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Protection of workers from exposure to carcinogens or mutagens: second proposal (CMD 2)

Impact assessment (SWD (2017) 7 final, SWD (2017) 8 final (executive summary)) of a Commission proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (COM(2017) 11 final)

Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's [impact assessment](#) (IA) accompanying the above [proposal](#), adopted on 10 January 2017 and referred to Parliament's Committee on Employment and Social Affairs (EMPL).¹ The proposal intends to amend the Carcinogens and Mutagens [Directive 2004/37/EC](#)² (CMD) by establishing binding occupational exposure limit values³ (BOELVs) for the inhalation route of exposure and/or binding skin notations for seven carcinogenic chemical agents.⁴ The current proposal ('CMD 2') follows and complements a previous one,⁵ covering thirteen carcinogenic chemical agents, while work has already started on a third proposal concerning five additional carcinogenic chemical agents⁶ with a view to its presentation in early 2018. All together, the three proposals concern 25 priority chemical agents that have been selected through a consultative approach involving stakeholders at Member State and social partner levels (IA, p. 15).

According to the findings of the [SHEcan project](#) described in a report prepared by the Institute of Occupational Medicine ('IOM Study'),⁷ referenced throughout the IA, at least 20 million workers in the EU are, to a lesser or greater extent, exposed to one or several of these 25 chemical agents. They represent around 5 % of the agents identified until August 2015 by the International Agency for Research on Cancer (IARC) as being *carcinogenic to humans* (IARC Group 1, eleven substances), *probably carcinogenic to humans* (IARC Group 2A, four substances), and *possibly carcinogenic to humans* (IARC Group 2B, 10 substances).

¹ See N. Scholz, [Limits on exposure to carcinogens and mutagens at work: Second proposal](#), EU Legislation in progress, EPRS, 2017.

² Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual directive within the meaning of Article 16(1) of Council Directive 89/391/EEC). See also M. Remáč, [Exposure to carcinogens and mutagens at work](#), implementation appraisal, EPRS, 2016.

³ To simplify the text, the current and previous IAs use the term 'occupational exposure level' (OEL) to refer to any occupational exposure limit (value).

⁴ These are: [Trichloroethylene](#) (TCE), [4,4'-Methylenedianiline](#) (MDA), [1-Chloro-2,3-epoxypropane](#) (epichlorohydrin), [1,2-Dibromoethane](#) (ethylene dibromide or EDB), [1,2-Dichloroethane](#) (ethylene dichloride or EDC), [Benzo\[a\]pyrene](#), [mineral oils as used engine oils](#). The hyperlinks refer to the detailed individual reports included in the 'IOM Study' (see footnote 7 below).

⁵ [COM\(2016\) 248 final](#) of 13 May 2016; see also A.-A. Georgescu, [Protection of workers from exposure to carcinogens or mutagens](#), initial appraisal of a Commission IA, EPRS, 2016, and N. Scholz, [Limits on exposure to carcinogens and mutagens at work](#), updated EU Legislation in progress, EPRS, 2017.

⁶ Beryllium and beryllium compounds, Hexachlorobenzene (HCB), diesel engine exhaust emissions, rubber process fumes and dust, and 4,4'-Methylene bis 2-chloroaniline (MbOCA). The IA explains why they were excluded from the current proposal (pp. 22-26).

⁷ IOM (2011), Health, social-economic and environmental aspects of possible amendments to the EU directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, [Final Summary Report Project P937/99](#) and [Final Executive Summary Report Project P937/100](#).

The current proposal:

- fulfils the obligation provided under Article 16 of the CMD, establishing that OEL values should be set and revised for all those carcinogens or mutagens for which the available information make this possible;⁸
- is part of a new initiative, set out in [COM\(2017\) 12 final](#), which aims to modernise the overall structure of the EU occupational safety and health (OSH) legislation and policy ('*acquis*');
- is meant to contribute to delivering on the objective of a 'Social Triple A'⁹ Europe rating set by the Commission's President Jean-Claude Juncker in his political guidelines (IA, p. 18);
- follows a European Parliament [resolution](#)¹⁰ highlighting the importance of protecting workers from carcinogens, mutagens and reprotoxic substances, and calling on the Commission to revise the CMD.

