

Initial Appraisal of a European Commission Impact Assessment

Protection of workers from exposure to carcinogens or mutagens: third proposal

Impact assessment (SWD(2018) 88, SWD(2018) 87 (summary)) accompanying 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(2018) 171)

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's [impact assessment](#) (IA) accompanying the above-mentioned [proposal](#), adopted on 5 April 2018 and referred to Parliament's Committee on Employment and Social Affairs (EMPL). The proposal seeks to amend the Carcinogens and Mutagens [Directive 2004/37/EC](#) (CMD) by establishing binding occupational exposure limit values (OELs) for five carcinogenic chemical agents.¹

The current proposal is the third one adopted under the Juncker Commission, complementing those adopted on [13 May 2016](#)² and on [10 January 2017](#)³ covering respectively thirteen and seven carcinogens, processes and process-generated substances (PGSs). It fulfils the requirement under Article 16 of the CMD, that OEL values be set in respect of all those carcinogens or mutagens for which it is possible, based on the available information, including scientific and technical data. In addition, the proposal is part of a new initiative, set out in [COM\(2017\) 12 final](#), aiming to modernise the structure of EU occupational safety and health (OSH) legislation and policy (*'acquis'*). In it, the Commission identified the need to step up the fight against occupational cancer as one of the top three priorities for action in the area of occupational safety and health. Finally, the proposal aims to contribute to delivering on the objective of a 'Social Triple A'⁴ Europe rating set by Commission President Jean-Claude Juncker in his political guidelines.

The proposal follows a European Parliament [resolution](#) highlighting the importance of protecting workers from carcinogens, mutagens and reprotoxic substances. The resolution also called on the Commission to propose a revision of the CMD based on scientific evidence, adding more binding occupational exposure limit values where necessary. In addition, the initiative follows the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council [conclusions](#) of 5 October 2015. These stressed that 'increasing the level of protection of workers against carcinogens, mutagens and any other hazardous chemical agents at the workplace is a major and urgent priority', and invited the Commission to 'consider improvements to the legislation on carcinogens and mutagens, by reviewing the existing binding occupational limit values and adding new ones, as appropriate based on impact assessment and evidence'.

Problem definition

The IA identifies **occupational ill-health** as the **main problem**. This is because 'the negative impact of high exposure to carcinogens and mutagens at the workplace ... can cause a broad range of other significant health problems' in addition to cancers, such as muscular and skeletal illnesses, circulatory diseases, and injuries (explanatory memorandum, p. 1).⁵

The IA identifies **four underlying drivers** (pp. 4-10), namely:

- the need to further update the CMD (regulatory driver): according to the IA, 'updating the CMD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be updated accordingly in all Member States' (IA, p. 11). This is because 'the existing employers' practices as well as protective measures at Member State level do not always reflect available scientific and technological knowledge' (IA, p. 10);
- the inadequate, diverging or non-existing OELs at national level (regulatory driver): according to the IA, without EU action the current differences in the Member States (IA, Annex 5, Table 36, pp. 87-89) would remain. This would probably mean that some Member States would remain without limit values for certain carcinogens or those values would be too high to ensure adequate worker protection. A minimum standard across the EU would not therefore be ensured, affecting workers' protection (IA, p. 11);
- the exposure of workers to carcinogens (market driver): according to the IA, without EU action about 1.07 million workers would continue to be exposed to at least one of the five carcinogens considered (IA, p. 5). This would lead to a higher burden of disease, and to additional health costs. However, the IA does not detail how this figure has been obtained from the ranges illustrated in its Table 1 (IA, p. 5);
- partial exploitation of modern production technologies allowing lower exposure to carcinogens (market driver): according to the IA, 'state-of-the-art industrial production processes allowing for the further reduction of occupational exposure ... in the workplace exist [see examples provided in the IA] but their adoption is not generalised' (IA, p. 9). However, based on the text provided in the IA, the analysis illustrating this driver does not appear to be well developed.

The evolution of the problem without EU action is outlined briefly but the IA would have benefited from providing more comprehensive explanations. More evidence could also have been provided to support the statement that inadequate, diverging or non-existing OELs at national level (regulatory driver) may distort competition and 'may lead to complications [legal, administrative, organisational] for businesses operating in different EU Member States' (p. 9).

