BRIEFING

Initial Appraisal of a European Commission Impact Assessment

European Parliament

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

Impact assessment (SWD(2020) 183, SWD(2020) 184 (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

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's impact assessment (IA) accompanying the above-mentioned proposal,[1] adopted on 22 September 2020 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) with a view to establishing binding occupational exposure limit (OEL) values for two carcinogenic chemical substances (acrylonitrile and nickel and the compounds of the latter), and revising the binding OEL value already established for one carcinogenic chemical substance (benzene). The current proposal is the fourth one adopted by the Commission, and follows those adopted on 13 May 2016,[2] 10 January 2017[3] and 5 April 2018,[4] which covered 13, seven, and five carcinogenic substances respectively. These updates and possibly others in the future, fulfil the obligations provided under Article 16 of the CMD, establishing that OEL values must be set (in its Annex III) for all those carcinogens or mutagens for which this is possible, based on the available information, including scientific and technical data.

Problem definition

The IA identifies **occupational ill-health** as the **main problem** (IA, Figure 2 – problem tree, p. 5) because in addition to cancer, which 'remains the first cause of work-related deaths in the EU' (IA, p. 1) with an attributed 52 % of annual occupational deaths in the EU, exposure to carcinogens and mutagens also leads to other significant health problems, such as circulatory diseases (Figure 1 – work-related deaths in the EU, p. 1). **Four underlying drivers** are identified by the IA, namely (pp. 6-11):

- The exposure of workers to carcinogens (market driver): according to the IA, without EU action an estimated 1.1 million workers would continue to be exposed to at least one of the three carcinogens considered by the proposal (IA, p. 6), leading to a higher burden of disease, as quantified in Table 2 of the IA (p. 8). The IA states that 'for each substance the most reliable number has been taken forward for the baseline scenarios and for the cost-benefit assessments related to the retained options for establishing limit values';
- The need to further update the CMD (regulatory driver): according to the IA, the availability of new scientific and technical evidence could lead to either updating existing OEL values, which is the case regarding benzene, or establishing new OEL values, as required by the aforementioned Article 16. The IA describes the added value for the employers of having binding OEL values established at EU level, e.g. in terms of the risk management measures that they would have implemented (IA, pp. 8-9);
- Diverging situations regarding the OEL values established (if any) at national level (regulatory driver): according to the IA, without EU action the current differences in the Member States (IA, Table 3, p. 10), would remain (e.g. seven of them have no OEL for

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acrylonitrile). This would probably mean that some Member States would continue to not have OEL values for two of the carcinogens considered by the current proposal, acrylonitrile and nickel compounds (the third, benzene, having already been included in Annex III of the CMD). In addition, for those Member States having already established an OEL value for acrylonitrile and/or nickel compounds, there are differences between the lowest (i.e. strictest) and the highest (i.e. least strict) *national* OEL value. According to the IA, the differences existing at national level would lead to different levels of protection of EU workers, in addition to having an impact on those businesses operating in several Member States (p. 10);

- Partial exploitation of modern production technologies allowing lower exposure to carcinogens (market driver): according to the IA, although modern production technologies allow to further reduce the occupational exposure, 'their implementation is not yet generalised in all the companies dealing with the three substances addressed in this initiative' (IA, p. 10). However, based on the text provided in the IA, the analysis illustrating this driver does not appear to be sufficiently developed.

The IA's problem tree (IA, p. 5) mentions the 'consequences' for businesses, for Member States and for workers (e.g. higher costs due to absenteeism, higher social security costs, etc.). Annex 3 of the IA ('who is affected and how?', pp. 63-65) identifies and describes the 'practical implications' deriving from the implementation of the legislative proposal, which appear to be identical for the three substances included in the proposal. The IA states that 'substitution may be possible for some carcinogens in the future' (IA, p. 11), but it is unclear whether the IA is referring to the three substances considered by the current proposal or, rather, if it is making a statement about carcinogens in general. As regards the future evolution of the problem, the IA highlights some of the inherent difficulties in making forecasts and anticipating all the developments regarding the subject, one such being the 'scarcity of relevant data'. The analysis regarding the definition, scope, scale and evolution of the problem without EU action, appears to be clear and sufficient.

