagnetic fields only takes account of their short-term effects. This approach was defined as provisional and pragmatic at the time the directive was being drafted. In our view, the time has now come to start preparatory work taking account of the long-term effects of electromagnetic fields.

7.5 We also consider it imperative to carry out a review of the radiation protection rules contained in Directive 2013/59/Euratom with regard to workers exposed to ionizing radiation.

7.6 Occupational exposure to radon and radon progeny is also an important cause of work related cancers even at relatively low exposure level. Specific prevention measures for the workers should be addressed in EU legislative instruments.

7.7 Research into night work and posted work points to such work contributing to occupational cancers. This question must also be taken into account in the EU strategy for eliminating occupational cancers.

7.8 In 2008, the Commission launched the first stage of consultation on a possible legislative initiative on environmental tobacco smoke (ETS) at work. The second stage never took place. In October 2013, the Commission stated – in the context of REFIT – that, while the initiative was not being abandoned, the possible adoption of a legislative proposal would depend on future developments. We call on the Commission to state its intentions in this field. It needs to be checked to what extent an EU legislative initiative would allow the existing national provisions to be upgraded (including the development of e-cigarettes)

7.9 There is a need to improve workers' protection in the EU legislation in three important fields: occupational exposure to nanomaterials, occupational exposure to endocrine disruptors and occupational exposure to pesticides. It should be part of a European strategy against occupational cancer.

Catching up and preparing for the future

8. We would like to emphasise that the majority of issues discussed in our paper up to now were already on the 2004 agenda put forward on opening the consultation with the social partners on revising the CMD. The cumulative delays have had dramatic consequences, helping to aggravate social health inequality within the European Union. The legislative moratorium adopted in 2013 in the context of the REFIT programme in the field of workplace health was unjustifiable, presenting the legal rules governing workers' health and lives as an administrative burden. The fact that the Commission adopted its first batch of proposals during the Dutch presidency, more than six months before finishing its assessment of the existing directives, shows the extent to which this moratorium was a wrong political decision. The various CMD aspects on the agenda to be revised by 2020 are

nothing but catching-up measures aligning the CMD with the scientific knowledge and with the prevention possibilities of the late 20th century. In the meantime, new scientific knowledge is appearing, especially in the field of the causes of cancer (carcinogenesis), the role played by epigenetic processes, endocrine disruptors, the transgenerational effects of certain occupational exposures, the risk associated with the nanomaterials now finding their way onto the market, the role of multiple exposures (including interactions between exposures to chemical agents and other carcinogens), research into biomarkers reflecting physical harm to the body before a disease actually breaks out, the importance of working conditions in breaking down immune defences, etc. In our response, we have sought to provide urgent responses to problems that should have been resolved more than a decade ago. In our view, the current legislative revision is absolutely necessary. However, it must not block out the need to find legislative responses to a whole range of issues related to emerging risks or to a better understanding of the problems raised. In our view, the European Commission must organise a systematic monitoring of both scientific and regulatory developments allowing us to overcome the challenges in the field of preventing occupational cancers. For our part, we will continue to contribute to the analysis of these issues and to the search for appropriate preventive solutions.

Legislation is indispensable, but as yet not sufficient

9. The ETUC is convinced that modernising EU legislation on protecting workers against occupational cancers is a pre-condition to any improvement of prevention in this field. The potential added value of a dynamic EU policy is particularly high, to the extent that preventing occupational cancers relies on synergistic interventions in line with EU competences. An obvious complementarity exists between the rules of the market governing chemical agents and the social rules protecting workers against CMRs. In this respect, we would like to express our concern over the fact that occupational exposure is being neglected in the current procedures accompanying the implementation of the specific regulations on cosmetics and pesticides.

Over and above the indispensable improvements to the legislative framework, it is important to improve cooperation between Member States and EU interventions in the following fields:

9.1 Whatever the legislation, there is always a risk of it remaining a paper tiger when labour inspectorates do not have sufficient resources and competences to enforce compliance. We therefore ask for this aspect to be looked at, in particular by the Senior Labour Inspectors Committee. In addition, it is important to improve cooperation between the departments responsible for enforcing the rules of the market (mainly REACH) and labour inspectorates. The existence of a specific workers' representation for health and safety questions is also a determining factor in the implementation of any regulation. Trade unions and workplace reps have an important role to play here.There are many workers without such representation due to the size of the company they work for or other factors. While this question is obviously not a specific aspect of organising CMR-related prevention, it should be part of any national or European strategy. The development of preventive services with adequate expertise on work related cancers and reproductive risks is also an important challenge. In that field, a better prevention requires a multidisciplinary approach with a cooperation between occupational medicine, toxicology, ergonomics and other specialities.