Objectives of the initiative

The IA does not clearly define the general objective(s). Based on the second amendment of the CMD, it could be assumed that **ensuring a high level of protection of workers' health and safety in the EU is the general objective** of the proposal. At the same time, the IA states that 'modernising the legal framework setting updated OELs on exposure to carcinogens was also identified as the key priority in the OSH field by the Commission's Communication 'safer and healthier work for all' of 10 January 2017' (IA, p. 12). As such, **modernising the structure of the EU occupational safety and health acquis would also appear to be a general objective**. The IA identifies **three specific objectives** (p. 12):

- to reduce occupational exposure to carcinogens and mutagens in the EU;
- to increase the effectiveness of the EU framework for protecting workers by updating it on the basis of scientific expertise;
- to achieve a more balanced protection of workers across the EU against carcinogens while ensuring more clarity and a level playing field for economic operators.

These objectives appear to be clear and consistent with the manner in which the problem has been defined. In addition, they appear to be relevant, achievable, and sufficiently measurable, though not time-bound. Finally, they are consistent with other EU policies (see 'Simplification and other regulatory implications' section below), and with the [Charter of Fundamental Rights of the EU](#) (IA, p. 12), namely with its Articles 2 ('right to life') and 31 ('fair and just working conditions'). Operational objectives are defined after selecting the retained options, in line with the Commission's [better regulation toolbox](#) (tool #16, p. 100).

Range of options considered

The IA considers several options, as illustrated below (preferred options are indicated in grey).

Option	Description	Cadmium	Beryllium	Arsenic acid	Formaldehyde	MOCA	Decision
1	Baseline (no EU OEL)						R
2	Lowest EU OEL value #	1 µg/m ³ +	0.1 µg/m ³	10 µg/m ³ +	0.15 mg/m ³	5 µg/m ³	RfA
3	Intermediate EU OEL value #	4 µg/m ³ §	0.2 µg/m ³ +	25µg/m ³	0.37 mg/m ³ +	10 µg/m ³ +	RfA
4	Highest EU OEL value #	10 µg/m ³	0.6 µg/m ³ §	50µg/m ³	0.6 mg/m ³	20 µg/m ³	RfA
A	Ban the use of the carcinogenic chemical agents						D
B	Provide industry-specific scientific information without amending the CMD						D
C	Apply market-based instruments (e.g. financial incentives such as subsidies or incentives in social insurance schemes) to promote prevention measures						D
D	Industry self-regulation (e.g. the Charter for the safe use of Trichloroethylene in metal cleaning established by the European chlorinated solvents association)						D
E	Regulation under other EU instruments (REACH)						D
F	Directly adopting the most stringent national OELs						D
G	Guidance documents						D
H	Adapted solutions for SMEs						D

Source: author, based on IA

Legend: #=8h-TWA value (eight hour time-weighted average)

+ =ACSH value §=ACSH transitional period value

R=Retained RfA=Retained for Assessment D=Discarded

Almost all of them, with the exception of options G and H, were already considered and assessed in the IA accompanying the second amendment of the CMD. Considering the explanations briefly provided in the IA for the discarding of options A-H (pp. 15-17), the following aspects can be highlighted:

- Option G: the development of, inter alia, guidance documents as a non-regulatory alternative was already considered by the IA accompanying the first amendment of the CMD, [SWD\(2016\) 152 final](#), but as a 'complementary measure', and not as 'alternative options to updating the CMD' (IA, pp. 26-27);
- Option H: it is not clear why this option was considered (and then discarded) in the first place. Article 3(1) of the CMD ('scope - determination and assessment of risks') states that the directive 'shall apply to activities in which workers are or are likely to be exposed to carcinogens or mutagens as a result of their work'. As such, all companies are concerned.