Problem definition

The **main problem** identified by the IA is **occupational cancer** because cancer is the first cause of work-related deaths in the EU28. According to the data referred to in the IA, 53 % of work-related deaths in 2011 were, in fact, attributed to occupational cancers. In addition, the IA identifies (one) market and (two) regulatory drivers relating to occupational cancer, namely: significant exposure of workers to carcinogens (market driver), outdated EU legal framework for carcinogens, and inadequate national OELs (regulatory drivers) (IA, pp. 7-8). This is in line with the Commission's [better regulation guidelines](#), which indicate that policy proposals are built on a clear problem definition and an identification of the underlying factors and behaviours (or 'drivers'). However, the drivers in question are not analysed in the current IA, as this was done in the previous impact assessment, [SWD\(2016\)152 final](#), accompanying the first proposal.¹¹ While consequences for employers, national authorities and workers are briefly mentioned, the IA, as with the previous one, does not analyse in detail who is affected by the problem and how, providing just a summary table in Annex 3 (pp. 75-76). The evolution of the problem without EU action is comprehensively outlined; the IA provides projections of the expected number of deaths and cancer cases, the estimated numbers of workers exposed, and the estimated health costs for the period 2010-2069¹² under the baseline scenario (pp. 10-12, Table 1 and pp. 77-81, Annex 4). However, more evidence could have been provided to support the statement that less stringent OELs, or no exposure limit values at all, may provide a potential incentive for companies to locate their production facilities in Member States with the lower standards (p. 13).

Objectives of the legislative proposal

According to the explanatory memorandum of the proposal (pp. 2-3), and to the IA (pp. 17-18), the proposal presents:

- one *general* objective: to ensure and maintain a high level of protection of workers' health and safety in the EU;
- three *specific* objectives: to further improve workers' health protection; to increase the effectiveness¹³ of the EU framework for protecting workers; to ensure more clarity, facilitate implementation, and contribute towards a better level playing field for economic operators.

These objectives appear to be clear and consistent with the manner in which the problem has been defined, as well as with other EU policies, such as the EU Strategic Framework on Health and Safety at Work 2014-2020 (see section on simplification and other regulatory implications), and the Charter for Fundamental Rights (p. 18). In addition, they seem to be relevant, sufficiently measurable, and achievable, though not time-bound. The IA sets two *operational* objectives, after having identified the retained option (see under evaluation and monitoring), in

⁸ According to the IA, available scientific evidence points to the need to establish new OELs in Annex III of the CMD for a number of substances for inhalation exposure; in addition, information for other routes of exposure should be included. Finally, there is scientific information which could serve as a background to including mineral oils as used engine oils in Annex I to the CMD (p. 12).

⁹ On this issue, see M. Lecerf, [What is 'Social Triple A'?](#) EPRS, 2016.

¹⁰ European Parliament resolution of 25 November 2015 on the EU Strategic Framework on Health and Safety at Work 2014-2020 (2015/2107(INI)).

¹¹ This is the general approach followed by the IA, which states that '*...the supplementary analysis presented here should be read in conjunction with the earlier impact assessment (IA)...The most essential points are carried over and supplemented by additional information and analysis regarding these seven additional carcinogens...*' (p. 7).

¹² The IA points out that the 2010-2069 period was chosen by the SHEcan project, and therefore has been kept the same throughout the IA (p. 9, footnote 13).

¹³ According to the explanatory memorandum, the aim is also to improve the *efficiency* of the EU framework (p. 2).

line with the Commission's better regulation toolbox, which indicates that such objectives are option-specific ([tool no 13](#), pp. 80-81).

