

# **CD287 - Carcinogens and Mutagens – Revision of limit values in EH40/2005 “Workplace Exposure Limits”**

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# The Consultation Document

This consultative document is issued by the Health and Safety Executive (HSE). HSE is undertaking this consultation in compliance with its duty to consult under section 50 (3) of the Health and Safety at Work Act 1974.

HSE tries to make their consultation procedures as thorough and open as possible. A summary of responses to this consultation document will be made available on the consultation webpage after the close of the consultation period where they can be viewed by members of the public.

Information provided in response to this consultation may be subject to publication or disclosure in accordance with the following access to information regimes: the Freedom of Information Act 2000 (FOIA); the Data Protection Act 2018; General Data Protection Regulations (GDPR); and the Environmental Information Regulations 2004 (EIR). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide as confidential, please explain your reasons for this in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data collected as part of this consultation in accordance with the General Data Protection Regulations. HSE's Privacy Policy Statement can be available on the [HSE website](#).

Enquiries should be sent to:

Written: HSE – Health and Chemicals Unit, Health and Safety Executive, 2.1 Redgrave Court, Merton Rd, Bootle, Merseyside, L20 7HS

Email: <mailto:CMD.consultation@hse.gsi.gov.uk>

## Code of Practice on Consultation

HSE is committed to best practice in consultation and to the Government's Consultation Principles. The Government is improving the way it consults by adopting a more proportionate and targeted approach, so that the type and scale of engagement is proportional to the potential impacts of the proposal. The emphasis is on understanding the effects of a proposal and focussing on real engagement with key groups rather than following a set process.

Additional guidance can be found at:

<https://www.gov.uk/government/publications/consultation-principles-guidance>

If you require a more accessible format of this document, please send details to [HSE.Online@hse.gov.uk](mailto:HSE.Online@hse.gov.uk) and your request will be considered.

## Quality assurance and complaints

If you have any complaints about the consultation process (as opposed to comments about the issues, which are the subject of the consultation) please address them to:

Susan Robinson,  
HSE Consultation Coordinator,  
2.2 Redgrave Court, Merton Road, Bootle. L20 7HS  
Email: [susan.robinson@hse.gov.uk](mailto:susan.robinson@hse.gov.uk)

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF or HSE's Acting Chief Executive, David Snowball at Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. You can also write and ask your MP to take up your case with us or with Ministers. Your MP may also ask the independent Parliamentary Commissioner for Administration (the Ombudsman) to review your complaint.

## **Purpose of this consultation**

This consultation relates to the implementation of Directive 2017/2398 (Appendix 1) which amends the Carcinogens and Mutagens Directive (CMD) 2004/37/EC and sets 11 new and binding OELVs and amends 2 existing OELVs for carcinogenic substances to help protect workers from the ill-health effects of exposure to these substances in the workplace. The Directive also classifies Respirable Crystalline Silica (RCS) as a carcinogen where it is generated as a result of a work process. Skin notations for four substances also added.

The consultation will focus on the initial limits which come into effect in January 2020. Directive 2017/2398 also includes extended transition periods for further lower limits for hardwood dust and chromium (VI) (see Table A). HSE will carry out a further consultation on these limits at a later stage.

Directive 2017/2398 came into force on 17 January 2018 and EU Member State have until 17 January 2020 to transpose its requirements into their national legislation. This Consultative Document sets out the HSE's proposals for establishing Workplace Exposure Limits (WELs) for the substances listed in the Directive, subject to the ongoing negotiations on our relationship with the EU.

## Phase 1 CMD proposals – Table A:

Substance	Existing UK Workplace Exposure Limit and notation	New OELV (8-hour Time Weighted Average) and notation	HSE proposal
Respirable Crystalline Silica – (RCS)	0.1mg/m <sup>3</sup>	0.1mg/m <sup>3</sup>	Retain existing WEL and introduce carcinogen notation for RCS generated as a result of a work process
Hardwood dusts	5mg/m <sup>3</sup>	3mg/m <sup>3*</sup>	Adopt CMD 8-hour TWA limit and reduce existing WEL
Chromium (VI) Compounds	0.05mg/m <sup>3</sup>	0.010 mg/m <sup>3****</sup> (non-process generated) 0.025mg/m <sup>3***</sup> (process generated)****	Adopt CMD 8-hour TWA limits and reduce existing WEL
Hydrazine	0.03mg/m <sup>3</sup> and skin notation	0.013mg/m <sup>3</sup> and skin notation*****	Adopt CMD 8-hour TWA limit and reduce existing WEL
Acrylamide	0.3mg/m <sup>3</sup> and Skin notation	0.1mg/m <sup>3</sup> and skin notation	Adopt CMD 8-hour TWA limit and reduce existing WEL
Refractory Ceramic Fibres	1f/ml	0.3f/ml	Adopt CMD 8-hour TWA limit and reduce existing WEL
Vinyl Chloride Monomer	7.8mg/m <sup>3</sup>	2.6mg/m <sup>3</sup>	Adopt CMD 8-hour TWA limit and reduce existing WEL
O-Toluidine	0.89mg/m <sup>3</sup> and skin notation	0.5mg/m <sup>3</sup> and skin notation	Adopt CMD 8-hour TWA limit and reduce existing WEL
1,3 Butadiene	22mg/m <sup>3</sup>	2.2mg/m <sup>3</sup>	Adopt CMD 8-hour TWA limit and reduce existing WEL
Bromoethylene (vinyl bromide)	None	4.4mg/m <sup>3</sup>	Adopt CMD 8-hour TWA limit and introduce WEL
Ethylene Oxide	9.2mg/m <sup>3</sup>	1.8mg/m <sup>3</sup> and skin notation	Adopt CMD 8-hour TWA limit and reduce existing WEL. Introduce skin notation
1,2 Epoxypropane	12mg/m <sup>3</sup>	2.4mg/m <sup>3</sup>	Adopt CMD 8-hour

(propylene oxide)			TWA limit and reduce existing WEL
2-Nitropropane	19mg/m <sup>3</sup>	18mg/m <sup>3</sup>	Adopt CMD 8-hour TWA limit and reduce existing WEL

\* If hardwood dust is mixed with other wood dust the limit will apply to all wood dusts present in that mixture).

\*\* The Directive includes a transitional period ending on 17 January 2023, after which a lower limit of 2mg/m<sup>3</sup> applies for hardwood dust. HSE will consult separately on this at a later date.

\*\*\* The Directive includes a transitional period ending on 17 January 2025, after which a lower limit of 0.005mg/m<sup>3</sup> applies for Chromium (VI) compounds. HSE will consult separately on this at a later date.

\*\*\*\* 'Process generated' refers to exposures to Chromium (VI) and its compound generated as a result of a work process, such as in fumes from welding.

\*\*\*\*\*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.

This Consultation Document seeks your views on:

- the initial assessment of the costs and benefits of the new and changed OELVs as set out in the impact assessment;
- the proposed transposition approach.

This consultation relates to regulations that will apply in England, Scotland and Wales.

The Health and Safety Executive for Northern Ireland will follow a similar process for implementing the Directive in Northern Ireland.

## Background

1. OELVs are set to help protect workers from the ill-health effects of exposure to hazardous substances. In the case of CMD this is in relation to substances that are carcinogens or mutagens. The CMD amending directive (2017/2398) adds 11 and amends 2 existing OELVs in the original CMD. It requires Member States to establish, or amend, their national exposure limits to match those in the Directive.
2. The original CMD contained binding OELVs for 3 carcinogenic substances (Hardwood dust, Benzene and Vinyl Chloride Monomer). In the UK these limit values are transposed as Workplace Exposure Limits (WELs) in the Health and Safety Executive (HSE) publication EH40/2005.
3. The EU Commission has embarked on a programme to add OELVs for other carcinogens and mutagens to the original CMD through a series of amending directives. This consultation relates to the first of these amendments.
4. The OELVs listed in the amending Directive have been discussed by the Working Party on Chemicals (WPC), a sub-group of the EU's tripartite Advisory Committee on Safety and Health at Work (ACSH). The WPC opinions on appropriate exposure limit values for these substances were subsequently endorsed by the ACSH.
5. HSE officials consulted UK industry stakeholders as part of the WPC discussions on the OELVs.
6. The final OELVs in the Directive were agreed by the European Council and European Parliament.