As regards the retained options, the IA states that 'in addition to the baseline scenario, OELs have been considered at the level proposed by the Advisory Committee on Safety and Health at Work (ACSH) and at one or two additional reference points (e.g. the strictest limit value observed among Member States' (IA, p. 14). However, considering the inhalable fractions, in at least the case of beryllium it would appear that Portugal has a stricter value of 0.05 µg/m³ (IA, Annex 5, Table 36, pp. 87-89). In addition, the IA does not explain how the highest values were determined, except for beryllium which is a transitional value set by the ACSH. As regards Option 4, in considering EU legal requirements less stringent than those already established by some Member States, the IA would appear not to be consistent with the objective of ensuring a high level of protection of workers' health and safety. However, the IA states that 'the most stringent national OEL might not always be feasible as an EU standard', for the reasons provided in the IA (pp. 14-15). Based on the analysis carried out (pp. 17-40), the IA selects the **values recommended by the ACSH as the preferred options**. For cadmium and beryllium, the preferred values would be set after a transitional period

of seven and five years, respectively, during which they will be fixed at the higher value indicated by Options 3 and 4, respectively. For arsenic acid, a transitional period is envisaged for copper smelting, as 'a limit value of 0.01 mg/m³ may be difficult to be complied with', though the IA does not indicate its duration. For three carcinogens, the preferred options are supplemented by notations (see 'Quality of data, research and analysis' section below). For each carcinogen, the IA provides a summary table illustrating how the retained options compare with respect to the criteria of effectiveness, efficiency, and coherence (IA, pp. 23, 27, 31, 35, 38). However, for cadmium it is not clear why Options 2 and 3 score the same in terms of effectiveness, especially in the light of the ACSH opinion. In addition, for all carcinogens, it is not clear how the options have been scored with respect to the coherence criterion.

Scope of the impact assessment

The IA provides an assessment of the economic, environmental, and social impacts of the retained options, quantifying them whenever possible. The economic impact is assessed, inter alia, in terms of administrative and compliance costs to businesses in order to meet the proposed OELs, and in terms of broader operating costs and capital expenditures, as requested by the Regulatory Scrutiny Board (RSB). For instance, compliance and administrative costs for cadmium are assessed to range from €14-44 million (Option 4) to €447 million (Option 2) (IA, p. 22). Capital expenditures are estimated to range from zero (MOCA) to €875 million (beryllium) over a period of 60 years, and operating costs from €10 million (arsenic acid) to €128 million (beryllium). No impact is expected for innovation. This is rather surprising as it would be reasonable to assume that the need to meet lower OEL values might induce the development of new production technologies, for example. No or limited impacts are expected for consumers, though no supporting analysis is provided. Social impacts are analysed in terms of ill health avoided and employment, based on information sources that are not always referenced. No or limited impact on employment is expected for four carcinogens, while a moderate impact (€17-180 million), in terms of salary lost due to ill health, is expected for beryllium, but only under the strictest value of Option 2. However, it is not clear whether the IA attributes the same meaning to 'job lost' and 'salary lost', as both are mentioned in the multi criteria analysis. As regards health impacts, in quantifying the ill health avoided it is not clear why intangible costs are not (explicitly) mentioned for cadmium and MOCA. The IA states that for the retained options, no environmental impacts are expected for arsenic acid, formaldehyde and MOCA, while they are expected to be neutral for beryllium and zero or limited for cadmium. This might have merited further justification, given that the proposal deals with carcinogenic chemicals.

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 European Union (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, based on Article 153(2)(b) (p. 5). Based on these provisions, the IA states that Article 16(1) of the CMD provides a specific legal basis for action, allowing for the adoption of limit values for those carcinogens (or mutagens) for which this is possible, considering the available scientific knowledge (IA, p. 10), which is constantly developing. In addition, establishing OELs in Annex III to the CMD would provide a 'common reference point that employers, workers and enforcers could use as a practical tool to assess compliance' with its general requirements, therefore contributing to improved clarity and enforcement (IA, p. 11). For all carcinogenic chemical agents where OELs are proposed, there is a range of differing national OELs. However, at least 15 Member States have not yet established OELs for one or more of the substances being considered (IA, Annex 5, Table 36, pp. 87-89). Proportionality is considered in the explanatory memorandum. It states that the provisions included in the proposal 'do not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties, in the form for example of lower limit values' (p. 7). Proportionality has been considered

mainly when assessing the number of workers in the EU for whom legal protection could be improved by adoption at EU level of OELs for each chemical agent (IA, Table 1, p. 5). No reasoned opinions by national parliaments on the proposal's compliance with the principle of subsidiarity had been submitted by the deadline of 5 June 2018.