Subsidiarity / proportionality

The IA justifies EU action from both a Treaty and a value-added perspective (IA, pp. 13-15). 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 scientific knowledge available (IA, p. 13). Subsidiarity and proportionality (and REFIT) are mentioned in two specific sections of the IA (pp. 13-15, and pp. 44-45). As regards subsidiarity, the IA states that action taken by individual Member States in response to newer scientific evidence 'would risk increasing divergences between Member States with potential competition on the basis of OELs set at different levels' (IA, p. 44), providing specific examples. In the light of the diverging national situations regarding two carcinogenic chemical substances for which OEL values are proposed (see under 'problem definition' above), the IA amply justifies the need for and added value of EU action. As regards proportionality, the IA states that the preferred option offers a certain margin of flexibility to Member States, as it envisages transition periods for mitigating businesses' burdens and supporting their compliance, which have also been discussed by the relevant stakeholders. In addition, the IA reminds that Member States are not prevented from maintaining or introducing more stringent protective measures compatible with the Treaties, based on the provisions of Article 153(4) of the TFEU, for example by establishing lower (i.e. stricter) OEL values (IA, p. 45). Proportionality has also been considered when assessing the estimated number of EU workers whose protection and health could be improved with the proposed initiative (IA, Table 4, p. 12). At the time of writing, no reasoned opinions had been submitted by national parliaments, (deadline was 18 November 2020).

Objectives of the initiative

The IA identifies **two general objectives** of the proposal (p. 15): **ensuring to the [EU] workers the right to a high level of protection of their health and safety at work**, and **preventing death**

caused by work-related cancer and other health problems. The IA identifies **three specific objectives** (p. 15): to further improve protection from occupational exposure to carcinogens and mutagens in the EU; to increase the effectiveness of the EU framework [for the protection of workers] by updating it based on scientific expertise; to ensure more clarity, facilitate implementation, and contribute towards a more 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. The operational objectives were defined once the retained options had been selected (IA, pp. 45-46), in line with the Commission's Better Regulation Guidelines (tool #16, p. 100); that said, they do not appear to be operational enough. Of note, there are two operational objectives but three specific objectives.

Range of options considered

The IA considers three options in addition to the baseline, as illustrated below. Of note, the IA indicates them as 'other options', very likely because, for each substance, the criterion used to select their OEL values is different. The preferred options are indicated in grey, although for nickel compounds and benzene, OEL values at the level of option 4 (indicated in italics) have been included in the preferred options but only for a *transitional period*, as explained below.

Option	Description	Acrylonitrile	Nickel compounds	Benzene	Decision
1	Baseline	no EU OEL	no EU OEL	current EU OEL 1 ppm (3.25 mg/m^3)	R
2	'other option' (#)	0.5 mg/m^3 (*)($)	0.03 mg/m^3 (*)(^)	0.05 ppm (0.16 mg/m^3) (^)	RfA
3	'other option' (#)	1 mg/m^3 (*)(+)	0.05 mg/m^3 (*)(/)	0.2 ppm (0.66 mg/m^3) (/)	RfA
4	'other option' (#)	2 mg/m^3 (*)	*0.1 mg/m^3 (*)(§)*	*0.5 ppm (1.62 mg/m^3) (§)*	RfA
A	Ban the use of the carcinogenic chemical agents				D
B	Directly adopt the most stringent national OEL values				D
C	Provide industry-specific scientific information without amending the CMD				D
D	Apply market-based instruments (e.g. financial incentives such as subsidies or incentives in social insurance schemes) to promote prevention measures				D
E	Industry self-regulation (e.g. the Charter for the safe use of Trichloroethylene in metal cleaning established by the European Chlorinated Solvents Association)				D
F	Regulation under other EU instruments (REACH)				D
G	Guidance documents				D
H	Adapted solutions for SMEs				D

Source: author, based on IA (Table 5, p. 18 and Annex 9, pp. 160-162) and RAC opinions

Legend: *=inhalable #=8h-TWA value (eight-hour time-weighted average) **$**= for acrylonitrile only, this is the lowest OEL value set by a Member State ^=RAC recommended value to the ACSH +=ACSH (RAC) value /=ACSH value **§**=ACSH transitional value **R**=Retained **RfA**=Retained for Assessment **D**=Discarded