## The Occupational Exposure Limit System

7. In 2005, the then Health and Safety Commission introduced a new framework for setting occupational exposure limits (OELVs) following an amendment to the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (S.I. 2004 No. 3386). The new system dispensed with the previous system of Maximum Exposure Limits (MELs) and Occupational Exposure Standards (OESs) and replaced both with a single type of limit, the Workplace Exposure Limit or WEL.
8. The requirements for compliance with WELs are set out in regulation 7(7) of the COSHH Regulations 2002 (as amended) (COSHH). For substances identified as carcinogens or mutagens regulation 7(7) requires that exposures must also be reduced to as low as is reasonably practicable.
9. It is a legal requirement that the WEL should not be exceeded. A WEL is defined as the concentration of a hazardous substance in the air that people breathe, averaged over a specified reference period referred to as a time-weighted average (TWA). Two periods are used: long-term exposure limit (8 hours) and short-term exposure limit (STEL) (15 minutes). All of the OELVs in this consultation relate to the long-term exposure limit (8 hours).
10. OELVs are published as WELs in the HSE publication EH40 Workplace Exposure Limits, available on the HSE website at: [www.hse.gov.uk/pubns/priced/eh40.pdf](http://www.hse.gov.uk/pubns/priced/eh40.pdf)
11. For more information on employers' duties under COSHH, you should refer to HSE's booklet "**Working with Substances Hazardous to Health**" - INDG136 (rev4), available on the HSE website at: [www.hse.gov.uk/pubns/indg136.pdf](http://www.hse.gov.uk/pubns/indg136.pdf).

### What are OELVs?

12. OELVs are European limit values that are set to protect the health of workers in the European Union from the ill-health effects of hazardous substances in the workplace. Their legal status derives from the CMD 2004/37/EC. In relation to occupational exposure, article 2(c) of that Directive states that 'limit value' "means, unless otherwise specified, the limit of the time-weighted average of the concentration for a carcinogen



or mutagen' in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III of the Directive”.

## **Current legislative provisions for OELVs in the UK**

13. OELVs, including those for carcinogens and mutagens, are implemented in GB by updating the HSE publication EH40/2005. Table 1 of EH40/2005 lists current workplace exposure limits and has special legal status under the Control of Substances Hazardous to Health Regulations 2002 (as amended).

## **Transposition approach**

14. HSE plans to transpose the Directive by amending the statutory table within HSE publication: EH40/2005. This transposition approach takes account of the Government's policy on transposing EU Directives and its commitment not to go beyond the minimum requirements of the Directive. It also implements the Directive in a way that is proportionate to the risks and takes into account existing controls and therefore minimises the impact on businesses. The new OELVs will be transposed on the latest possible transposition date.
15. The Directive recognises that there may be technological challenges and associated costs for the woodworking and welding industries across Europe in complying with the proposed lower limit values for Hardwood dust and Chromium (VI) Compounds. In recognition of the challenges in these industries the Directive includes extended transitional periods until January 2023 (Hardwood dust) and January 2025 (Chromium (VI) (where process generated) during which Member States must apply the initial OELVs for these substances (see Table A). A further consultation for the lower limit values will be undertaken at a later stage, ahead of the implementation dates.

## **What will the new OELVs mean for stakeholders?**

16. The transposition approach will be supported by targeted communications which will explain clearly and simply what action needs to be taken by duty-holders. There will also be on-going collaborative working with stakeholders throughout and beyond the transposition period.

## **Impact of the amended Directive in the UK**

17. A draft Impact Assessment (IA) (Appendix 2) has been prepared, which sets out HSE's current assessment of the potential impacts on businesses of implementing the Directive, including the research and

stakeholder engagement undertaken to date. This assessment estimates that there should not be significant additional costs, because either the OELV is not significantly lower than the existing WEL, there is little or no use in GB, or, businesses should already be meeting the WEL if they have adequate controls in place under current requirements.

### **Invitation to comment**

18. HSE invites comments on these proposals. We are happy to receive your written comments in any form convenient to you. We will acknowledge receipt of all comments sent to us and will give them careful consideration. HSE would also like to know what you think about this consultation, both in terms of content and layout. Your views will help us to improve future consultations.
19. Examples of comments that would be helpful to us include information on uses of these substances which have not been accounted for, or costs or benefits associated with implementation of these OELVs such as additional costs that would result from taking additional measures necessary to comply with these limits.

# Appendix 1

## DIRECTIVE (EU) 2017/2398 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2017

amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

Whereas:

- (1) Directive 2004/37/EC of the European Parliament and of the Council<sup>3</sup> aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values established on the basis of available information, including scientific and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, are important components of the general arrangements for the protection of workers established by that Directive. The minimum requirements provided for in that Directive aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.

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<sup>1</sup> OJ C 487, 28.12.2016, p. 113.

<sup>2</sup> Position of the European Parliament of 25 October 2017 and decision of the Council of 7 December 2017.

<sup>3</sup> Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

- (2) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations on employers pursuant to that Directive, in particular the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, in so far as is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure. In that context, it is essential to take the precautionary principle into account where there are uncertainties.
- (3) For most carcinogens and mutagens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens and mutagens pursuant to this Directive does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure in the stepwise and goal-setting approach pursuant to Directive 2004/37/EC. For other carcinogens and mutagens, it is scientifically possible to identify levels below which exposure is not expected to lead to adverse effects.
- (4) Maximum levels for the exposure of workers to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, must not be exceeded. Those limit values should be revised and limit values should be set for additional carcinogens and mutagens.
- (5) On the basis of the implementation reports submitted by Member States every five years pursuant to Article 17a of Council Directive 89/391/EEC<sup>1</sup>, the Commission is to evaluate the implementation of the occupational safety and health legal framework, including Directive 2004/37/EC, and, where necessary, to inform the relevant institutions and the Advisory Committee on Safety and Health at Work (ACSH) of initiatives to improve the operation of that framework, including, where necessary, appropriate legislative proposals.
- (6) The limit values set out in this Directive should be revised where necessary in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of workers and opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL) and of the ACSH. Information related to residual risk, made publicly available at Union level, is valuable for future work to limit risks from occupational exposure to carcinogens and mutagens, including by revising the limit values set out in this Directive. Transparency of such information should be further encouraged.

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<sup>1</sup> Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

- (7) Due to the lack of consistent data on substance exposure, it is necessary to protect exposed workers or workers who are at risk of exposure by enforcing relevant health surveillance. It should therefore be possible for appropriate health surveillance of workers, for whom the results of the assessment referred to in Article 3(2) of Directive 2004/37/EC reveal a risk to health or safety, to continue after the end of exposure following an indication by the doctor or authority responsible for the health surveillance. Such surveillance should be carried out in accordance with the national law or practice of the Member States. Article 14 of Directive 2004/37/EC should therefore be amended to ensure such health surveillance for all workers concerned.
- (8) Appropriate and consistent data collection by Member States from employers is necessary to ensure the safety and proper care of workers. The Member States are to provide the Commission with information for the purposes of its reports on the implementation of Directive 2004/37/EC. The Commission already supports best practices with regard to data collection in Member States and should propose, as appropriate, further improvements to the data collection required pursuant to Directive 2004/37/EC.
- (9) Directive 2004/37/EC requires employers to use existing appropriate procedures for the measurement of exposure levels to carcinogens and mutagens at the workplace, in consideration of the fact that SCOEL notes in its recommendations the feasibility of monitoring exposure at any recommended occupational exposure limit value and biological limit values. The improvement of the equivalence of methodologies for measurement of the concentration in the air of carcinogens and mutagens in relation to limit values set out in Directive 2004/37/EC is important in order to reinforce the obligations provided for therein and ensure a similar and a high-level of health protection for workers and a level playing field across the Union.
- (10) Amendments to Annex III to Directive 2004/37/EC provided for in this Directive are the first step in a longer term process to update it. As the next step in that process, the Commission has submitted a proposal for the establishment of limit values and skin notations with regard to seven additional carcinogens. Moreover, the Commission stated in its Communication of 10 January 2017, 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy', that there are to be further amendments to Directive 2004/37/EC. The Commission should, on an ongoing basis, continue its work on updates of Annex III to Directive 2004/37/EC, in line with Article 16 thereof and established practice. That work should result, where appropriate, in proposals for future revisions of the limit values set out in Directive 2004/37/EC and in this Directive, as well as proposals for additional limit values.
- (11) It is necessary to consider other absorption pathways of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.
- (12) SCOEL assists the Commission, in particular in identifying, evaluating and analysing in detail the latest available scientific data, and in proposing occupational exposure limit values for the protection of workers from chemical risks, which are to be set at Union level pursuant to Council Directive

98/24/EC<sup>1</sup> and Directive 2004/37/EC. As regards the chemical agents o-toluidine and 2-nitropropane, there were no SCOEL recommendations available in 2016 and therefore other sources of scientific information, adequately robust and in the public domain, have been considered.