9.2 Only very few Member States have precise data on workers' exposure to CMR substances. At European level, data on occupational exposures to reproductive risks is

completely non-existent, while data on exposure to carcinogens is more than 20 years' old, compiled at the time the European Union was co-financing the Carex programme. The importance of this question was acknowledged in the Commission Communication of 10 January 2017. In our view, it is essential for this acknowledgement to be turned into concrete, systematic and ambitious initiatives. Moreover, the aim of an amendment resulting from the agreement between the European Parliament and the Council on the first batch of proposals was to have Member States collect relevant data in their reports on the Directive's application. It is important that the Commission uses this data to improve the European strategy in this field. The development of databases, involving all the Member States of the EU, as well as, the improvement and transparency of information sources would facilitate the identification of occupations and activities with higher risk of cancer. It could produce alerts in order to stimulate the research on work related cancers. Databases should identify possible differences between men and women.

9.3 The development of R&D programmes can also help improve the prevention of occupational cancers. Greater attention to occupational exposure and to social health inequality is needed in cancer research programmes co-financed by the EU. Development programmes on ways of substituting CMR substances need to be supported, especially on the basis of sectoral approaches. The work of informing workers and heightening their awareness carried out by the EU-OSHA can also play an important role in improving prevention. The campaign on dangerous substances planned for 2018-19 can play a significant role here. We also support the various initiatives taken in the context of the "Roadmap from Amsterdam to Vienna".

9.4 In the majority of Member States a marked dividing line currently exists between public health policies and workplace health policies. In particular, cancer statistics and statistics on reproductive risks are insufficient, as they do not allow the occupations of cancer patients and thus of the associated CMR exposure to be identified. There are however positive experiences, such as the NOCCA programme based on the cancer registers of the Nordic countries. Pro-actively researching the occupational exposure of people suffering from cancer also has the potential to come up with data of use in better targeting prevention, as shown by the OCCAM survey in Italy and the GISCOP93 survey in France. The European Union can base its work on such initiatives, and thus contribute to the production of more systematic data. This would in turn allow policies intended to reduce social health inequality in Europe to be better targeted.

The role of social dialogue

10. The Commission has asked us whether we would like to see the revision of the CMD taking place within the framework of the social dialogue procedures provided for under TFEU Article 155.

10.1 The ETUC informs the Commission that similar to the process for adopting batch 1 and batch 2 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 our discussing issues together with employers and seeking to find convergent positions on certain questions, as was the case with formaldehyde.

10.2 We consider that social dialogue – whether sectoral or cross industry – can play 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 unjustifiable delay in implementing this agreement via a directive is however not an encouraging sign for social dialogue on such issues. As much as we believe that the consultation of unions and employer organisations is a fundamental aspect of the legislative process, it can be no substitute for the responsibility of public authorities for ensuring worker's and citizen's right to health and life.

Conclusions

In the view of the ETUC, the Commission must draw its conclusions from the legislative process regarding the first batch of revision proposals. A very large majority of European Parliament parties considered the original Commission proposals as totally insufficient. A significant proportion of the amendments adopted by the European Parliament served in turn as a basis for a compromise within the Council. During the Council discussions, many Member States also supported a more ambitious approach. In the view of the ETUC, this positive experience indicates that more ambitious proposals need to be put forward by the Commission in the next steps of revising the CMD. The Commission should also adopt an open attitude in the "trilogue" with regard to amendments possibly put forward by the European Parliament concerning the second batch of proposals. These would allow the European Union to show that it can positively contribute to improving the working and living conditions of all EU citizens.

Ends

Annex 1: List of potentially relevant carcinogens (or groups of carcinogens) proposed by ETUC for which the derivation of a BOEL under the CMD should be added in batch 4

No.	Substance / group of substances	CAS no.	Classification harmonised (or notified) / Inclusion in annex I of CMD	registered tonnage band [t/a] / process-generated substance	comments
Candidates for batch 4					
Process-generated and legacy substances					
9	Benzo(a)pyrene (Benzo(def)chrysene)	50-32-8	C 1B, H350	not registered / process-generated / legacy substance	
31	Diesel engine exhaust emissions		annex I (recomm.) **IARC**: 1 (2013)	process-generated	
42	Leather dust		**IARC**: 1 (2012)	process-generated	
46	N-Nitroso diethanolamine (2,2'-(Nitrosoimino)bisethanol)	1116-54-7	C 1B, H350	not registered / process-generated	
47	N-Nitroso diethylamine (Diethylnitrosoamine)	55-18-5	notified: C 1B, H350 **IARC** 2A (1987)	not registered / process-generated	
48	N-Nitroso dimethylamine	62-75-9	C 1B, H350	not registered / process-generated	
49	N-Nitroso di-n-propylamine (Nitrosodipropylamine)	621-64-7	C 1B, H350	not registered / process-generated	
51	2,3,4,7,8-Pentachlorodibenzo-furan	57117-31-4	**IARC**: 1 (2012)	not registered / process-generated	
53	Polychlorinated biphenyls (PCB)	1336-36-3	STOT RE2, H373 **IARC**: 1 (2016)	not registered / legacy substance	