Range of options considered

The IA considers several options: apart from one, which is new, all the others were already considered and assessed in the previous IA. This approach is not surprising given that the current and the previous proposal differ only for the carcinogens considered, while the problem, the main drivers, and the objectives are the same. In what follows, and consistent with the approach used in the IA, retained options are indicated in figures, while discarded options are indicated in capital letters.

OPTION	DESCRIPTION OF CONSIDERED OPTIONS	DECISION
1	Baseline: no further EU action	Retained
A	<i>Banning the use of the carcinogenic chemical agents</i>	Discarded
B	<i>Providing industry-specific scientific information without amending CMD</i>	Discarded
C	<i>Market-based instruments</i>	Discarded
D	<i>Industry self-regulation (voluntary agreements)</i>	Discarded
E	<i>Regulation under other EU instruments (REACH)</i>	Discarded
F	<i>Directly adopting the most stringent national OELs</i>	Discarded
2	Directly reflecting the Opinion agreed by the Advisory Committee on Safety and Health at Work (ACSH)	Preferred
3	Adopting more stringent EU legal requirements (compared with the ACSH's Opinion)	Retained
4	Adopting less stringent EU legal requirements (compared with the ACSH's Opinion)	Retained

(Source: author's reworking of IA text)

The reasons for discarding options A-E are briefly provided (pp. 26-27); this is reasonable, though not very effective, as the IA points out that they were detailed in the previous IA (pp. 27-30). As regards option D, it is important to highlight that it regards only one of the seven carcinogens considered in the IA (Trichloroethylene, used in metal cleaning); however, it is likely that the shortcomings of self-regulation, described in the IA, are the same independently of the substances considered (pp. 26-27). As regards the retained options, their presentation is extremely brief, with the IA pointing out that options 3 and 4 ('flanking options') were drawn from the IOM study (pp. 27-28). In addition, in considering EU legal requirements less stringent than those already established by many Member States and industries, option 4 does not seem consistent with the spirit of the objectives of the proposal, notably with regard to ensuring and maintaining a high level of protection of workers' health and safety. Finally, the IA does not explain why two of the retained options, 3 and 4, are sometimes missing altogether from the tables comparing them with respect to their economic, environmental, and social impacts, and with respect to the criteria of effectiveness, efficiency, and coherence, while in other cases they are included alternatively. On the basis of the extensive analysis carried out for the seven carcinogens considered (pp. 29-57), the IA concludes by selecting option 2 as the preferred option; it provides a summary table illustrating how the retained option compares with respect to five aspects: stakeholders' acceptance; legal clarity; size of the problem; health benefit; limited costs for business (pp. 57-59).

Scope of the impact assessment

Wherever possible, the IA provides a brief assessment of the economic, environmental, and social (health-related) impacts of the retained options, analysing them separately for each of the seven carcinogens considered. In addition, it briefly illustrates the overall impact of the retained options with respect to workers, businesses (further broken down into impacts on SMEs and on competition and competitiveness), Member States/national authorities, and fundamental rights (pp. 59-62). However, further information on the administrative burden for public authorities and businesses would have been welcomed since the proposal aims to revise the regulatory landscape for health and safety. A comparison of the retained options with respect to the criteria of effectiveness, efficiency, and coherence is also provided (pp. 31-59); however, the meaning of the criteria themselves, and how they fed into the overall policy considerations, is not clear. When describing the individual carcinogen, additional information regarding the corresponding sector structure (e.g. in terms of number of employees) is provided. The economic impact is assessed in terms of costs of compliance to businesses in order to meet the proposed OELs and, sometimes, in terms of broader operating costs and conduct of businesses. The methodology used for estimating the current cancer burden is comprehensively explained in Annex 5 (pp. 84-91), but the presentation