- (13) The limit values for vinyl chloride monomer and hardwood dusts set out in Annex III to Directive 2004/37/EC should be revised in the light of more recent scientific and technical data. The distinction between hardwood and softwood dust should be further assessed as regards the limit value set out in that Annex, as recommended by SCOEL and the International Agency for Research on Cancer.
- (14) Mixed exposure to more than one species of wood is very common, which complicates the exposure assessment of different species of wood. Exposure to dust from softwood and hardwood is common among workers in the Union and may cause respiratory symptoms and diseases, with the most serious health effect being the risk of nasal and sinonasal cancers. It is therefore appropriate to establish that if hardwood dusts are mixed with other wood dusts, the limit value set out in the Annex for hardwood dust should apply to all wood dusts present in that mixture.
- (15) Certain chromium (VI) compounds meet the criteria for classification as carcinogenic (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>2</sup> and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for chromium (VI) compounds that are carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate to establish a limit value for those chromium (VI) compounds.
- (16) With regard to chromium VI, a limit value of 0,005 mg/m<sup>3</sup> may not be appropriate and, in some sectors, may be difficult to achieve in the short term. A transitional period should therefore be introduced during which the limit value of 0,010 mg/m<sup>3</sup> should apply. For the specific situation where the work activity concerns work involving welding or plasma cutting processes or similar such processes that generate fume, a limit value of 0,025 mg/m<sup>3</sup> should apply during that transitional period, after which the generally applicable limit value of 0,005 mg/m<sup>3</sup> should apply.
- (17) Certain refractory ceramic fibres meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for refractory ceramic fibres that are carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate to establish a limit value for those refractory ceramic fibres.

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<sup>1</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

<sup>2</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (18) There is sufficient evidence of the carcinogenicity of respirable crystalline silica dust. On the basis of available information, including scientific and technical data, a limit value for respirable crystalline silica dust should be established. Respirable crystalline silica dust generated by a work process is not subject to classification in accordance with Regulation (EC) No 1272/2008. It is therefore appropriate to include work involving exposure to respirable crystalline silica dust generated by a work process in Annex I to Directive 2004/37/EC and to establish a limit value for respirable crystalline silica dust ('respirable fraction') that should be subject to review, in particular in light of the number of workers exposed.
- (19) Guides and examples of good practices produced by the Commission, the Member States or the social partners, or other initiatives, such as the Social Dialogue 'Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it' (NEPSi) are valuable and necessary instruments to complement regulatory measures and in particular to support the effective implementation of limit values, and should therefore be given serious consideration. They include measures to prevent or minimise exposure such as water-assisted suppression to prevent dust from becoming airborne in the case of respirable crystalline silica.
- (20) Ethylene oxide meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. SCOEL has identified, for ethylene oxide, the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for ethylene oxide and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (21) 1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to identify an exposure level below which exposure to that carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish a limit value for 1,2-epoxypropane.
- (22) Acrylamide meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. SCOEL has identified, for acrylamide, the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for acrylamide and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (23) 2-Nitropropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to

set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for 2-nitropropane.

- (24) o-Toluidine meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for o-toluidine and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (25) 1,3-Butadiene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for 1,3-butadiene.
- (26) Hydrazine meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for that carcinogen. SCOEL has identified, for hydrazine, the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for hydrazine and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (27) Bromoethylene meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for bromoethylene.
- (28) This Directive strengthens the protection of workers' health and safety at their workplace. Member States should transpose this Directive into their national law. They should ensure that competent authorities have a sufficient number of trained staff and other resources necessary to carry out their tasks related to the proper and effective implementation of this Directive, in accordance with national law or practice. Application of this Directive by employers would be facilitated if they had guidance, where relevant, to identify better ways to achieve compliance with this Directive.
- (29) The Commission has consulted the ACSH. It has also carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union.
- (30) In its opinions, the ACSH has referred to a review period for binding occupational exposure limit values for several substances, such as respirable crystalline silica dust, acrylamide and 1,3-butadiene. The Commission is to



take into account those opinions when prioritising substances for scientific evaluation.

- (31) In its opinion on refractory ceramic fibres, the ACSH agreed that a binding occupational exposure limit value is necessary but failed to reach a common position on a threshold. The Commission should therefore encourage the ACSH to submit an up-to-date opinion on refractory ceramic fibres with a view to reaching a common position on the limit value for that substance, without prejudice to the working methods of the ACSH and the autonomy of the social partners.
- (32) At the workplace, men and women are often exposed to a cocktail of substances, which can increase health risks and cause adverse effects, inter alia, on their reproductive systems, including impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances which are toxic to reproduction are subject to Union measures providing for minimum requirements of the protection of health and safety of workers, in particular those provided for in Directive 98/24/EC and Council Directive 92/85/EEC<sup>1</sup>. Reprotoxic substances that are also carcinogens or mutagens are subject to the provisions of Directive 2004/37/EC. The Commission should evaluate the need to extend the application of the measures for the protection of health and safety of workers provided for in Directive 2004/37/EC to all reprotoxic substances.
- (33) This Directive respects fundamental rights and observes the principles enshrined in the Charter of Fundamental Rights of the European Union, in particular the right to life and the right to fair and just working conditions provided for, respectively, in Articles 2 and 31 thereof.
- (34) The limit values set out in this Directive will be kept under review in the light of the implementation of Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>2</sup>, in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.
- (35) Since the objectives of this Directive, which are to improve working conditions and to protect the health of workers from the specific risks arising from exposure to carcinogens and mutagens, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out

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<sup>1</sup> Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

- (36) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.
- (37) Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 2004/37/EC is amended as follows:

- (1) in Article 6, the following paragraph is added:

‘The Member States shall take into account the information under points (a) to (g) of the first paragraph of this Article in their reports submitted to the Commission under Article 17a of Directive 89/391/EEC.’;

- (2) Article 14 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Member States shall establish, in accordance with national law or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3(2) reveal a risk to health or safety. The doctor or authority responsible for the health surveillance of workers may indicate that health surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned.’;

(b) paragraph 8 is replaced by the following:

‘8. All cases of cancer identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen or mutagen shall be notified to the competent authority.

The Member States shall take into account the information under this paragraph in their reports submitted to the Commission under Article 17a of Directive 89/391/EEC.’;

- (3) the following Article is inserted:

*‘Article 18a*

## Evaluation

The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value for respirable crystalline silica dust. The Commission shall propose, where appropriate, necessary amendments and modifications related to that substance.

No later than in the first quarter of 2019, the Commission shall, taking into account the latest developments in scientific knowledge, assess the option of amending the scope of this Directive to include reprotoxic substances. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.;

(4) in Annex I, the following point is added:

‘6. Work involving exposure to respirable crystalline silica dust generated by a work process’;

(5) Annex III is replaced by the text in the Annex to this Directive.

### *Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 January 2020. They shall immediately inform the Commission of the text of those measures.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the measures of national law which they adopt in the field covered by this Directive.

### *Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

### *Article 4*

This Directive is addressed to the Member States.  
Done at Strasbourg, 12 December 2017.

