

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION AND DOCUMENTS

**7733 /18
COM(2018) 171 final**

Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Submitted by the Department for Work & Pensions on 24 April 2018

SUBJECT MATTER

1. On 5 April 2018, the European Commission published a proposal for a third phase of amendments to the Carcinogens and Mutagens Directive (2004/37/EC). This sets out occupational exposure limit values (OELVs) for five substances with an additional skin notation¹ for one of them.
2. These OELVs are binding limits that set the maximum level of exposure to specific chemical agents (substances) used/generated in the workplace. They take into account health effects and socio-economic factors. OELVs and skin notations have a role to play in helping employers to protect their employees from harm. In this case, managing the risk of developing cancer as a result of exposure to carcinogenic substances in the workplace.
3. The Health and Safety Executive (HSE) estimates that every year around 3,500 people in Great Britain (GB) die from occupational cancer caused by exposure to carcinogenic substances in the workplace (other than asbestos, which is subject to separate legislation). It is therefore vital to control exposure to these substances.
4. This is the third phase of amendments to the Carcinogens and Mutagens Directive. It supplements the two earlier phases of amendments published in May 2016 and January 2017. Negotiation and transposition of the three phases will run in parallel but to different timelines. The substances have been discussed over several years in the Working Party on Chemicals (WPC), a sub-group of the European Union's Advisory Committee on Safety and Health at Work (ACSH). The UK is one of four Member State governments represented on the WPC. The WPC opinions on appropriate limits and notations for these substances were subsequently endorsed by the ACSH. These form the basis of the Commission's proposal.

SCRUTINY HISTORY

5. The first phase of amendments (EM 8962/16) was published in the Official Journal of the European Union in December 2017 and must be transposed by Member States by January 2020. The second phase of amendments (EM 5251/17) remains under scrutiny by the House of Commons European Scrutiny Committee pending further information on its progress through trilogues, which will commence shortly. The scrutiny history for Directive 2004/37/EC is attached as annex A.

¹ A 'skin notation' assigned to a substance identifies the possibility of significant exposure through the skin which contributes to the total body burden of exposure and consequently to possible health effects.

MINISTERIAL RESPONSIBILITY

6. The Secretary of State for Work and Pensions, advised by HSE, has the main responsibility for policy questions arising from this document. The Secretary of State for Transport has an interest arising from his responsibilities for health and safety at work at sea.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

7. Under the UK's devolution settlements, occupational safety and health matters are reserved to Great Britain, but devolved to Northern Ireland. In this case, the Northern Ireland Executive has an interest as it would have to implement an amended Directive.

LEGAL AND PROCEDURAL ISSUES

- 8.
- i. Legal basis: Article 153(2) of the Treaty on the Functioning of the European Union;
 - ii. European Parliament Procedure: Ordinary legislative procedure (co-decision);
 - iii. Voting procedure: Double qualified majority voting;
 - iv. Impact on United Kingdom Law: The Directive, if agreed, would need to be transposed by amending workplace exposure limits which support the Control of Substances Hazardous to Health Regulations 2002, the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003, and through changes to relevant merchant shipping legislation.
 - v. Application to Gibraltar: Yes;
 - vi. Fundamental rights analysis; No fundamental rights issues arise.

APPLICATION TO THE EUROPEAN ECONOMIC AREA

9. The Directive is applicable to the European Economic Area.

SUBSIDIARITY

10. The government agrees with the subsidiarity analysis of the Commission, in that while the protection of the health and safety of workers does not fall under the exclusive competence of the EU, the proposed action can only take place at EU level as member states acting by themselves cannot amend the Directive affected.

11. It is efficient that occupational exposure limits are set at EU level as this means that the extensive scientific and other work necessary to provide the evidence on which a limit is based is done only once. It also ensures a level economic playing field for industry, with all member states working to the same limits.

POLICY IMPLICATIONS (including Exit implications where appropriate)

12. In March 2018 the UK and the EU agreed an implementation period immediately after the end of the Article 50 period in March 2019 until 31 December 2020, during which the UK and EU would continue to access each other's markets on current terms using the existing structure of EU rules and regulations. This is so that

people, businesses and public services will only have to plan for one set of changes in the relationship between the UK and the EU.

