Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States

REPORT BY DIRECTIVE: DIRECTIVE 2004/37/EC ON THE PROTECTION OF WORKERS FROM THE RISKS RELATED TO EXPOSURE TO CARCINOGENS OR MUTAGENS AT WORK
Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States

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# CONTENTS

List of abbreviations .................................................. 7

Executive summary ..................................................... 9

1 Introduction .......................................................... 17

2 The Directive .......................................................... 20
   2.1 Background and objective ................................... 20
   2.2 Risks ............................................................. 21
   2.3 Provisions ....................................................... 23
   2.4 Intervention logic .............................................. 25
   2.5 Measuring impacts ............................................. 27

3 Implementation in Member States ............................... 29
   3.1 MQ1: Common Processes and Mechanisms ............. 29
   3.2 MQ2: Derogations and transitional periods ............ 35
   3.3 MQ3: Compliance .............................................. 35
   3.4 MQ4: Accompanying actions ............................... 40
   3.5 MQ5: Enforcement ............................................ 43
   3.6 MQ6: Vulnerable groups .................................... 45
   3.7 MQ7: SMEs and microenterprises ....................... 46

4 Assessment of relevance .......................................... 47
   4.1 EQR1: Current relevance .................................. 49
   4.2 EQR2: Future relevance .................................... 58

5 Assessment of effectiveness ...................................... 66
   5.1 EQE1: Effect on occupational safety and health .... 67
5.2  EQE2: Effect of derogations and transitional periods 76
5.3  EQE3: Effect of Common Processes and Mechanisms 76
5.4  EQE4: Effect of enforcement 77
5.5  EQE5: Benefits and costs 78
5.6  EQE6: Broader impacts 78
5.7  EQE7: Objective achievement 79

6  Assessment of coherence 80
6.1  EQC1: Coherence and complementarity between the CMD and the other OSH Directives (Internal coherence) 80
6.2  EQC2: Coherence between the CMD and other EU measures and policies / international instruments (External coherence) 88

7  Conclusions and recommendations 97
7.1  Implementation 97
7.2  Relevance 98
7.3  Effectiveness 100
7.4  Coherence 101
7.5  Overall discussion 102
7.6  Overall Recommendations 103

APPENDICES

Appendix A  References
### List of abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGS</td>
<td>Committee on Hazardous Substances</td>
</tr>
<tr>
<td>CLP</td>
<td>Classification, Labelling and Packaging</td>
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<td>CPM</td>
<td>Common Processes and Mechanisms</td>
</tr>
<tr>
<td>CSA</td>
<td>Chemical Safety Assessment</td>
</tr>
<tr>
<td>DNEL</td>
<td>Derived No Effects Levels</td>
</tr>
<tr>
<td>EAP</td>
<td>Environment Action Programme</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EQC</td>
<td>Evaluation question Coherence</td>
</tr>
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<td>EQE</td>
<td>Evaluation question on Effectiveness</td>
</tr>
<tr>
<td>EQR</td>
<td>Evaluation question on Relevance</td>
</tr>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>EU-OSHA</td>
<td>European Agency for Safety and Health at Work</td>
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<td>ILO</td>
<td>International Labour Organisation</td>
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<td>KR</td>
<td>Key requirement</td>
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<td>LFS</td>
<td>Labour Force Survey</td>
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<tr>
<td>MAPP</td>
<td>Major-accident Prevention Policy</td>
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<td>MQ</td>
<td>Mapping question</td>
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<tr>
<td>MS</td>
<td>Member State</td>
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<tr>
<td>NACE</td>
<td>Nomenclature of Economic Activities</td>
</tr>
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<td>NIR</td>
<td>National Implementation Report</td>
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<td>OEL</td>
<td>Occupational Exposure Limit Value</td>
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<td>OLV</td>
<td>Occupational Limit Value</td>
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<td>OSH</td>
<td>Occupational Safety and Health</td>
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<td>PPE</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
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<td>---------------------------------------------------</td>
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<tr>
<td>2000/21/EC</td>
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<td>SBS</td>
<td>Structural Business Statistics</td>
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<tr>
<td>SDS</td>
<td>Safety Data Sheets</td>
</tr>
<tr>
<td>SLIC</td>
<td>Senior Labour Inspectors Committee</td>
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<td>SME</td>
<td>Small to Medium Enterprise/s</td>
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<tr>
<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Executive summary

Directive 2004/37/EC on the protection of workers from the risks related to exposure carcinogens or mutagens at work (the Carcinogens and Mutagens Directive or CMD) was designed to lay down minimum requirements for the protection of workers from risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens and mutagens during their work.

During the period of this study, which was commenced in 2013, Directive 2014/27/EU1 was adopted. This amended:

- the citation of the asbestos directive in Article 1(4) to reflect the adoption of a revised version;
- the definitions of ‘carcinogens’ and ‘mutagens’;
- replaced the use of the term ‘preparation’ (or ‘preparations’) with ‘mixture’ (or ‘mixtures’) in various articles.