No.	Substance / group of substances	CAS no.	Classification harmonised (or notified) / Inclusion in annex I of CMD	registered tonnage band [t/a] / process-generated substance	comments
61	2,3,7,8-Tetrachlorodibenzo-para-dioxin	1746-01-6	**IARC**: 1 (2012)	not registered / process-generated	
new 4/17	Welding fumes		**IARC**: 1 (in prep.)	process-generated	
Substances classified as C 1A/1B (or due to be classified)					
1	Acetaldehyde (ethanal)	75-07-0	C 1B, H350	0 – 10 a)	agreed at RAC-38
5	Anthraquinone	84-65-1	C 1B, H350	1,000 – 10,000	agreed at RAC-35
12	4,4'-Bis(dimethylamino)-4''-(methylamino)trityl alcohol	561-41-1	C 1B, H350	10 – 100	
17	2-Chloro-1,3-butadiene (Chloroprene)	126-99-8	C 1B, H350	10,000 – 100,000	
19	α-Chlorotoluene	100-44-7	C 1B, H350	10 – 100	
21	C.I. Basic Violet 3	548-62-9	C 1B, H350	0 – 10	
22	C.I. Solvent Blue 4	6786-83-0	C 1B, H350	10 – 100	
23	Cobalt compounds classified as C 1B	7646-79-9 10124-43-3 …	C 1B, H350	1,000 – 10,000	
25	Poly[(aminophenyl)methyl]-aniline (technical MDA)	25214-70-4	C 1B, H350	100 – 1,000 a)	
30	1,2-Dichloropropane	78-87-5	C 1B, H350 **IARC**: 1 (2016)	1,000 – 10,000 a)	to be included via 9. ATP
new 9/16	1,2-Dihydroxybenzene (pyrocatechol)	120-80-9	C 1B, H350	10,000– 100,000 a)	agreed at RAC-38
32	N,N-Dimethylhydrazine	57-14-7	C 1B, H350	0 – 10	
34	2,3-Epoxypropyl methacrylate (glycidyl methacrylate)	106-91-2	C 1B, H350	1,000 – 10,000	agreed at RAC-35
	Ethylene imine	151-56-4	C 1B, H350	100+ a)	
37	Gallium arsenide	1303-00-0	C 1B, H350	10 – 100	
40	Isoprene (2-Methyl-1,3-butadiene)	78-79-5	C 1B, H350	100,000 – 1,000,000	

No.	Substance / group of substances	CAS no.	Classification harmonised (or notified) / Inclusion in annex I of CMD	registered tonnage band [t/a] / process-generated substance	comments
43	Methylhydrazine	60-34-4	C 1B, H350	10 – 100 a)	agreed at RAC-34
50	2-Nitrotoluene	88-72-2	C 1B, H350	10 – 100 a)	
	4,4'-Oxydianiline and its salts	101-80-4	C 1B, H350	10 – 100	
52	Phenolphtalein	77-09-8	C 1B, H350	10 – 100	
54	Potassium bromate	7758-01-2	C 1B, H350	0 – 10	
55	1,3-Propanesultone	1120-71-4	C 1B, H350 **IARC**: 2A (2016)	10 – 109 a)	
	1,3-Propiolactone (3-propanolide)	57-57-8	C 1B, H350	0 – 10	
58	Quinoline	91-22-5	C 1B, H350	100 – 1,000 a)	
60	Styrene oxide ((Epoxyethyl)benzene)	96-09-3	C 1B, H350	100 – 1,000 a)	
68	1,2,3-Trichloropropane	96-18-4	C 1B, H350	1,000 – 10,000	
CLH process currently under way					
new 2/16	2,2-Bis(bromomethyl)propane-1,3-diol	3296-90-0	proposed: C 1B, H350	100 – 1,000	2: 1/2017
14	Butanone oxime	96-29-7	proposed: C 1B, H350	1,000– 10,000	2: 11/2016
new 6/16	Cobalt metal	7440-48-4	proposed: C 1B, H350	10,000+	2: 4/2016
33	1,4-Dioxane	123-91-1	proposed: C 1B, H350	1,000+	2: 4/2016
new 4/16	N-(Hydroxymethyl)acrylamide (NMA)	924-42-5	proposed: C 1B, H350	1,000 – 10,000	2: 4/2016
59	Silicone carbide fibres	409-21-2	proposed: C 1B, H350 **IARC**: 2A (in prep.)	100,000+	2: 2/2015

Numbering of substances:

The numbering of substances in the above tables corresponds to the following publication: https://www.etui.org/Publications2/Reports/Carcinogens-that-should-be-subject-to-binding-limits-on-workers-exposure

Explanation of notes

Column "Harmonised classification / inclusion in annex I of CMD":

IARC: IARC classification; year of publication

Column "Registered tonnage band / process-generated substance":

a) additional registration(s) for "intermediate use only"

Column "Comments":

re. REACH and CLP processes

2) CLH process initiated; date of initiation