Budgetary or public finance implications

The explanatory memorandum states that the proposal does not require additional budget and staff resources for the EU budget or EU bodies (p. 12). The IA states that additional administrative and enforcement costs might be incurred by enforcing authorities. However, according to the IA, they are not quantifiable but 'it is not expected ... to be significant' (IA, p. 42).

SME test/competitiveness

The IA provides two short sections dealing with the impact on SMEs (p. 41), and on competition and competitiveness (pp. 41-42). It states that costs incurred by SMEs will be affordable, with the most significant one assessed to be for SMEs dealing with formaldehyde and beryllium. The most relevant costs relate to investment in closed systems or substitution of the substances where technically feasible. However, according to the IA, they should remain below 1 % of their turnover, and no SME closures or employment effects are expected on the basis of the proposed OELs. The IA states that 'SMEs specificities, their limitations and particular challenges have been duly taken into account in the overall analysis' (IA, p. 41), even though this is not immediately apparent. Based on the comprehensive information provided in its Annex 7 (IA, pp. 100-155), illustrating uses/activities/sector concerned by the five carcinogens, the IA states that beryllium is 'mostly used by SMEs' (IA, p. 24), as 92 % of the 5 800 companies are small and 7 % are medium sized. In addition, it states that 'all affected companies of a possible OEL for MOCA are SMEs' (IA, p. 35). As such, the multi criteria analysis regarding these two substances appears to refer mainly to SMEs. As regards competition and competitiveness, the IA states that 'the retained options 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' (IA, p. 41). According to the IA, the retained options 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 (IA, pp. 41-42). However, no supporting evidence is provided to substantiate these two statements. 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. The overarching [Directive 89/391/EEC](#) (the 'Framework Directive') lays down principles for the introduction of measures to encourage improvements in the safety and health of workers. These principles are further developed in individual directives, introducing inter alia provisions related to exposure to dangerous chemicals of workers across sectors. The Chemical Agents [Directive 98/24/EC](#) (CAD), the Asbestos [Directive 2009/148/EC](#), [Regulation \(EC\) No 1907/2006](#) ('REACH'), and the CMD itself are the main pieces of a comprehensive framework for protecting workers from exposure to carcinogens and mutagens substances and/or any hazardous chemicals. The proposal's explanatory memorandum states that the CMD and REACH are complementary (p. 4). However, even considering the interactions between the two, the IA does not explain clearly why addressing the current issues under REACH is not enough. The changes to the CMD are also meant to contribute to delivering on the [European Pillar of Social Rights](#), aiming to adapt EU legislation to changing work patterns and society.

Quality of data, research and analysis

The analysis carried out in the IA is not entirely new, as 'it should be read in conjunction with the earlier [impact assessment for the first proposal](#),⁶ which provided an exhaustive consideration of the

CMD, the policy and legal context'. The most essential points are carried over and supplemented by additional information and analysis regarding these five additional carcinogens' (IA, p. 3). In addition, the IA states that the results of the [ex-post evaluation of the EU OSH acquis](#) (REFIT evaluation) as well as the preliminary conclusions of the [second REACH review](#) (REFIT evaluation) have fed the current analysis (IA, p. 2). For the substances covered by this proposal, the scientific advice regarding [cadmium](#), [beryllium](#), and [formaldehyde](#) has been provided by the Scientific Committee on Occupational Exposure Limits (SCOEL), while such advice has been provided by the Committee for Risk Assessment (RAC) of the European Chemical Agency (ECHA) with regard to [MOCA](#) and [arsenic acid and its inorganic salts](#). In addition, the Commission has consulted the Advisory Committee on Safety and Health at Work (ACSH), which has adopted opinions⁷ for all priority substances envisaged by the proposal,⁸ recommending to include in Annex III to the CMD a binding OEL for all of them. In addition, notations are mentioned for two of them, namely a skin notation for MOCA, and a notation for respiratory and dermal sensitisation for beryllium. However, Annex 2 of the IA mentions a notation (dermal sensitisation) for a third substance, formaldehyde, explaining the reason for doing this (IA, pp. 57-59). As regards the methodology used to quantify the impacts of the different policy options, Annex 4 (IA, pp. 64-86) describes clearly the steps undertaken and the analytical assumptions made, including the approach followed to monetise the health impacts. However, the annex does not provide information regarding the multi criteria analysis (MCA) used to assess the likely impact of the policy options. This analysis requires several assumptions before being carried out, as illustrated in the Commission's better regulation toolbox (tool #63, pp. 516-520). This lack of explanation therefore prevents any comment about how it was performed. In addition, it is not evident how the figures reported in the tables of the five carcinogens were obtained. A specific section regarding the analytical challenges encountered in carrying out the IA is provided in the chapter comparing the retained options (IA, 18-19) and in Annex 7 (IA, pp. 107-108). Considering all five carcinogens, the tables representing the baseline scenario show different percentages among them in the values of past/future exposure levels and past/future number of exposed workers. The IA simply states that the indicated changes are 'expected or assumed'. As regards the sources of information used, the IA could have been more 'transparent on how data were gathered and from which sources to generate monetised information', as required by the better regulation toolbox (tool #31, p. 241). In addition, the supporting study specifically commissioned for this initiative, carried out by a [consortium](#) led by RPA (Risk & Policy Analysts) between July 2017 and February 2018, was not available at the time of writing, preventing additional assessments.