For the European Parliament, The President A. TAJANI

For the Council, The President M. MAASIKAS

## ANNEX

## 'ANNEX III

## Limit values and other directly related provisions (Article 16)

## A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EC No. ( <sup>1</sup> )	CAS No. ( <sup>2</sup> )	Limit values ( <sup>3</sup> )			Notation	Transitional measure
			mg/m <sup>3</sup> ( <sup>4</sup> )	ppm ( <sup>5</sup> )	f/ml ( <sup>6</sup> )		
Hardwood Dusts	-	-	2 ( <sup>7</sup> )	-	-	-	Limit value 3mg/m <sup>3</sup> until 17 January 2023
Chromium (VI) compounds which are carcinogens within the meaning of point (i) of Article 2(a)  (as chromium)	-	-	0,005	-	-	-	Limit value 0,010 mg/m <sup>3</sup> until January 2025  Limit value: 0,025 mg/m <sup>3</sup> for welding or plasma cutting processes or similar work processes that generate fume until 17 January 2025
Refractory Ceramic Fibres which are carcinogens within the meaning of point (i) of Article 2(a)	-	-	-	-	0.3	-	
Respirable crystalline silica dust	-	-	0,1 ( <sup>8</sup> )	-	-	-	
Benzene	200-753-7	71-43-2	3,25	1	-	skin ( <sup>9</sup> )	
Vinyl chloride monomer	200-831-0	75-01-4	2,6	1	-	-	
Ethylene oxide	200-849-9	75-21-8	1,8	1	-	skin ( <sup>9</sup> )	
Name of agent	EC No. ( <sup>1</sup> )	CAS No. ( <sup>2</sup> )	Limit values ( <sup>3</sup> )			Notation	Transitional measure
			mg/m <sup>3</sup> ( <sup>4</sup> )	ppm ( <sup>5</sup> )	f/ml ( <sup>6</sup> )		
1,2-Epoxypropane	200-879-2	75-56-9	2,4	1	-	-	
Acrylamide	201-173-7	79-06-01	0,1	-	-	skin ( <sup>9</sup> )	
2-Nitropropane	201-209-1	79-46-9	18	5	-	-	
o-Toluidine	202-429-0	95-53-4	0,5	0,1	-	skin ( <sup>9</sup> )	
1,3-Butadiene	203-450-8	106-99-0	2,2	1	-	-	
Hydrazine	206-114-9	302-01-2	0,013	0,01	-	skin ( <sup>9</sup> )	
Bromoethylene	209-800-6	593-60-2	4,4	1	-	-	

(<sup>1</sup>) EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.

(<sup>2</sup>) CAS No: Chemical Abstract Service Registry Number.

(<sup>3</sup>) Measured or calculated in relation to a reference period of eight hours.

- (4)  $\text{mg/m}^3$  = milligrams per cubic metre of air at 20C and 101,3 kPa (760 mm mercury pressure).
  - (5) ppm = parts per million by volume in air ( $\text{ml/m}^3$ ).
  - (6) f/ml = fibres per millilitre.
  - (7) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all the wood dusts present in that mixture.
  - (8) Respirable fraction.
  - (9) Substantial contribution to the total body burden via dermal exposure possible.
- 

## B. OTHER DIRECTLY RELATED PROVISIONS

p.m.’

## Appendix 2 – IA

<b>Title:</b> Implementation of the amended Carcinogens and Mutagens Directive <b>IA No:</b> <b>RPC Reference No:</b> <b>Lead department or agency:</b> Health and Safety Executive <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>			
	<b>Date:</b>			
	<b>Stage:</b> Consultation			
	<b>Source of intervention:</b> EU			
	<b>Type of measure:</b> Secondary Legislation			
	<b>Contact for enquiries:</b>			
Anne Strype				
Mike Zand				

### Summary: Intervention and Options

RPC Opinion: N/A

#### Cost of Preferred (or more likely) Option

Total Net Present Value	Business Net Present Value	Net cost to business per year	One-In, Three-Out	Business Impact Target Status
Nil	Nil	Nil	Nil	Out of Scope

#### What is the problem under consideration? Why is government intervention necessary?

HSE estimates that every year around 3,500 people in the UK die from occupational cancer caused by exposure to carcinogenic chemicals, so it is important to control exposure to these substances. The Carcinogens and Mutagens Directive provides the regulatory framework in the EU to help protect workers from risks related to exposure to Carcinogens and Mutagens at work. The amended Carcinogens and Mutagens Directive was adopted on 27 December 2017 and published in the official journal of the European Union on 17 January 2018. The Directive sets 11 new occupational exposure limit values (OELVs) and amends 2 existing limit values for carcinogenic substances.

This impact assessment and consultation will focus on the initial limits to be introduced in January 2020. We will conduct a further impact assessment and consultation on the substances with an extended transposition date closer to the implementation dates of 2023 and 2025.

#### What are the policy objectives and the intended effects?

- To improve worker protection from carcinogenic substances.
- To ensure, where possible, consistency of application with other Government Departments.
- To ensure a level playing field across Member States.
- To fulfil the UK's obligations under EU law.

#### What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The options considered are i) do nothing or ii) transpose the OELVs in EH40/2005, which is the preferred option. The requirements of the Carcinogens and Mutagens Directive are transposed in Great Britain via domestic legislation through the Control of Substances Hazardous to Health Regulations 2002 (COSHH) by amending the statutory table in the HSE publication EH40 Workplace Exposure Limits. Additional GB legislation is not required as the rest of the requirements of CMD are already covered by the COSHH Regulations. Equivalent measures will need to be taken in Northern Ireland and Gibraltar. Separate action will be required to amend the Mines Regulations 2014.

#### Will the policy be reviewed? It will be not be reviewed. If applicable, set review date:

Does implementation go beyond minimum EU requirements?	No			
Is this measurement likely to impact on trade and investment?	Yes / No / N/A			
Does this measure comply with our international trade and investment obligations, including those arising under WTO agreement, UK free trade agreements, and UK Investment Treaties?	Yes / No / N/A			
Are any of these organisations in scope?	<b>Micro</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes	<b>Large</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)	<b>Traded:</b> N/A		<b>Non-traded:</b> N/A	

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible

Date:



# Summary: Analysis & Evidence

# Policy Option 1

Description: Do Minimum – update table 1 of the HSE publication EH40 and amend COSHH Regulations

## FULL ECONOMIC ASSESSMENT

Price Base Year N/A	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: Nil	High: Nil	Best Estimate: Nil

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Nil	Nil	Nil
High	Nil	Nil	Nil
Best Estimate	Nil	Nil	Nil

### Description and scale of key monetised costs by 'main affected groups'

As there are no significant additional costs to business estimated, this assessment is below the £5 million EANDCB de minimus limit. See 'Key assumptions/sensitivities/risks' below for further information.

### Other key non-monetised costs by 'main affected groups'

N/A

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Nil	Nil	Nil
High	Nil	Nil	Nil
Best Estimate	Nil	Nil	Nil

### Description and scale of key monetised benefits by 'main affected groups'

### Other key non-monetised benefits by 'main affected groups'

We do not expect significant health benefits from implementation of the 2020 limits, given that businesses complying with current requirements should not need to make changes to controls and, by consequence, exposure levels, if they are meeting current requirements. Health benefits may arise where implementation raises compliance with the requirements but these are not additional and are extremely difficult to quantify, so are not included in this assessment.

### Key assumptions/sensitivities/risks

### Discount rate (%)

This assessment estimates that there should not be significant additional costs to businesses from introducing the limits with a transposition date of 2020, given existing patterns of use, control or the current level of requirements in GB. There may be some impacts in practice in certain construction and manufacturing sectors, where it is possible that the new limits go beyond what is currently required, but these are not expected to exceed the de minimis limit of £5 million EANDCB. Our understanding of current use and control in GB will be tested during consultation.

There is potential for higher costs to these sectors in the future if the lower limits for Hardwood Dust and Chromium (VI) are transposed in January 2023 and 2025 respectively. The transitional periods are intended to negate some of the impact by providing time for industry to phase-in improvements in controls and working practices to achieve compliance with the lower OELVs. These will be subject to a separate consultation and assessment in the future, prior to implementation.

## BUSINESS ASSESSMENT (Option 1)

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>Score for Business Impact Target (qualifying provisions only) £m:</b>
<b>Costs:</b> Nil	<b>Benefits:</b> Nil	<b>Net:</b> Nil	N/A

# 1 Problem under consideration

## 1.1 Carcinogens and Mutagens Directive 2017/2398

1. On 13 May 2016 the European Commission, advised by SCOEL (Scientific Committee on Occupational Exposure Limits), published a proposal for an amendment to the Carcinogens and Mutagens Directive (CMD) 2017/2398 setting eleven new binding occupational exposure limit values (OELVs) and amending two existing values for carcinogenic substances. The Amending Directive was adopted on 27 December 2017 and must be transposed into UK law by 17 January 2020, with transitional arrangements for implementation of lower limits for Hardwood Dust (17 January 2023) and Chromium (VI) Compounds (17 January 2025).
2. OELVs are concentration limits for hazardous substances present in a workplace atmosphere where ill-health effects are likely to occur. Exposure to hazardous substances can have a wide range of damaging effects on human health, including developing cancer. There are many ways that humans can be exposed to these carcinogenic substances at work, which are influenced by the physical form of the substances, whether they readily evaporate or create dust, how they are used, and a number of other factors.
3. OELVs introduced by European Union (EU) Directives are transposed in Great Britain (GB) as Workplace Exposure Limits (WELs) via amendment to statutory table 1 in the Health and Safety Executive (HSE) publication EH40/2005.
4. During development of the Directive, the OELVs were discussed by the Working Party on Chemicals (WPC), a sub-group of the EU's tripartite Advisory Committee on Safety and Health at Work (ACSH), on which the UK is one of only four governments represented. The WPC opinions on appropriate exposure limit values for these substances were subsequently endorsed by the ACSH, which provides opinion on the recommendation to the European Commission.