The IA states that several other options had already been considered and assessed in the IAs accompanying the previous amendments of the CMD, but were considered 'disproportionate or less effective in reaching the objectives' and therefore discarded (IA, p. 18). In addition, the IA states that, for nickel compounds and for benzene, it has not been possible to consider additional options consisting of a combination of a transitional and a target OEL value, as the associated costs and benefits have not been assessed in a supporting study prepared by COWI A/S (not available). Based on the explanations provided in Annex 9 of the IA for the discarding of options A-H (pp. 160-162), it

can be observed that the development of, inter alia, guidance documents as a non-regulatory alternative (option G) was already considered by the IA accompanying the first amendment of the CMD, but as a 'complementary measure', and not as 'alternative options to updating the CMD' (SWD(2016) 152, pp. 26-27).

In addition, it is unclear why option H 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 option 4 for acrylonitrile, in considering EU legal requirements that are less stringent than those already established by some Member States (one, in this case), 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 it provides on pp. 17-18, and this explanation is understood as concerning all the substances considered by this proposal, and not only acrylonitrile. Based on the analysis carried out (pp. 17-39) in accordance with the methodology illustrated in Annex 8 (IA, pp. 156-159), the IA selects the two options described below, which are summarised in its Table 15 (p. 39).

The preferred option for acrylonitrile sets its value at 1 mg/m³ as recommended by the Committee for Risk Assessment (RAC) and indicated by the Advisory Committee on Safety and Health at Work (ACSH) (**option 3**). A short-term exposure limit (STEL) of 4 mg/m³, not indicated among the retained policy options, is also included in the preferred option 3, together with a skin notation. In addition, a four -year transitional period (calculated from the date of entry into force of the directive amending the CMD) is introduced for both aforementioned values. However, it is unclear why the IA did not explain why the biological monitoring that was included in the RAC's opinion, recommending a biological limit value (BLV), was not included in the preferred option. Finally, the IA does not indicate whether other STELs were considered under options 2 and 4.

The preferred option for nickel compounds sets their values at 0.05 mg/m³ and for benzene at 0.2 ppm, as indicated by the ACSH (option 3); the values recommended by the RAC were not accepted. These preferred values would be set after a transitional period (ending on 18 January 2025 for nickel compounds, while for benzene this would be set from two up to four years after the entry into force of the directive), during which they would be fixed at the higher value indicated by the ACSH as specified in option 4 (0.1 mg/m³, inhalable fraction, and 0.5 ppm, respectively). The preferred options are supplemented by notations: a skin and respiratory sensitisation notation for nickel compounds, and a skin notation for benzene, the latter having already been included in Annex III to the CMD when the latter first entered into force in 2004. Finally, and more importantly, the IA does not mention the fact that the stricter OEL value(s) recommended by the RAC (but not chosen by the ACSH) 'were considered [by RAC] also protective for reproductive effects' (RAC opinion, p. 12). As regards benzene, it is unclear why the IA did not mention the fact that the preferred option did not consider the BLVs (biological limit values) and BGVs (biological guidance values) recommended by the RAC in its opinion, while in its opinion the ACSH states that 'the three Interest Groups [representing national governments, trade unions and employers' organisations] also agreed on the usefulness of biomonitoring as proposed by RAC but note that, at present, BLVs are not proposed under the CMD' (p. 2). For each chemical substance, the IA provides a summary table illustrating how the retained options compare with respect to the criteria of effectiveness, efficiency and coherence (IA, Tables 12, 13 and 14, pp. 36-38), although for none of the three carcinogens, based on the explanations provided, does it become clear how the options have been scored with respect to the coherence criterion. However, the IA does not indicate how the retained options compare with respect to the fourth criterion, proportionality, which is mandatory.