Stakeholder consultation

As laid down in Article 154 TFEU, the Commission must consult the European social partners prior to presenting any legislative proposal concerning employment and social affairs set out in Article 153 of the Treaty. This was carried out through a compulsory two-stage consultation procedure, which ran between 26 July and 22 December 2017.⁹ In addition, the Commission consulted the Chemicals at the Workplace (WPCs) Working Party of the ACSH, which adopted opinions on all carcinogens considered under the current initiative (see the 'Quality of data, research and analysis' section above). The outcomes of these consultations are described in Annex 2 of the IA (pp. 51-59). Finally, the Commission carried out additional consultation activities (e.g. telephone interviews, site visits, face-to-face meetings), as illustrated in Annex 4 (IA, pp. 80-82). Seven European social partners replied (pp. 51-53). It appears that the stakeholders who replied represented a significant number of national level social partner organisations of employers and trade unions.¹⁰

Monitoring and evaluation

The IA identifies two indicators, and the sources of data, for monitoring the operational objectives identified for the preferred option. These are firstly, the reduction of occupational diseases and occupational-related cancer cases in the EU, and, secondly, the reduction of costs related to occupational cancer for economic operators and for social security systems in the EU (IA, p. 44).

However, the operational objectives appear to be quite broad. The IA states that a two-stage compliance assessment (transposition and conformity checks) for the transposition of the limit values is envisaged (p. 44). In addition, it states that, considering the data challenges, 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 planned CMD revision. 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. This is why the IA states that the Commission and EU-OSHA are actively working on improving data quality and availability, also in order to develop additional indicators (IA, p. 44). Evaluation of the practical implementation of the proposed amendments could possibly be based on the 2017-2022 period. Finally, 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. Based on these reports, the Commission would evaluate the implementation of the CMD and inform the Parliament, the Council, the European Economic and Social Committee and the ACSH of the results and possible improvements (p. 44).

Commission Regulatory Scrutiny Board

On 23 February 2018 the Commission's Regulatory Scrutiny Board (RSB) adopted a [positive opinion](#) on a draft version of the IA report of 30 January 2018, recommending that the IA:

- explain more fully the different steps of the process and the weighting of different prioritisation criteria for selecting which chemical substances require OELs, highlighting also possible differences in roles, structures and approaches between different bodies, and indicate how to achieve the Commission's commitment to reach a total of 50 OELs by 2020;
- clarify to what extent and under what circumstances the preferred option could deviate from the OELs agreed by the ACSH Committee;
- better present the distribution over time of benefits and costs needed for possible significant upfront investments, distinguishing between one-off investments and operating costs.

The final version of the IA summarises how it has addressed the RSB's recommendations in the overview table of Annex I (IA, pp. 46-47), in line with the better regulation guidelines. The IA does appear to have addressed most of the RSB's recommendations. However, it does not indicate how the Commission intends to meet its commitment to reach a total of 50 OELs by 2020. Also, at least with regard to cadmium, the IA does not appear to have explained what risks follow from exceeding the recommended limit indicated by the ACSH, as indicated by SCOEL in its [opinion](#) (p. 10).