in the core part of the IA seems to be weak, and it is not evident how the figures reported were obtained. Health impacts for each option are quantified by using non-monetary approaches, such as the Disability Adjusted Life Years (DALY), and a mix of monetary methods, such as value of life years lost (VLYL), cost of illness (COI), and willingness to pay (WPA). However, it seems that the monetary methods have been used simultaneously to calculate the cost variables (low and high estimates) for all types of identified cancers associated with the seven carcinogens. Environmental impacts are claimed to be insignificant for all carcinogens considered, without any explanation being provided. This might arguably have required some justification, especially considering that the individual IOM reports do contain some explanations. In this regard it is worth pointing out that, generally speaking, the IOM reports analyse a broader number of dimensions than those included in the IA (e.g. for Epichlorohydrine, innovation and research, macroeconomic impact, changes in end products). In addition, the IA does not consider the same aspects for the seven substances, omitting in any case some impacts that could perhaps have been usefully included in the current analysis (e.g. impact on research).

Subsidiarity / proportionality

The IA justifies EU action from both a Treaty and value-added perspective. The explanatory memorandum of the proposal states that Article 153(1)(a) of the Treaty on the Functioning of the EU (TFEU) empowers the EU to support and complement the activities of the Member States regarding the protection of workers' health and safety and to adopt minimum requirements for gradual implementation by means of directives, on the basis of Article 153(2)(b) (p. 7). According to the IA, establishing OELs in Annex III to the CMD could provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with its general requirements. Indeed, for all carcinogenic chemical agents where OELs are proposed in the current proposal, at least half of the Member States have not yet established legally enforceable OELs or have less protective ones than the value recommended by ACSH (p. 12). The IA does not contain a specific section on proportionality, which has been considered mainly when assessing the percentage of workers in the EU for whom legal protection could be improved by adoption at EU level of OELs for each chemical agent (p. 32). In addition, proportionality has hardly been assessed at all for public authorities. This would have been welcomed since, in some cases, Member States either have no OELs or have ones that are less protective of worker health than the value recommended by ACSH. The deadline for the submission of reasoned opinions by national parliaments on whether the proposal complies with the principle of subsidiarity was 15 March 2017. At the time of writing, no reasoned opinions had been submitted, though scrutiny was completed by the parliaments of eight Member States, and in progress in the parliaments of eight Member States. Among the eight parliaments that had completed their scrutiny, political dialogue was ongoing in the parliaments of three Member States.

Budgetary or public finance implications

The explanatory memorandum indicates that the proposal does not require additional budget and staff resources for the EU budget or EU bodies (p. 16); the IA further specifies that no additional costs will arise for [EU-OSHA](#), the European Agency for Safety and Health at Work (p. 63). As regards the Member States, in justified cases they undertake to accompany the notification of transposition measures with one or more explanatory document; the explanatory memorandum estimates this one-off additional administrative burden as not disproportionate (p. 17). In addition, while acknowledging that administrative and enforcement costs will differ according to the present status of each chemical agent in each Member State, they should not be significant (p. 15). Additional administrative costs might be incurred by authorities as regards the necessity to provide staff information and training on the revision, as well as to revise compliance checklists. However, these costs are considered minor in comparison with the overall functioning costs incurred by the national enforcement authorities. Finally, it is claimed that the legislative proposal would contribute to mitigating financial losses sustained by Member States' social security systems (expl. mem., p. 15), even though not significantly (IA, p. 61). However, the IA does not quantify either the amount of such losses or the reduction resulting from implementing the legislative proposal.

SME test / Competitiveness

The IA provides two short sections dealing with the impact on SMEs, and on competition and competitiveness. According to it, the analysis has shown that in most cases costs that will be incurred by SMEs are affordable for

them, and that the most relevant relate to investment in closed systems for using Trichloroethylene. In addition, among those companies not having already made the investments to protect workers either through closed systems or substitution, SMEs could be more vulnerable to the capital cost of a closed system. Should they decide to close down, as a consequence, there could be some limited effects on employment (pp. 60-61). Overall, however, it can be concluded that a quantitative cost-benefit analysis for SMEs does not seem to have been performed. As regards competitiveness, the IA concludes that the retained option would have a positive impact on competition within the internal market by, for instance, decreasing competitive differences between firms operating in Member States with different national OELs. At the same time it should not have a significant impact on the external competitiveness of EU firms because, in most cases, the retained option fits into the lower range of equivalent measures established in non-EU countries (p. 61). Considering both aspects, the analysis provided in the IA could, perhaps, have been further developed, and made more informative.