Assessment of impacts

The IA assesses the economic and social impacts of the retained options, quantifying specific dimensions but only for those sectors where this was possible, and assessing the environmental

impact only qualitatively (IA, pp. 39-44). Economic impacts are quantified in terms of the administrative and compliance costs that businesses would incur for having to invest in risk management measures (RMMs) required to meet the proposed OELs, the administrative costs for the Member States, the avoided costs for businesses and the public sector (e.g. payments related to sick leave), and company closures due to intra-EU competition (IA, table 7, pp. 23-24, and Table 11, p. 34). In addition, the IA provides a few specific quantifications of the expenditures linked to RMMs that would be needed in some of the sectors using the three substances for implementing (some of) the OEL values envisaged by the retained options. Limited impacts are expected for consumers, though no supporting analysis is provided. An impact on research and development (R&D) is mentioned when considering the RMMs estimated to be required for meeting the proposed OELs, with the IA envisaging an inverse correlation between the two (i.e. the higher the capital expenditures, the lower the investment in R&D, especially for SMEs). However, the IA does not provide any supporting analysis but just a few examples drawn from some of the affected sectors, such as the catalysts and batteries sectors. A qualitative assessment is provided for the impacts on consumers and international competitiveness (see the 'SMEs/Competitiveness' Section). Social impacts are quantified in terms of ill health avoided (number of avoided cancer and non-cancer cases but only for a few specific health endpoints) and in terms of health benefits, calculated in terms of the costs of ill health avoided, although the assessment is limited to the most sensitive cancer endpoints and other adverse health effects (see the section on 'supporting data and analytical methods used' below), therefore determining a likely underestimation of the benefits for workers and the society as a whole (IA, p. 40). No impact on employment (considered in terms of jobs lost and social costs) is expected for acrylonitrile, while for nickel compounds the number of jobs lost are estimated to be 19 000, 10 000 and 1 500 for options 2, 3 and 4 respectively. Social costs are estimated to be equal to €1.6 billion, €779 million and €127 million, depending on how low (i.e. strict) the OEL would be. Finally, as regards the impact on employment for benzene, no job losses are estimated for options 3 and 4, and just a few (but not quantified) for option 1. Social costs would therefore be equal to zero for options 3 and 4, while for option 2 they have not been quantified. As regards environmental impacts, these are expected to be limited for acrylonitrile, limited/null for nickel compounds, and small but positive for benzene, due to reduced fugitive and diffuse emissions. The IA mentions a few examples drawn from those sectors employing the three substances considered, but the analysis included in the short specific section of the IA (pp. 42-43) could perhaps have substantiated more clearly why the adoption of the preferred OEL values should have a zero or limited positive impact on the environment.

SMEs / Competitiveness

The IA includes a dedicated section on the overall impact of the preferred options on SMEs (pp. 40-42). SMEs are mentioned very briefly when the preferred option for acrylonitrile is compared with respect to the coherence criterion (IA, p. 36), and when the impacts of the policy options regarding acrylonitrile and nickel compounds are analysed. In the first case, the IA states that SMEs usually encounter 'more difficulties' to comply with lower (i.e. stricter) OEL values if compared to large companies, given their lower turnover. In the second one, the IA states that the costs of compliance with an OEL of 0.05 mg/m^3 (i.e. option 3) and above would 'represent a sustainable percentage of overall turnover, even for SMEs'. A few estimates are provided for both substances. SMEs are also mentioned when illustrating the results of the stakeholder consultation in Annex 2 (IA, pp. 53-62). Finally, they are considered in Annex 9 when discussing the discarded option H, 'adapted solutions for SMEs' (IA, p. 162). The information included in the IA provides some indication of the likely impact the proposed amendment to the legislation would have on SMEs, although it could have been developed further and more systematically in Annex 6 of the IA (pp. 110-152), which describes the relevant sectors, uses and activities of the three chemical substances considered in the legislative proposal. As regards competitiveness, the IA states that for acrylonitrile, 'the impact of introducing any of the OELs ... [is] estimated to be relatively modest', except for a 'very limited number of companies interviewed' (IA, p. 22). As regards nickel compounds, the IA appears to be less conclusive as regards the impact of the preferred option on the competitiveness of EU companies (IA, p. 28). As regards benzene, the IA

states that 'as this industry is confronted with global competition, companies will not be able to pass on these costs to the users further down the value chain or consumers. At the strictest OEL, it is likely that companies operating in this sector would lose competitiveness' (IA, p. 32). However, it is not clear what industry/sector the IA is specifically referring to, as several industries/sectors are mentioned under the baseline (IA, p. 30). Overall, the analysis in the IA provides just an indication of the impact on competitiveness and could perhaps have been made more precise/less ambiguous, especially as regards nickel compounds and benzene.