## 1.2 Current GB regulatory framework

5. Great Britain – and the rest of the United Kingdom – has a well-established regulatory environment for the control of workplace risks associated with use of carcinogens and mutagens in the system of WELs and the COSHH Regulations.

6. With the development of the COSHH/WEL system, GB policy shifted from domestic limit setting to the adoption of European limits. This reflected the increasing efforts at a European level to develop and apply similar levels of control across the EU, avoided duplication of risk assessment work at the domestic level, and helps ensure that British business benefits from a level playing field with other EU Member States.
7. Under the existing GB regulatory framework, an employer's first objective must be to prevent exposure to carcinogens or mutagens. Carcinogenic or mutagenic substances should not be used, or processes carried on, if the employer can use a suitable non-hazardous or less hazardous substitute. If it is not reasonably practicable to prevent exposure to a carcinogen or mutagen, the employer must put into place all the measures and appropriate controls to reduce exposure to as low as is reasonably practicable.
8. Given the existing requirement to reduce exposures to as low as reasonably practicable, along with other factors such as customer pressure, developing technologies, and shifting market forces - as well as a general drive on the part of industry to move away from use of hazardous substances – HSE does not expect that implementation of the initial 2020 limits will result in significant additional costs to business. This is discussed further in Section 5.

## **2 Rationale for intervention**

9. The UK is legally obliged to transpose the Directive and OELVs for thirteen substances into UK law by the transposition deadline of 17th January 2020.
10. The rationale for the approach to transposition follows the UK Government's Guiding Principles for EU Legislation. Whilst ensuring that standards are maintained, we will ensure that the UK does not go beyond the minimum requirements of the Directive.
11. Where possible, the UK will use copy-out from the Directive, except where doing so would adversely affect UK interests. In this case, the revised OELVs from the Annex to the Directive will be implemented as WELs in EH40/2005.
12. Effective implementation as proposed above will ensure the UK avoids infraction proceedings and associated costs for failure to fully implement the Directive.

## **2.1 Implementation date and scope of this impact assessment**

13. Member states are required to transpose the Directive by 17 January 2020. There is an extended transitional period for the lower limits for Hardwood Dust (17 January 2023) and Chromium (VI) Compounds (17 January 2025). This extended period is granted in recognition of the particular technological challenges faced by these industries.
14. This impact assessment (IA) and the consultation will focus on the initial 2020 limits only (i.e. those set out in Table 1 - Summary of existing and proposed limits by substance). A further impact assessment and consultation will be undertaken at a later stage, ahead of the 2023/2025 implementation dates.

## **3 Policy objectives**

15. In considering the most appropriate method to transpose the requirements of the Directive, the policy objectives are:
- To improve worker protection from carcinogens and mutagens.
  - To ensure, where possible, consistency of application with other UK Government Departments and Agencies.
  - To ensure a level playing field across Member States.
  - To bring the UK regime in line with the latest recommendations from SCOEL and to fulfil the UK's obligations under EU law.

## **4 Description of options considered**

### **4.1 Do nothing**

16. When considering options for transposition of the Directive within the IA, the 'do nothing' option was not considered viable as it would not deliver the policy objective and the UK's obligations under EU law. Therefore, the 'do nothing' or status quo option has not been analysed further in this IA, in accordance with Better Regulation guidance on IAs. It appears in this IA only as the notional baseline against which the other options are assessed.

### **4.2 Option 1: Do minimum – update table 1 of the HSE publication EH40**

17. Option 1 is presented as the 'do minimum' option, which assesses the costs and benefits of implementing the Directive in a way that does not introduce new requirements which go beyond the scope of the Directive. In this option, HSE would implement the Directive by updating statutory table 1 of the HSE publication EH40/2005 Workplace Exposure Limits, which supports the requirements of the Control of Substances Hazardous to Health Regulations.

18. Separate action will be required to amend the Mines Regulations 2014.
19. Implementing the Directive in this way would minimise changes to existing arrangements, so this option is the least burdensome to duty holders who are already familiar with current requirements and the legislative framework. This option meets the requirement to implement the Directive and is achievable within the implementation timescale.
20. This 'do minimum' option will fully implement the Directive and limits burdens on businesses. It also maintains current standards, and in some cases offers additional protection for workers.

### **4.3 HSE's preferred Option**

21. Option 1 is HSE's preferred option, as it implements the requirements of the Directive and places the minimum burden on UK business. It also minimises Ministerial and Parliamentary time and resource and helps keep the Regulations future-proof.

### **4.4 Summary of Proposed changes to substances**

22. The amended Directive establishes OELVs for 11 substances and amends 2 existing values, which are summarised in Table 1 below. In the UK OELVs are transposed as Workplace Exposure Limits (WELs) and Short-Term Exposure Limits (STELs).<sup>9</sup>

**Table 1 - Summary of existing and proposed limits by substance**

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<sup>9</sup> A WEL is defined as the concentration of a hazardous substance in the air that people breathe, averaged over a specified reference period referred to as a time-weighted average (TWA). Two periods are used: long-term exposure limit (8 hours) and short-term exposure limit (STEL) (15 minutes).

Substance	Current WEL	New WEL	Transposition date
Respirable Crystalline Silica – (RCS)	0.1mg/m <sup>3</sup>	0.1mg/m <sup>3</sup>	17 January 2020
Hardwood Dusts (inc mix)	5mg/m <sup>3</sup>	3mg/m <sup>3</sup> 2mg/m <sup>3</sup> *	17 January 2020 January 2023*
Chromium (VI) Compounds	0.05mg/m <sup>3</sup>	0.010 mg/m <sup>3</sup> (non-process-generated) 0.025mg/m <sup>3</sup> (process-generated) 0.005mg/m <sup>3</sup> * (for all)	17 January 2020 17 January 2020 17 January 2025*
Hydrazine	0.03mg/m <sup>3</sup>	0.013mg/m <sup>3</sup> and skin**	17 January 2020
Acrylamide	0.3mg/m <sup>3</sup>	0.1mg/m <sup>3</sup> and skin	17 January 2020
Refractory Ceramic Fibres	1f/ml	0.3f/ml	17 January 2020
Vinyl Chloride Monomer	7.8mg/m <sup>3</sup>	2.6mg/m <sup>3</sup>	17 January 2020
O-Toluidine	0.89mg/m <sup>3</sup>	0.5mg/m <sup>3</sup> and skin	17 January 2020
1,3 Butadiene	22mg/m <sup>3</sup>	2.2mg/m <sup>3</sup>	17 January 2020
Bromoethylene (vinyl bromide)	None	4.4mg/m <sup>3</sup>	17 January 2020
Ethylene Oxide	9.2mg/m <sup>3</sup>	1.8mg/m <sup>3</sup> and skin	17 January 2020
1,2 Epoxypropane (propylene oxide)	12mg/m <sup>3</sup>	2.4mg/m <sup>3</sup>	17 January 2020
2-Nitropropane	19mg/m <sup>3</sup>	18mg/m <sup>3</sup>	17 January 2020

\* Indicates that these limits are out of scope of this assessment. See Section 2.1.

\*\* 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.

## 5 Monetised and non-monetised costs and benefits of each option (including administrative burden)

### 5.1 Baseline

23. Better Regulation Principles are that an IA should only capture those costs which are in addition to the current regulatory framework and any IA should assume 100% compliance with the proposed changes for any costs and benefits estimates, unless there is evidence to the contrary<sup>10</sup>. So, it is assumed that industry is compliant with the current legislative requirements of COSHH under the existing legislative and only costs directly related to the additional requirements stemming from implementing the revised Directive will be considered in this assessment.

### 5.2 Research already undertaken

24. During the development and negotiation of the Directive, details of manufacturers, importers, formulators, and other users for all substances in question were obtained

by relevant trade associations, literature and internet sources. HSE contacted the relevant organisations to gather information regarding potential impacts and ensured that, where possible, their views were taken into account at an early stage.