Simplification and other regulatory implications

The EU Occupational Safety and Health (OSH) *acquis* is made up of 24 directives including, inter alia, [Directive 89/391/EEC](#) (the 'Framework Directive'), the Chemical Agents [Directive 98/24/EC](#) (CAD), and the CMD itself.¹⁴ The explanatory memorandum of the proposal states that the Framework Directive and the CAD apply as general law without prejudice to more stringent and/or specific provisions contained in the CMD (p. 5). The IA explains the interactions between the CMD and [Regulation \(EC\) No 1907/2006](#) ('REACH') in order to justify why addressing the current issues under REACH is not enough. It explains, for instance, that REACH does not include process-generated substances (PGS), considered under Annex I to the CMD, and does not set OELs (pp. 102-103). In addition, [Regulation \(EC\) No 1272/2008](#) (CLP) relates to the CMD by providing a link to the hazard classification of chemical agents and mixtures (e.g. chemical agents and mixtures classified as carcinogens or mutagens category 1A or 1B) to which the CMD applies (p. 102). Finally, the CMD is one of the pieces of legislation, covering hazard identification and classification, currently being subject to a [fitness check on the most relevant chemicals legislation \(excluding REACH\)](#) as well as related aspects of legislation applied to downstream industries, carried out by the Commission. According to the explanatory memorandum (pp. 5-6), the proposal fits within the Commission's strategic goal to ensure a safe and healthy work environment for workers in the EU, as outlined in its communication [COM\(2014\)332 final](#) regarding the EU strategic framework on health and safety at work for the 2014-2020 period. This framework identifies three key challenges that are common across the Union, one of these being to improve the prevention of work-related diseases, such as occupational cancers (pp. 5-6). It is also in line with the Commission's work to establish a fair and truly pan-European labour market that provides workers with decent protection and sustainable jobs, which includes occupational health and safety protection, social protection, and rights connected to the employment contract. The changes to the CMD, as a results of the EU OSH legislation review, fit within the Commission's ongoing work on a [European Pillar of Social Rights](#), setting out twenty key principles and rights to support fair and well-functioning labour markets and welfare systems, aiming to adapt EU legislation to changing work patterns and society. A comprehensive summary of all relevant legislation related to the CMD is provided in Annex 8 of the IA (pp. 99-103).

Quality of data, research and analysis

The analysis carried out in the IA is not entirely new, as it is mainly based on the previous impact assessment,¹⁵ even though it is complemented by two very recent studies.¹⁶ It also includes the consultation of the Scientific Committee on Occupational Exposure Limits (SCOEL), and the Advisory Committee on Safety and Health at Work (ACSH) who, inter alia, helped the Commission in setting the OELs values included in the proposal. However, it is

¹⁴ An [ex-post evaluation](#) of the EU OSH *acquis* ([REFIT evaluation](#)), required by the Framework Directive, has concluded that specific provisions of individual directives have become outdated or obsolete, and has stressed the need to find ways to address new risks.

¹⁵ This, in turn, has mainly relied upon the 'IOM study', and the 'RPA study': Risk & Policy Analysts (2003), Assessment of the Impact of the New Chemicals Policy on Occupational Health, [Final Report](#) prepared for the European Commission.