Simplification and other regulatory implications

Regulation (EC) No 1907/2006 (REACH) and the CMD are the main building blocks of the legislative framework on protecting workers from exposure to carcinogenic and mutagenic substances and/or any hazardous chemicals. The IA states that 'consistency [of the CMD] with the REACH Regulation is ensured' (IA, p. 2). However, the IA does not appear to have succeeded in explaining clearly in the report how this consistency between the two pieces of legislation is ensured.

Monitoring and evaluation

The IA identifies two indicators and a number of data sources for monitoring the operational objectives for the preferred options. These indicators are, i) the reduction of occupational diseases and occupational-related cancer cases in the EU, and ii) the reduction of costs related to occupational cancer for economic operators and for social security systems in the EU (IA, Table 16, pp. 45-46). As regards the first indicator, the IA identifies one *potential* source as being Eurostat 'if the results of the on-going feasibility study are positive', without providing any further details on this study (IA, p. 46). As regards collecting reliable data, the IA mentions, among the ongoing projects (not specified), the cooperation with national authorities on the European Occupational Diseases Statistics (EODS) data collection (IA, p. 46). The IA states that a two-stage compliance assessment (transposition and conformity checks) for the transposition of the limit values is envisaged (p. 46). Finally, the IA states that national authorities, particularly national labour inspectorates, would monitor the application and enforcement of the CMD.

Stakeholder consultation

It appears from the IA (pp. 53-62) that the Commission consulted extensively a wide number of stakeholders, including social partners, Member States, the RAC of the European Chemical Agency (ECHA), and 'other' stakeholders. As laid down in Article 154 TFEU, the Commission must consult the EU social partners prior to presenting any legislative proposal concerning employment and social affairs. This was carried out through a compulsory two-stage consultation procedure, which ran between 26 July and 22 December 2017. This same consultation also addressed the third amendment of the CMD, which explains why it was held almost three years ago. Stakeholders, other than the EU social partners and the Member States, were consulted by the external contractor through various modalities (e.g. telephone interviews, site visits, face-to-face meetings, targeted online questionnaires, workshops), as indicated in Annex 2 (IA, pp. 59-62). The outcomes of these consultations are described in Annex 2 of the IA (pp. 53-62), which appears to report on the contributions of the different categories of stakeholders in sufficient detail.

Supporting data and analytical methods used

The IA states that the analysis carried out is not entirely new, as 'it should be read in conjunction with the earlier impact assessment for the first proposal'. The Commission appealed to external expertise (in this case, COWI A/S) to support the analysis performed in the IA. However, the resulting study was not available at the time of writing, although the IA states that 'the outcome of this study ... is summarised in the relevant sections of this document' (IA, p. 52). Detailed information regarding workers' exposure to the substances, their production and uses by the industry and downstream users are provided in Annex 6 of the IA (pp. 110-152), which warns that in some cases the data extracted from the selected datasets were not comparable, e.g. because the sectors did not

match (IA, p. 111). Following a Commission request to ECHA on 9 March 2018, the RAC adopted opinions on the 'scientific relevance of occupational exposure limits' for acrylonitrile, benzene, nickel and its compounds (IA, Annex 1, pp. 50-51). These opinions were based on the more articulated proposals (acrylonitrile, benzene, nickel and its compounds) prepared by ECHA, which were made publicly available for comments and were further developed into *background documents* annexed to the RAC opinions (Annex 1-acrylonitrile, Annex 1-benzene, Annex 1-nickel and its compounds). These background documents, which 'extensively reviewed recent primary literature in critical areas', were subsequently taken into account by the RAC, in addition to previous reviews (RAC opinion, p. 5). On 4 June 2019, the ACSH adopted opinions regarding the EU binding OELs for acrylonitrile, benzene, nickel and its compounds (IA, Annex 2, pp. 57-59). The IA mentions (p. 3) the ex-post evaluation of the EU OSH *acquis* (REFIT evaluation), completed in 2017, and the second REACH review ('REACH REFIT evaluation'), completed in 2018, although it is not clear how their findings have fed into the current analysis. Information regarding the methodology applied is included in Annex 4 ('analytical methods', IA, pp. 70-94), which also includes a short section illustrating the analytical challenges regarding the cost-benefit analysis performed (IA, pp. 90-91). For each substance, the IA includes tables illustrating the results of a multi-criteria analysis, based on the COWI A/S study (IA, Table 7, pp. 23-24, Table 9, pp. 29-30, and Table 11, pp. 33-34), although the analysis performed in the IA appears to be a more traditional cost-benefit analysis. Based on the background section of the three opinions, the RAC's evaluation of the scientific relevance of the occupational exposure limits appears to have been based on robust and recent scientific literature. However, in estimating the disease burden, the IA states that the future burden of disease 'only reflects cases occurring as a result of future exposure' and openly acknowledges that this methodological approach leads to an underestimation of the number of cancers (IA, p. 20), which could be further underestimated because not all health endpoints could be quantified for the three substances considered, and because of 'several limitation of the data/calculations, which are further explained in the analytical challenges section [pp. 90-91] of the annex 4' (IA, p. 7). This is, however, a common shortcoming in cases like this.[5]