25. In addition, during the SCOEL process the draft recommendations underwent a stakeholder consultation to allow interested parties to submit health-based scientific comments and further data, and the European Commission (EC) also provided an IA on each of the substances. The information we have taken from these consultations has helped HSE understand the potential impacts of the proposed limits.

26. Based on this information, HSE prioritised substances based on the potential for significant costs to business in preparation for the present assessment. This process identified three substances: Chromium (VI) Compounds, Hardwood Dusts, and (to a lesser extent) 1,3 Butadiene. Further research effort has been focussed on these substances.

27. The evidence gathering undertaken to inform the present assessment is summarised below:

- High-quality measurements of Hardwood Dust exposure and controls in woodworking sites, undertaken by HSE scientists, *'Updating the HSE evidence base on wood dust exposure risks in woodworking industries'* (to be published).
- On-line questionnaire. Hardwood Dust was identified in the EU IA as having the potential to incur costs for GB industry. A questionnaire targeted the wood-working industry was distributed through the Wood Safety Group (WSG) which is a group of trade associations which represent the sector. It received over 300 responses from businesses.
- Telephone interviews with trade associations for Chromium (VI) Compounds and Hardwood Dusts.
- Discussions with HSE occupational hygiene specialists and inspectors about current exposures and current legal requirements under the COSHH Regulations.
- Discussions with HSE 'Registration, Evaluation, Authorisation and Restriction of Chemicals' (REACH) specialists about restrictions for substances under REACH and the use of these substances in GB.
- Engagement via email with representative trade associations to validate use and current exposure levels on all substances.

28. In addition, we emailed key chemical industry associations to validate the assessment of 'no additional costs to business' arising from a change in the WEL for



those substances indicated in Table 2 – Overview of expected impact by substance. Throughout these activities, we also took the opportunity to gather early evidence on the impacts of lower limits for Chromium (VI) Compounds and Hardwood Dusts, in preparation for a future assessment and consultation.

### 5.3 Costs - Do nothing

29. Whilst this is not a valid option, as this proposal relates to the transposition of a European Directive, do nothing is used as the notional baseline.

### 5.4 Costs – Option 1: implement the Directive by establishing the new/revised OELV as a WEL in EH40/2005

30. Option 1 satisfies the requirement that new legally binding WELs be introduced into UK law to reflect those listed in the CMD.

31. An assessment of whether each new WEL would impose costs is presented below. Each assessment of cost is based on evidence provided by industry (through early initial consultation by SCOEL and the EU Commission) and HSE’s occupational hygienists, economists and social researchers. The information presented reflects our best estimates given available information and will be subject to further revision following the formal consultation. Table 2 below provides a summary of the expected impact of implementing the revised WELs for 13 substances for ease of reference. Further detail substantiating the assessment is provided in the following sections.

**Table 2 – Overview of expected impact by substance**

Substance	No additional impact	Potential for some additional impact	Reason (see explanation below 1,2,3,4)
Respirable Crystalline Silica Dust - (RCS)	X		2
Hardwood Dusts (inc mix)		X	4
Chromium (VI) Compounds		X	4
Hydrazine	X		3
Acrylamide	X		3
Refractory Ceramic Fibres	X		3
Vinyl Chloride Monomer	X		3
O-Toluidine	X		3
1,3 Butadiene		X	4
Bromoethylene (vinyl bromide)	X		1
Ethylene Oxide	X		3
1,2 Epoxypropane (propylene oxide)	X		1
2-Nitropropane	X		2

**Notes:**

- **Reason 1** – There is very little/no manufacture or use in GB

- **Reason 2** - The new EU OELV is at or is very close to the current GB WEL
- **Reason 3** – Current practices already lead to compliance with the new WELs (e.g. because the substance is already used within closed systems) or is only used as an intermediate where there are already very high standards of control
- **Reason 4** – Known use in several sectors in GB and potential impact highlighted during negotiation phase of Directive

#### 5.4.1 *WELs with no additional impact*

32. For all 10 substances listed in Table 1 under ‘No Potential Impact’, information was gathered from HSE specialists and industry stakeholders indicate that no additional costs are expected. The basis for this is summarised in Table 2 and discussed further below. The formal consultation period will be used to gather further evidence and information to confirm this assessment.

#### Substances with no/little manufacture or use in GB

- **Bromoethylene:** There is no current WEL set in GB for Bromoethylene, as there is no use of this substance in the GB. Therefore, there will be no additional costs for GB industry meeting the new WEL.
- **1,2 Epoxypropane:** 1,2 Epoxypropane is used mainly in the manufacture of polyurethane and the production of propylene glycol. There are only a small number of workers exposed; the EC IA estimates between 35 to 75 workers are exposed during its manufacture across the EU. There are no known sites in the UK manufacturing 1,2 Epoxypropane and its only use is as an intermediate to manufacture other chemicals and plastic products. Where being used as an intermediate, processing is usually in closed or automated systems where exposure levels are already tightly controlled. No issues or costs were raised during the validation exercise with the Chemical Industries Association (CIA).

#### Substances where the new EU OELV is at or very close to the current GB WEL

- **2-Nitropropane:** 2-Nitropropane is used in the manufacture of chemicals, manufacture of aircraft and spacecraft. The current WEL in GB is 19 mg/m<sup>3</sup> and the new WEL will be 18 mg/m<sup>3</sup>. As there will be no significant change, we expect that the standard of controls already in place will mean that industry will already be operating at or below the new WEL. No issues or costs were raised during the validation exercise with the CIA.
- **Respirable Crystalline Silica (RCS):** RCS exposure is prevalent in construction, quarrying, foundries, stoneworkers, manufacturing and mining; up to 500,000 workers in the UK may be exposed. The new EU OELV for RCS of 0.1 mg/m<sup>3</sup> is the same as the current WEL in GB (except for mining activities – see below) and so businesses would not be expected to do anything additional to what they should be doing now to reduce workers exposure to RCS.

In 2007, the WEL was disapplied for the mining sector and an action limit of 0.3 mg/m<sup>3</sup> introduced (the level at which action must be taken to reduce exposure), due

to mining operations' difficulties in meeting 0.1 mg/m<sup>3</sup>. In the development of this assessment, HSE contacted the Mining Industry Leadership Group in 2018, which advised that all except one or two of their members are now compliant with the 0.1mg/m<sup>3</sup> WEL. One of these mines is yet to be developed and the other may be exhausted by the time the 2020 WEL comes in to force, so any potential impacts should be limited.

### 33. *Substances where current practices already lead to compliance with the forthcoming WEL*

- **Refractory Ceramic Fibres (RCFs):** RCFs are used in manufacturing, fibre production, finishing, and installation and assembly operations. The EC IA estimates that 10,000 workers are exposed across the EU but does not provide a breakdown by country. HSE attended an industry meeting and gave a briefing on the change to the WEL in relation to RCFs. All the main associations were in attendance and no issues were raised regarding compliance costs or impacts.
- **Vinyl Chloride Monomer (VCM):** VCM is mainly used in the manufacture of chemicals, and chemical products (VCM and polyvinyl chloride (PVC) production). The EC IA estimates that 15,000 workers are exposed to VCM at plants that produce VCM and/or PVC; they do not provide a breakdown by country. Informal consultation with the industry suggests that businesses have very high standards of control in place and should already be operating at or below the new WEL. The British Plastics Federation have confirmed there should be no consequences for downstream users of PVC resin. They also provided information that when PVC resin is supplied to EU markets by EU manufacturers, businesses are already required to conform to the VCM requirements in the Food Contact Regulations 2004, where the maximum level of residual vinyl chloride should mean that any workplace exposures are below the new WEL.
- **Ethylene Oxide:** Ethylene Oxide is mainly used in the extraction of crude petroleum and natural gas, the manufacturing of chemicals and in the production of consumer goods. The EC IA suggest there are approximately 2,600 exposed workers in the UK, although it is unclear how they arrived at this figure. A review of the scientific literature conducted by the authors of the EC IA suggests that the current exposure levels in the EU are below the new EU OELV and therefore no additional costs or benefits are expected to industry. HSE occupational hygiene specialists agree that if GB businesses have the current control requirements in the COSHH Regulations, they will already be reducing exposure to the new WEL. In addition, its main use in GB is as an intermediate, where processing is usually in closed or automated systems where exposure levels are already tightly controlled. No issues or costs were raised during the validation exercise with the CIA.
- **Acrylamide:** Acrylamide is used in chemical, water treatment and manufacturing industries. 99.9% of acrylamide production is used in polyacrylamide manufacture using continuous process with good control measures already in place. The EC IA suggests there is one business that produces acrylamide in the UK but does not specify the number of businesses which use it as an intermediate. The EC IA also

assumes that all workers across the EU are currently exposed to acrylamide at levels less than the new EU OELV resulting in no additional costs or benefits to industry. To validate this, HSE occupational hygiene specialists sought feedback from three companies in GB in 2012. The feedback suggests that any company that decants or repackages acrylamide or that uses it as an intermediate will not have to do anything to comply with the new WEL. There was one instance highlighted where there may be small costs<sup>11</sup> but these would be minimal and not additional to current requirements under the COSHH Regulations.