¹⁶ ECHA, European Chemicals Agency (2016), [Valuing selected health impacts of chemicals - Summary of the Results and a Critical Review of the ECHA study](#); W.P. Jongeneel et al. (2016), [Work-related cancer in the European Union: size, impact and options for further prevention](#), Rijksinstituut voor Volksgezondheid en Milieu - RIVM (National Institute for Public Health and the Environment - RIVM), Letter report 2016-0010. See also the ECHA's website regarding the [willingness to pay to avoid certain health impacts](#).

not clear how these values were chosen; in addition, the interaction between SCOEL and ACSH is not clear. Overall, the analysis seems to be robust and convincing. However, there is a general issue regarding the availability of timely and reliable data, as well as the scarcity of available epidemiologic evidence, which is acknowledged in the IA (pp. 31 and 64, and p. 31 respectively).¹⁷ In addition, even when figures are provided, in at least a few cases either the corresponding sources cannot be verified or the corresponding figures refer to a different aggregate.¹⁸ As regards the projections of the expected number of deaths and cancer cases, the estimated numbers of workers exposed, and the estimated health costs under the baseline scenario, these are used, but not always consistently, in the individual tables included in the section analysing the impacts of the retained options.¹⁹ In addition, the data used in the IA come from different sources, without the IA providing any consideration regarding their comparability, which is not always possible due to the definitions/methodologies used by different organisations to gather and classify data. A final remark regards the total number of workers estimated to be exposed to at least one of the seven carcinogens considered. According to the IA, this amounts to 12 million (p. 8). However, this figure does not seem to be consistent with the one reported in the explanatory memorandum of the proposal, which states that updating the CMD with regard to the seven carcinogens will result in an increased protection for an estimated 4 million workers at least (p. 2). The methodology used in the IA to quantify the impacts of the different policy options is illustrated extensively in its Annex 5 (pp. 83-94), complementing some considerations regarding the uncertainties in the assessments of the health²⁰ (p. 18, Table 3.1) and socio-economic impacts (p. 4, Table 3.2, and pp. 19-20). The annex describes in a very clear way the steps undertaken and the analytical assumptions made. It also includes a specific paragraph regarding the methodological challenges encountered (pp. 92-94), providing additional explanations to those already illustrated under chapter 5.1 (pp. 29, 31). Something the IA could perhaps have emphasised more are the challenges relating to the cost of illness (COI) methodology used to analyse (and value) the economic impact of ill-health (pp. 87-90). It seems, in fact, that these are mainly attributed to the difficulty in gathering the information required to estimate direct and indirect costs and the values of production and production lost for each sector affected (p. 89). However, these are just some of the challenges encountered when performing a COI analysis.²¹ In addition, this type of analysis implies the assessment of the epidemiological and toxicological evidence available, as well as assumptions regarding, for instance, the population attributable fraction.²² Also, in some settings, the value of the estimates may be questionable.²³ One of the outcomes of these complexities is that reported estimates have been sometimes found inconsistent across studies, thereby raising concerns over the validity of these estimates and the methods used to calculate them. For at least the reasons explained, the estimates reported in Table 1 (pp. 10-12) and Table 1 of Annex 4 (pp. 77-81) of the IA need to be considered in the light of the analytical assumptions and challenges faced to obtain them, including the evolution in exposure to carcinogenic chemical agents (p. 30).

¹⁷ The IA mentions how the Commission and the EU-OSHA are actively working on improving data quality and availability in order to evaluate the efficiency of Community legislation on health and safety at work, also through Commission-funded projects such as the [HazChem@Work](#) project, for which the [final report](#) was recently made available.

¹⁸ This is the case, for instance, when the IA states that, in 2011, 53 % of work-related deaths were attributed to occupational cancers (p. 7). This percentage does not in fact refer to the EU28, as claimed, but to the EU28 *and other developed countries*. See Figure 3 ('work-related annual death in the EU28 *and other developed countries*') included in a paper by J. Takala (2015), [Eliminating occupational cancer in Europe and globally](#), European Trade Union Institute (ETUI), Working Paper 2015.10, pp. 9-10, which is referenced in the 2016 IA (footnote 9).