Follow-up to the opinion of the Commission Regulatory Scrutiny Board

On 29 May 2020 the Commission's RSB adopted a positive opinion with reservations on a draft version of the IA report of 24 April 2020, noting the presence in the report of 'significant shortcomings' regarding, for instance, the impacts of the various transitional periods and the relative weights assigned to the consultative processes and to the cost benefit analysis for selecting the preferred options; the criteria for selecting the preferred options; and the assessment of the proportionality of the preferred options. The final version of the IA summarises in a table included in its Annex 1 the RSB's recommendations and how they have been addressed (pp. 48-50), in line with the Better Regulation Guidelines. The IA does appear to have addressed most of the RSB's recommendations. However, it would appear that it has not succeeded in explaining convincingly how the second REACH review ('REACH REFIT evaluation') has fed into the IA (as already indicated in the previous section of this briefing), and how the existing OEL value for benzene has worked so far and the need to revise it, which the IA appears to justify in order to 'ensure a more appropriate minimum level of protection across the EU' (IA, p. 14). As regards the impacts of the various transitional periods included in the preferred options, in reply to the RSB's request, the IA clarifies that the (combination of) OEL values introduced with the transitional periods were 'recommended by the ACSH while the COWI study was already at an advanced stage so that it was not possible anymore to assess their costs and benefits' (IA, p. 49 and p. 35).

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 annex accompanying the IA, which amends Annex III of the CMD according to the preferred options.

The IA defines clearly the problem to be addressed and its underlying drivers. The 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. The IA considers a wide range of options, and those retained for further assessment appear to be reasonable and/or justified. However, the IA would have benefited from providing greater clarity on those components that were either included in (STELs) or excluded (BLVs) from the preferred options, but did not appear in the overview table of the retained options. The analysis of impacts focuses on their economic and social dimension, mainly linked to health, and is consistent with the manner in which the problem has been defined. Environmental impacts are found to be limited for acrylonitrile and nickel compounds, and small but positive for benzene, but the analysis could have been substantiated more thoroughly. The IA acknowledges that a cost-benefit analysis of the transitional OEL values included in the preferred options was not performed, as the associated costs and benefits were not assessed in the supporting COWI A/S study. A wide number of stakeholders were consulted and their opinions have been satisfactorily reported. 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 See N. Scholz, Limits on exposure to carcinogens and mutagens at work: Fourth proposal, briefing, EPRS, European Parliament, 2020.

2 See N. Scholz, Limits on exposure to carcinogens and mutagens at work, briefing, EPRS, European Parliament, 2018. See also A.A. Georgescu, Protection of workers from exposure to carcinogens or mutagens, initial appraisal of a Commission IA, EPRS, European Parliament, 2016.

3 See N. Scholz, Limits on exposure to carcinogens and mutagens at work: Second proposal, briefing, 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 N. Scholz, Limits on exposure to carcinogens and mutagens at work: Third proposal, briefing, EPRS, European Parliament, 2017. See also S. Vettorazzi, Protection of workers from exposure to carcinogens or mutagens: third proposal, initial appraisal of a Commission IA, EPRS, European Parliament, 2018.

5 See S. Vettorazzi, Protection of workers from exposure to carcinogens or mutagens: Third proposal, detailed appraisal of a Commission IA, EPRS, European Parliament, 2018.

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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