- **O-Toluidine:** O-Toluidine is used in the manufacture of pigments and dyes. Discussions with HSE occupational hygiene specialists suggest that there is no manufacture of this substance in GB following a search for any users in 2011. It is however used in GB as an intermediate in the manufacture of other chemicals. Where a substance is used as an intermediate, processing is usually in closed or automated systems where exposure levels are already tightly controlled, resulting in exposure below the new WEL. No issues or costs were raised during the validation exercise with the CIA.
- **Hydrazine:** Hydrazine is mainly used in chemical, agriculture and water treatment industries in closed systems. The supplier imports and decants using closed systems and supplies in bespoke containers which connect to an enclosed system, so exposure is controlled to minimal levels. The new WEL is lower than the current WEL, however, as industry already has a very high standard of controls in place and use is in closed systems, industry should have no problems in meeting the new WEL. Information provided by the Chemical Business Association (CBA) supports the assessment that use is in closed systems and that exposures should already be controlled to the new WEL.

34. For all the substances described above, as well as no additional cost in meeting the 2020 WELs, there should not be any additional monitoring costs because businesses should be monitoring already, to demonstrate compliance under the COSHH Regulations.

#### 5.4.2 **Potential Impact – Further information sought**

35. For the three substances listed in Table 2 under 'Potential Impact' (Hardwood Dusts, Chromium (VI) Compounds and 1,3 Butadiene), consultations during the negotiation phase of the Directive (including those undertaken by SCOEL, the EU Commission and HSE) indicated the potential for additional costs to industry from implementation of the 2020 WELs. On this basis, further evidence gathering focused on activities where use and exposure to these substances occur (as described in Section 5.2). Following this research, we now do not expect significant additional costs to industry for these substances.

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<sup>11</sup> The only type of company that could have an impact would be the manufacturer of acrylamide, of which the EC IA tells us there is only one in the UK. This manufacturer which responded to HSE were not able to estimate the costs to their own business in 2011 but were planning plant modifications, thus the costs are sunk.

36. The potential impact of the 2020 WELs for these substances is discussed further below.

#### Hardwood Dusts

37. The current WEL for Hardwood Dusts (and its mixtures) is  $5\text{mg}/\text{m}^3$ . In implementing the Directive, the WEL would first be reduced in 2020 to  $3\text{mg}/\text{m}^3$  and then to  $2\text{mg}/\text{m}^3$  in 2023.

38. Occupational exposure to Hardwood Dust is prevalent in wood-working, furniture manufacturing and construction services. The wood-working industry is often described as being composed of activities related to the initial processing of wood (i.e. from raw timber, such as sawmills, planing and treatment) and further processing of wood (e.g. joinery, carpentry and wooden packages). Where Hardwood Dusts are mixed with other wood dusts, the WEL applies to all wood dusts present in that mixture.

39. The Inter-Departmental Business Register (IDBR) 2018<sup>12</sup> suggests that around 41,000 business in GB work with Hardwood Dusts and/or mixtures<sup>13</sup>, and the EC IA estimates that between 350,000 and 400,000 employees may be exposed in the UK. Across the EU, the wood-working and furniture manufacturing industries are predominantly composed of small businesses (above 85%).

40. HSE exposure monitoring research on woodworking sites '*Updating the HSE evidence base on wood dust exposure risks in woodworking industries*' (to be published) found that almost all businesses implementing and maintaining controls under current requirements, meet the 2020 WEL. A small percentage of exposure samples exceeded  $3\text{mg}/\text{m}^3$  (around 16%). Where samples were above  $3\text{mg}/\text{m}^3$ , the report highlighted that simple and readily available improvements would see these businesses achieve adequate control under existing requirements. This study forms the basis of HSE occupational hygiene advice that businesses compliant with current requirements for adequate control should already meet the  $3\text{mg}/\text{m}^3$  WEL.

41. HSE undertook some supplementary research and consultation with the WSG (an industry group with representation from all major wood-working trade associations) via an on-line questionnaire, which received around 320 responses. The aim of the questionnaire was to gain a better understanding of the current level of controls and exposures in GB businesses. It also asked about potential compliance costs, but this focussed on moving to the 2023 WEL of  $2\text{mg}/\text{m}^3$ .

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<sup>12</sup>

<https://www.ons.gov.uk/businessindustryandtrade/business/activitysizeandlocation/bulletins/ukbusinessactivitysizeandlocation/2018>

<sup>13</sup> This is based on the three sectors outlined in the EC IA as; Manufacture of wood products (SIC:16), furniture manufacturing (SIC:31) and joinery installation (SIC:4332)

42. Although responses to the survey suggest that many businesses expect to incur costs in complying with  $2 \text{ mg/m}^3$  (and may do so to comply with  $3 \text{ mg/m}^3$ ), it demonstrates that many employers do not have the expected controls in place under current requirements and so – based on HSE’s research – these costs are likely to reflect the implementation of adequate controls expected under current requirements. Where sample data was provided by businesses, the vast majority was below the  $3 \text{ mg/m}^3$  WEL (around 75%), which supporting our assessment that businesses should already be able to achieve the 2020 WEL of  $3 \text{ mg/m}^3$  with current effective controls.
43. Our evidence gathering is consistent with a study by the Institute of Occupational Medicine (IOM) carried out to inform the European Commission’s impact assessment in 2011. They found, across the EU, average exposure to Hardwood Dusts is lower than the new 2020 WEL of  $3 \text{ mg/m}^3$ .
44. On this basis, we conclude that there should not be any additional cost due to the 2020 WEL. Similarly, there should not be any additional monitoring costs for Hardwood Dust because businesses should be monitoring already, to demonstrate compliance under the existing COSHH Regulations.
45. There could be some additional costs for the lower WEL of  $2 \text{ mg/m}^3$  and work has already begun with the relevant industries to understand the potential impact. A further consultation on the lower WEL will take place at a later stage ahead of the January 2023 implementation date.

#### **Chromium (VI) Compounds:**

46. The current WEL for Chromium (VI) Compounds is  $0.05 \text{ mg/m}^3$ . The WEL will first be reduced in 2020, to  $0.025 \text{ mg/m}^3$  for process-generated exposures (during welding) and  $0.010 \text{ mg/m}^3$  for non-process-generated exposures. The latter is not considered further by this assessment because it is already well-controlled in enclosed systems or restricted by the (REACH) Regulations. The WEL for all sources of exposure will then be reduced further in 2025 to  $0.005 \text{ mg/m}^3$ .
47. Chromium (VI) Compounds are not manufactured in GB but imported for use in metal coating, chromium production, catalyst manufacture and the manufacture of metal products. Occupational exposures take place principally in four broad sectors of the GB economy. The number of premises in GB as estimated in the 2018 Inter-Departmental Business Register are as follows:
- Manufacture of metal structures and parts of structures: around 3,005 premises (SIC code: 2511)
  - Manufacture of steel drums and similar containers: around 30 premises (SIC code: 2591)

- Manufacture of other fabricated metal products not elsewhere classified: around 3,390 premises (SIC code: 2599)
- Treatment and coating of metals: around 1,295 premises (SIC code: 2561)

48. The activity of primary concern for exposure to Chromium (VI) Compounds is stainless steel welding. HSE analysts undertook a semi-structured telephone interview with a senior representative from The Welding Institute (TWI), an engineering institution that provides registration, certification and research of welding and joining for members across a vast range of industries. HSE estimates around 80,000 workers weld stainless steel in GB and so are exposed to Chromium (VI) Compounds, based on information provided by TWI.