¹⁹ This is the case, inter alia, for the total attributable deaths due to exposure to Trichloroethylene (p. 48) and for the expected number of cancer cases and the total attributable deaths due to exposure to mineral oils as used engine oils (p. 55). In addition, in at least the case of 4,4'-Methylenedianiline (MDA), the table reported from the corresponding IOM report shows the existence of a *range* in the number of workers potentially exposed to this substance, 390 000-3 900 000 (p. 43), whereas in the overview Table 1 of the IA (p. 11), only the worst possible scenario has been provided.

²⁰ The methodology used within the SHEcan project for valuing health impacts is available as a [separate report](#).

²¹ On this issue see, for instance, Greenberg, D. et al. (2014), [What Are the Challenges in Conducting Cost-of-Illness Studies?](#) Value in Health Regional Issues. 4C:115-116.

²² The attributable fraction (AF) is the proportion of cases that would not occur in the absence of exposure (IA, pp. 84-85). On the conceptual problems in the definition and interpretation of attributable fractions see, for instance, Greenland S., Robins J.M. (1988), [Conceptual problems in the definition and interpretation of attributable fractions](#). Am J Epidemiol. 128(6):1185-97.

²³ Rockhill B., Newman B., Weinberg C. [Use and misuse of population attributable fractions](#). Am J Public Health 1998; 88(1):15-9.

Stakeholder consultation

As laid down in Article 154 TFEU, the Commission has the duty to consult European social partners prior to presenting any legislative proposal concerning employment and social affairs set out in Article 153 of the Treaty. This is carried out through a compulsory two-stage consultation procedure.²⁴ The Commission launched the first stage of a six-week consultation on 6 April 2004: in accordance with Article 154(2), social partners were asked to provide their opinions on the possible direction of EU action regarding the protection of workers from risks related to exposure to carcinogens, mutagens, and chemical agents toxic for reproduction at work. The second stage of a six-week consultation was launched on 16 April 2007: in accordance with Article 154(3), social partners were asked to provide their opinions on the content of the envisaged proposal (p. 69). These two consultations are clearly rather old, compared to the date of adoption of the two legislative proposals, and the IA does not provide any further consideration on this aspect. It only states that other consultations with stakeholders, as well as with the Working Party Chemicals at the Workplace (WPCs) of the ACSH, took place in the following years. These include a number of meetings which took place between 2013 and 2015, involving Commission services and a number of industry and workers' representatives concerned about specific chemical substances covered by the proposal (p. 73-74). The outcomes of these wide consultations are described in Annex 2 of the IA (pp. 69-74). Considering the first stage of the consultation, three rather broad questions were submitted; however, the directions given by the Commission regarding the actions to be considered were quite specific.²⁵ The IA states that nine European social partners replied (p. 69). At first sight, the small number of replies received seems to be insufficient to be representative of the European social partners' organisations that can be consulted under Article 154 TFEU, which currently amount to 87 organisations.²⁶ However, this figure assumes a completely different meaning if we consider who provided the feedback. According to a Eurofound study,²⁷ it can be concluded that the replies received were highly representative of all national level social partner organisations of employers and trade unions. Considering the second stage of the consultation, five specific points were submitted to European social partners (IA, p. 70).²⁸ Four of these points were already considered in the first stage consultation document, though not specifically asked within the three questions submitted for consultation. A fifth point, focusing on training and information requirements, was specific to the second stage. The Commission received replies from seven European social partner organisations, highly representative of all national level social partner organisations of employers and trade unions. Of note, the IA states that there was no agreement on the extension of the scope of the directive to include reprotoxic chemical agents, although it also states that workers took a positive view in order to extend the scope of the directive to cover them (p. 70). To assess if they should be included, the Commission thus launched the [RPA Study](#) (p. 72), but 'the results did not provide sufficient evidence that including these chemical agents under the scope of the CMD would lead to a higher protection of workers'; they were therefore excluded from the proposal (p. 68).