Coherence between the Commission's legislative proposal and IA

The proposal seems to be aligned with the analysis carried out in the IA, as illustrated by the accompanying Annex which amends Annex III of the CMD according to the preferred options. However, the length of two years for the transitional period for arsenic acid used in the copper smelting sector was not specifically indicated in the IA (recital 16 of the proposal).

Conclusions

The IA clearly defines the problem to be addressed; however it would have benefited from providing more comprehensive explanations of its likely evolution without EU action. The objectives appear to be relevant, sufficiently measurable and achievable, though not time-bound. The IA considers a wide range of options, and those retained for further assessment appear to be reasonable, and consistent with the approach followed in two previous amendments of the directive. The analysis of impacts focuses on the economic and social dimension, mainly health, and is consistent with the manner in which the problem has been defined. Environmental impacts are assessed to be broadly negligible: considering that the IA is dealing with carcinogenic chemical substances, this might

perhaps have required further justification. The IA acknowledges a general issue regarding, inter alia, the availability of data on the number of workers exposed, and the scarce and not always sufficiently robust, epidemiological evidence. The methodological annex does not provide information regarding how the multi criteria analysis has been performed. Finally, the IA appears to have addressed most of the RSB's recommendations and the legislative proposal seems to be consistent with the analysis carried out in the IA.

ENDNOTES

¹ These are: cadmium, beryllium, arsenic acid and its salts, formaldehyde, and 4,4'-methylene-bis(2-chloroaniline (MOCA). The first three also include their respective inorganic compounds within the scope of Directive 2004/37/EC (see also IA, Annex 6, pp. 95-99). Of note, in the IA accompanying the second proposal, the Commission stated that 'action in relation to five carcinogens [including diesel engine exhaust emissions (DEE)] should be at this stage withheld' (IA, p. 22). Only two of those mentioned in the previous proposal have been included in the current proposal (Beryllium and MOCA).

² See N. Scholz, [Limits on exposure to carcinogens and mutagens at work](#), EPRS, European Parliament, 2018.

³ See N. Scholz, [Limits on exposure to carcinogens and mutagens at work: Second proposal](#), EPRS, European Parliament, 2017. See also S. Vettorazzi, [Protection of workers from exposure to carcinogens or mutagens: second proposal](#), initial appraisal of a Commission IA, EPRS, European Parliament, 2017.

⁴ See M. Lecerf, What is '[Social Triple A](#)'?, EPRS, European Parliament, 2016.

⁵ Cancer alone, however, is the main work-related health problem in the EU28. According to data reported in a 2017 [article](#) published by the European Agency for Safety and Health at Work (OSHA), cancers were identified as the main factors responsible for almost 52 % of all EU28 fatalities in work-related accidents and illnesses.

⁶ See also A.-A. Georgescu, [Protection of workers from exposure to carcinogens or mutagens](#), initial appraisal of a Commission IA, EPRS, European Parliament, 2016.

⁷ ACSH's opinions: [cadmium](#) and its inorganic compounds, [beryllium](#) and its inorganic compounds, [arsenic acid](#) and its salts as well as its inorganic compounds, [formaldehyde](#), and [MOCA](#). See also Annex 2 of the IA (pp. 57-59).

⁸ The reasons for consulting three different bodies are explained in Annex 9 of the IA (pp. 161-164).

⁹ See consultation documents [C\(2017\) 5191 final](#), and [C\(2017\) 7466 final](#). See also the [questionnaires submitted by RPA](#) to companies, OSH consultants/experts, and Member State authorities.

¹⁰ Among the three trade unions that replied, ETUC (European Trade Union Confederation) and EFBWW (European Federation of Building and Wood Workers) considered it necessary to extend the scope of the CMD to include reprotoxic substances, which is also in line with the EP resolution mentioned above. ETUC, in addition, considered that diesel engine exhaust emissions (DEE) should be considered as a candidate for the fourth amendment of the CMD. In this regard, the Commission 'gave consideration' to a first list of four substances, including DEE, for 'subsequent' amendments of the CMD. As regards reprotoxic substances, 'the Commission will assess by the first quarter of 2019 the option of amending the scope of the CMD' to include them (IA, p. 54).

This briefing, prepared for the EMPL Committee, 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.

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