49. Based on discussions with TWI, consideration of available controls and operational experience, HSE occupational hygienists advise that welding businesses which adopt adequate controls as per COSHH guidance, exposures should already be below the new 2020 WEL of 0.025 mg/m<sup>3</sup>. HSE will seek to validate this assessment with exposure measurement research currently being undertaken by TWI, in addition to consideration of public consultation responses.

50. Businesses in the treatment and coating of metals (which includes the use and removal of chromate paint) must apply under existing EU REACH regulations for authorisation from the EC to use Chromium (VI) Compounds and demonstrate a high level of control. Based on our discussions with HSE REACH specialists, we understand that these businesses are operating well within the new 2020 WEL. This is achieved through mechanical controls including isolation and automation of the coating work.

51. We validated this through a questionnaire sent to the members of the British Coatings Federation (BCF). The majority of BCF members who completed the questionnaire reported there would not be any additional costs because of the new 2020 WEL. One respondent indicated the potential for some additional control costs, although did not provide enough details on which to base any estimate.

52. With regards to businesses involved in electroplating of metals with Chromium (VI) Compounds, HSE contacted the Surface Engineering Association (SEA) to ask their members on the potential impact of the 2020 WEL. They confirmed that businesses should not incur additional costs in meeting the WEL, as they are already operating within it.

53. For businesses involved in the manufacture and use of chemicals with exposure to Chromium (VI) Compounds, HSE contacted the CIA to ask their members on the potential cost impact of the 2020 WEL. They only received one response, from a large chemicals manufacturer, which manufactures Chromium (VI) Compounds as a

by-product. The firm's monitoring data shows that they can already meet the new 2020 WEL without any additional cost.

54. On this basis, we conclude that there should not be significant additional cost to business from the new 2020 WEL of  $0.025\text{mg}/\text{m}^3$  to industry. Similarly, there should not be any additional monitoring costs for Chromium (VI) Compounds because businesses should be monitoring already, to demonstrate compliance under the COSHH Regulations.

55. There is potential for significant additional costs due the lower 2025 WEL of  $0.005\text{mg}/\text{m}^3$  and work has already begun with the relevant industries to understand the potential impact. A further consultation on the lower WEL will take place at a later stage ahead of the January 2025 implementation date.

### **1,3 Butadiene**

56. The current WEL for 1,3 Butadiene is  $22\text{mg}/\text{m}^3$ . The WEL will be reduced in 2020 to  $2.2\text{mg}/\text{m}^3$ .

57. 1,3 Butadiene is used in the manufacture of refined petroleum products and in the manufacture of rubber and neoprene products as a chemical intermediate. The EC IA estimates that 27,600 workers are potentially exposed in the EU. There are only a small number of producers and manufacturers of 1,3 Butadiene in GB, although businesses may use it in production of other chemicals. The EC IA suggests that approximately 2% of businesses across the EU will need to invest additional control measures to reduce exposure but that they would merely be bringing the investment forward. They did not provide specific figures for GB.

58. HSE has sought information through the CIA. One concern was raised referring to additional costs to business from a large chemicals manufacturer. However, we have since consulted with this business to confirm that the costs are for improvements to business operations rather than a direct impact from the lowering of the WEL.

59. On this basis, we do not expect significant additional cost to business from the new 2020 WEL for 1,3 Butadiene. Similarly, there should not be any additional monitoring costs for 1,3 Butadiene because businesses should be monitoring already, to demonstrate compliance under the COSHH Regulations.

## **5.5 Familiarisation costs**

60. We expect familiarisation costs to be minimal. The WEL system is already well established in Great Britain and, as set out in Section 5.4, HSE does not expect that businesses complying with current requirements under COSHH will need to take additional action to comply with the new limits.



61. An amendment of the HSE publication EH40/Workplace Exposure Limits is normally launched with a press release, notifications to trade press and an announcement on the HSE website. If compliant with COSHH, businesses should have sufficient information about the occupational exposures their workers receive. This would mean that a brief review of the revised EH40 list would confirm they had no further action to take.
62. In practice, employers may decide to undertake monitoring to determine current exposures for workers. Given that COSHH already requires employers to undertake these measurements, these are not additional or attributable to the current assessment.

## **5.6 Summary of cost impacts**

63. Based on HSE's informal consultations with occupational hygiene specialists, REACH colleagues, industry stakeholders and businesses, HSE does not expect significant additional costs from the implementation of the 2020 WELs. Exposures to the 13 substances are or should already be below the new WELs, either because: there is little or no use in GB; the new WEL is equal or similar to the current WEL; or the current requirements under COSHH regulations to reduce exposures to as low as reasonably practicable mean that industry should already have the necessary controls in place to meet the new WELs.
64. Most notably, it is unlikely that HSE will amend operational guidance on enforcement following the introduction of the 2020 WELs; that is, it is unlikely that HSE inspectors would expect to see additional controls relative to current requirements. Therefore, any costs incurred by business will reflect improved awareness of and compliance with existing requirements.

## **5.7 Health and Safety Benefits**

65. The 11 substances with new binding OELVs and 2 substances with amended OELVs are known to be harmful to health and have the potential to cause occupational cancer. The potential benefits are a reduction in occupational cancer cases plus other occupational ill health arising from the same exposures.
66. Any reduction in new cases of occupational cancer would be realised over several decades, due to the long latency between exposures to carcinogens and any development of cancer. HSE's *Costs of Work-related Cancer* research estimates that the average case of work-related cancer results in costs to society of around £800,000, including costs to individuals, employers and government. This becomes a cost-saving for cases avoided due to improved exposure control.

67. The EC IA estimates potential for a reduction in 100,000 deaths over 50 years across the EU from the implementation of the Directive. Because of the level of existing requirements, HSE expects health benefits from the proposals would be much lower than indicated by a simple apportionment of the EU estimate. Given the assessment presented in Section 5.4 that, if complying with current requirements businesses should not need to take additional action to meet the new 2020 WELs, any health benefits realised in practice would reflect increased compliance with existing requirements, and so are not attributable to this assessment.

## **5.8 Other benefits**

68. Failure to establish exposure limits in national law which take the new OELVs into account would be a breach of Treaty obligations, with the resulting likelihood of infraction proceedings being brought against the Government by the European Commission.

## **5.9 Proportionality of approach**

69. This is an IA for a European Directive which must be implemented in the UK. Industry stakeholders across Europe have been widely consulted during the development of the Directive. Section 5.2 explains the considerable level of additional evidence gathering carried out by HSE to inform this assessment. Research effort was prioritised on the areas where potential costs were highlighted during the negotiation phase of the Directive (including SCOEL, the EU Commission HSE) for Chromium (VI) Compounds, Hardwood Dusts and – to a lesser extent – 1,3 Butadiene.

70. Evidence gathering has drawn on a range of sources, including the gathering of substantial primary data, such as on-site exposure measurements, bespoke questionnaire of wood-working businesses, and telephone interviews with trade associations. This has supplemented HSE's extensive operational, scientific and sector expertise to provide a sound and proportionate basis for the assessment.

71. HSE will use the formal public consultation to validate the present assessment and gather further information regarding any potential impact. Where consultation responses indicate further enquiry is necessary, HSE will undertake further, targeted evidence gathering to inform the final assessment.

## **5.10 Direct costs and benefits to business calculation**

72. As there are no significant additional costs to business estimated, this assessment is below the £5 million EANDCB de minimus limit. On this basis, it is not subject to scrutiny by the Regulatory Policy Committee.

73. It is also not in scope of One In, Three Out or the Business Impact Target because the changes result from a European Directive and there are no areas in which the UK will go beyond the scope of the Directive.

### **5.11 Summary and preferred option**

74. Option 1 is the preferred option: to implement the Directive by updating statutory table 1 of the HSE publication EH40/2005 Workplace Exposure Limits and adopting the transition periods for Hardwood Dusts and Chromium (VI) Compounds.

75. Implementing the Directive in this way would minimise changes to existing arrangements, so this option is the least burdensome to duty holders who are already familiar with current requirements and the legislative framework. This option meets the requirement to implement the Directive and is achievable within the implementation timescale.

This 'do minimum' option will fully implement the Directive in a way that does not introduce new requirements which go beyond the scope of the Directive and limits burdens on businesses. It also maintains current standards, and in some cases offers additional protection for workers. Given the level of existing requirements and current patterns of use & control, the implementation of the 2020 WELs is not expected to result in significant additional costs to business and other employers.