13. Although the terms of the implementation period are subject to the adoption of the final withdrawal agreement, we are proceeding on the basis that these amendments to the CMD will need to be transposed into UK law as the likely date of coming into force of the proposal will fall before 31 December 2020.
14. The proposal contains transition periods for Cadmium and Beryllium (of seven and five years respectively) during which an interim OELV will apply before a further reduction at the end of the transition periods. Also, for Arsenic acid, there is a two year transition period for the copper smelting sector before the OELV for that substance applies. The transition periods are intended to reduce the impact on EU businesses by making it possible to anticipate the changes, gradually introduce improvements and plan necessary investments. It is expected that they would end no earlier than 2026 for Cadmium; 2024 for Beryllium; and 2021 for Arsenic acid.
15. Although the transition periods for these substances will extend beyond the end of the proposed EU exit implementation period, we will apply the same evidence-based rigour to our assessment of these proposals as we have to the other limits proposed in this, and previous amendments to the Directive.
16. The government broadly welcomes the third phase of amendments as set out in the proposal. Tackling the cost of occupational ill-health is a key theme of the strategy for the health and safety system in Great Britain. Action to reduce the numbers of death and cases of ill-health from exposure to carcinogens and other hazardous substances is an important element of this. The key focus for controlling occupational exposure to carcinogens at work is effective risk management with emphasis on the application of good control practice. OELVs are set to help manage the risks posed by exposure to harmful substances. They have a role to play in setting out the duties of employers to protect their employees from harm.
17. The Carcinogens and Mutagens Directive is implemented in Great Britain by the Control of Substances Hazardous to Health (COSHH) Regulations 2002. There are parallel regulations in Northern Ireland and merchant shipping rules also apply in this area. These require carcinogens, where it is not reasonably practicable to prevent exposure, to be managed and controlled, and for workplace exposures to be reduced to as low a level as is reasonably practicable.
18. Under the COSHH Regulations, OELVs are implemented as Workplace Exposure Limits (WELs) set out in the HSE publication EH40/2005 Workplace Exposure Limits. The WELs will need to be updated as a result of this proposal.
19. The proposed OELVs for four of these substances are lower than the current UK WELs. For the 5th substance (MOCA) the current UK WEL is lower than that proposed by the Commission.
20. Current UK legislation already requires all routes of exposure to carcinogens to be considered, including skin. Exposures are required to be controlled to as low a level as is reasonably practicable.

CONSULTATION

21. The HSE has consulted stakeholders, including the industry sectors concerned throughout the negotiating process. Officials in Northern Ireland have been given the opportunity to comment on this Explanatory Memorandum.

IMPACT ASSESSMENT

22. An EU impact assessment has been presented for the proposed Directive. A 'checklist for analysis on EU proposals' accompanies this Explanatory Memorandum.

FINANCIAL IMPLICATIONS

23. The enclosed impact assessment checklist concludes that the impact of the introducing revised OELVs for Beryllium and Cadmium and Arsenic acid will be low for the UK. It is anticipated that there will be higher costs in relation to the OELV for Formaldehyde, as indicated in the enclosed checklist.

TIMETABLE

24. The proposed Directive was published on 5 April 2018. The EU Presidency has scheduled a meeting of the Social Questions Working Party on 24 April where the proposal will be presented by the European Commission.