Monitoring and evaluation

The IA identifies indicators, and the sources of data, for monitoring the *operational* objectives of the retained option, namely the reduction of occupational diseases and occupational-related cancer cases in the EU, and the reduction of costs related to occupational cancer for economic operators and for social security systems in the EU (pp. 63-64). The explanatory memorandum states that, considering the data challenges, and in light of the long latency periods to develop a cancer (10 to 50 years), the Commission suggests using the ex-post evaluation exercise 2012-2017 to define the baseline values (benchmark) that will allow the assessment of the effectiveness of the revision of the directive. However, the lack of data and different national reporting structures call into question the effectiveness of the indicators, although the Commission has recognised this issue (p. 64). Evaluation

²⁴ On how the consultation of European social partners works, see for instance: European Commission, [Consulting European social partners: Understanding how it works](#), Luxembourg: Publications Office of the European Union, 2011.

²⁵ See the [first stage consultation document](#) available on the DG EMPL website.

²⁶ The list of European social partners' organisations consulted under Article 154 TFEU is available on the DG EMPL [website](#).

²⁷ [Eurofound](#), European Foundation for the Improvement of Living and Working Conditions (2013), Representativeness of the social partners in the European cross-industry social dialogue, [executive summary](#) (pp. 3-4); a [report](#) is also available.

²⁸ See also the [second stage consultation document](#) available on the DG EMPL website.

of the practical implementation of the proposed amendments could possibly be based on the 2017-2022 period. Finally, it mentions that a compliance assessment for the transposition of the directive is envisaged (p. 17). The IA states that national authorities, particularly national labour inspectorates, would monitor the directive's application and enforcement. Member States would continue to provide a single report to the Commission every five years on the practical implementation of the EU OSH directives, in accordance with Art. 17(a) of Directive 89/391/EEC. The Commission would evaluate within 36 months of the five-year period and inform the Parliament, Council, European Economic and Social Committee and ACSH of the results and possible improvements (p. 64).

Commission Regulatory Scrutiny Board

The Commission's Regulatory Scrutiny Board (RSB) adopted a [positive opinion](#) with reservations on a draft version of the IA report of 3 October 2016, recommending to:

- set out the sequence of steps and underpinning evidence used when deciding to create an OEL and determining its level, and elaborate on the decision to refrain from setting OELs on four substances;
- demonstrate the added value and benefit of setting new OELs, and explain why the proposed OELs are not more ambitious;
- elaborate and provide context for the description of the complementarity and interface between the CMD and REACH;
- ensure consistency between the present initiative and the supporting IA by amending or removing references to biomonitoring in the IA, as a result of the Commission intention not to include voluntary biomonitoring in the proposed initiative.

The final version of the IA seems to have addressed the RSB's recommendations, as also illustrated in the table describing the revisions introduced in response to the RSB's opinion (IA, pp. 65-66).

Coherence between the Commission's legislative proposal and the IA

The legislative proposal is aligned with the recommendations set out in the IA (expl. mem., pp. 4-5).

Conclusions

The IA defines the problem clearly, and its evolution without EU action is comprehensively outlined. The objectives appear to be relevant, sufficiently measurable, achievable, and consistent with the manner in which the problem has been defined, as well as with other EU policies; however, they are not time-bound. The methodology used to compare the scope of impacts is well-developed, even though it is not always clear how the reported figures were obtained. However, the proposed range of options limits the scope of the analysis, and some of those retained for consideration are not entirely convincing. Environmental impacts are claimed not to be significant, without any explanation being provided. There is also a general issue regarding the availability of timely and reliable data, as well as the scarcity of available epidemiologic evidence. The Commission has consulted a broad range of stakeholders, and the replies received were highly representative of all national-level social partner organisations of employers and trade unions. Finally, the IA seems to have addressed the RSB's recommendations.

This note, prepared by the Ex-Ante Impact Assessment Unit for the European Parliament's Committee on Employment and Social Affairs (EMPL), analyses whether the principal criteria laid down in the Commission's own better regulation guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work.

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