OTHER OBSERVATIONS

25. None



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Annex A

Scrutiny history of Directive 2004/37/EC

1. The original Carcinogens Directive (90/394/EEC in its final form) was the subject of Explanatory Memorandum (EM) 8397/89 which was submitted by the Department of Employment on 10 October 1989. On 16 October 1989, the Chairman of the House of Lords Select Committee on the European Communities sif (653rd) cleared the EM. The EM was considered by the House of Commons Select Committee on European Legislation on 18 October 1989 (Report No 34 Session 1989/90). The Committee considered the document legally and politically important but not for debate at this stage and cleared it.
2. EM 6594/90 on the re-examined proposal following adoption of the common position on the Carcinogens Directive on 5 February 1990 was submitted by the Department of the Employment on 14 June 1990. On 18 June 1990, the Chairman of the House of Lords Select Committee on the European Communities sif (683rd) cleared the EM. The EM was considered by the House of Commons Select Committee on European Legislation on 20 June 1990 (Report No 26 Session 1989/90). The Committee considered the document legally and politically important but not for debate at this stage and cleared it.
3. The first Amendment to the Carcinogens Directive (97/42/EC) was the subject of EM 9931/95 which was submitted by the Department of the Environment on 28 November 1995. On 4 December 1995, the Chairman of the House of Lords Select Committee on the European Communities sif (868th) cleared the EM. The EM was considered by the House of Commons Select Committee on European Legislation on 6 December 1995. The Committee considered the document raised questions of political importance and requested a report on the outcome of the Department's consultation with interested parties.
4. A supplementary EM (9931/95) on consultation with interested parties and progress in the European Parliament and the Council was submitted by the Department of the Environment on 13 July 1996. On 22 July 1996, the Chairman of the House of Lords Select Committee on the European Communities sif (897th) cleared the supplementary EM. The supplementary EM was considered by the House of Commons Select Committee on European Legislation on 16 October 1996 (Report No 29 Session 1995/96). The Committee considered the document politically important but not for debate at this stage and cleared it.
5. EM 9931/95 was submitted by the Department of the Environment on 18 February 1997. On 22 February 1997, the Chairman of the House of Lords Select Committee on the European Communities sif (914th) cleared the EM. The EM was considered by the House of Commons Select Committee on European Legislation on 5 March 1997 (Report No 16 Session 1996/97). The Committee considered the document was not legally or politically important and cleared it.
6. EM 7607/97 was submitted by the Department of the Environment on 29 May 1997. On 3 June 1997, the Chairman of the House of Lords Select Committee on the European Communities sif (920th) cleared the EM. The EM was considered by the House of Commons Select Committee on European Legislation on 27 July 1997 (Report No 2 Session 1997/98). The Committee considered the document as not legally or politically important and cleared it.

7. EM 6925/98 was submitted by the Department of the Environment, Transport and the Regions on 21 April 1998. The Chairman of the House of Lords' Select Committee on the European Communities sift (954th) cleared the EM on 27 April 1998. The EM was considered by the House of Commons Select Committee on European Legislation on 6 May 1998 (Report No 27 Session 1997/98). The Committee considered the document politically important and requested further information from the Department.

8. A supplementary EM (6925/98) was submitted by the Department of the Environment, Transport and the Regions on 15 July 1998. On 20 July 1998, the Chairman of the House of Lords' Select Committee on the European Communities sift (965th) cleared the EM. The EM was considered by the House of Commons Select Committee on European Legislation on 22 July 1998 (Report No 35 Session 97/98). The Committee considered the document politically important and cleared it.

9. EM 12854/98 was submitted by the Department of the Environment, Transport and the Regions on 10 December 1998. The House of Commons European Scrutiny Committee considered the EM on 16 December 1998 (Report No 4 Session 1998/99). The Committee considered the document as not legally or politically important and cleared it. The Chairman of the House of Lords' Select Committee on the European Communities sift (978th) cleared the EM on 14 December 1998.

10. EM 7308/99 was submitted by the Department of the Environment Transport and the Regions on 10 May 1999. The Chairman of the House of Lords' Select Committee on the European Communities sift (996th) cleared the EM on 18 May 1999. The House of Commons European Scrutiny Committee considered the EM on 19 May 1999 (Report No.20 Session 1998/99). The Committee considered the document as not legally or politically important and cleared it.

11. EM 8729/03 on a codified text was submitted by Department for Work and Pensions to Parliament on 13 May 2003. The House of Commons European Scrutiny Committee considered the EM on 21st May 2003 (Report No 22 Session 02/03). The Committee considered the document as not legally or politically important and cleared it. The Chairman of the House of Lords' Select Committee on the European Communities, sift 1143rd, cleared the EM on 20 May 2003.