It did not therefore result in any substantive changes to the provisions embodied in the CMD (Directive 2004/37/EC). Because the scope of the present study is 2007-2012, and because clearly the changes adopted in this more recent directive had not necessarily come into force (the transposition date being June 2015), the study focussed primarily on the 2004 Directive. However, changes introduced by the 2014 Directive are noted in the text and commented upon where appropriate.

Findings are based on an analysis of the OSH legislation in each of the MSs (embodied in Country Summary Reports (CSRs) prepared by national experts for

the project), official statistics at national and EU level, National Implementation Reports (NIRs) (submitted to the Commission by the MSs by end of 2013) as well as on scientific articles, existing studies and interviews with both national and EU stakeholders.

As noted above, the CMD was adopted with the objective of the protection of workers from risks arising or likely to arise from exposure to carcinogens and mutagens during their work (although not all carcinogenic or mutagenic agents are covered by its provisions).

The CMD provides for a three-tiered mechanism to protect workers from these risks. This consists of:

- an obligation for the employer to reduce the use of a carcinogen or mutagen at the workplace, in particular by replacing it with a substance which is not ‘dangerous’ (or less dangerous);
- where it is not technically possible to replace the carcinogen or mutagen, to ensure that the carcinogen or mutagen is, in so far as it is technically possible, manufactured and used in a closed system;
- when this is not possible, it shall be ensured that the level of exposure of workers is reduced to as low a level is technically possible by various measures specified in the Directive.

The Directive also provides for binding limit values, currently for only three substances. Other elements provided in the Directive (unforeseen and foreseeable exposure, access to risk areas, hygiene measures) are complementary provisions to or overlap with core risk management measures.

For the purposes of this Directive, ‘carcinogen’ means (as modified by Directive 2014/27/EU):

(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council;

(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex.

‘mutagen’ means (as modified by Directive 2014/27/EU) a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008.

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### Implementation
In most cases (20/27) this Directive and its CPMs has been transposed into multiple pieces of legislation rather than one. Examination of the country summary reports showed that no infringements proceedings were initiated in any of the MSs and there were two cases of observed discrepancies between the CMD and national legislation although, in one of these (Estonia) this was regarded as a technical discrepancy which would be unlikely to have any meaningful impact on the protection provided to workers. In contrast, Hungarian legislation does not apparently include limit values for benzene and hardwood dusts.

### Compliance
The data from the MSs used to assess the degree of fulfilment was quite sparse. Only nine of the 27 MS presented any degree of compliance data for the CPMs, for all establishments. These reported degrees of compliance ranging from 14% up to 93% across all the CPMs. No information was found relating compliance to industrial sector of public or private enterprises. When considering size of establishment no data or estimates were available reflecting any differences in compliance. However, SMEs were discussed by the MSs in their NIRs. 15 of the 27 MSs discussed specific issues SMEs or micro enterprises have had when trying to comply with the provisions of the legislation.

The responses in these to a specific NIR question on substitution provided only a patchy picture but suggested that enterprises in a number of MSs found this to be problematic. Data on the extent of implementation of substitution gives little insight into the proportion of those instances where substitution was possible but not implemented.

### Accompanying actions
Considering accompanying actions adopted in the MSs, guidance documents were by far the most employed action with sixteen of the 27 MSs having developed at least one guidance document. At the EU level a considerable number of accompanying actions were identified from EU-OSHA relating to dangerous substances, although none appeared to focus specifically on carcinogens and mutagens, together with limited additional material from the European Chemicals Agency focussing on supply rather than use of chemicals. None of the MSs answered yes when asked directly whether there were any gaps. Furthermore, no data was available on the extent to which establishments used the available accompanying actions.

### Enforcement
Specific enforcement strategies or procedures for the implementation of this Directive were identified in nine of the 27 MSs. Furthermore, twelve of the MSs have specific criminal or specific sanctions for this Directive. Only three of the MSs have a specific authority responsible for the enforcement of this Directive. In the remainder, the enforcement of the CMD is the responsibility of the general authority for inspections/enforcement.

### Vulnerable groups
Specific tools or approaches focussed on particular vulnerable groups were identified only in France and the Netherlands; they provided specific provisions for pregnant workers. Otherwise a general approach to vulnerable groups is adopted amongst the MSs.

### SMEs and microenterprises
With regards to SMEs and microenterprises a similar approach was found across the MSs. Only three of the MSs provide specific lighter regimes or financial support...
for SMEs and microenterprises. Furthermore, only two of the MSs have included specific exemptions for SMEs or microenterprises. It is worth noting here that, in comparison to the majority of the OSH 24 Directives, this Directive prompted more MSs to develop specific measures for SMEs and microenterprises than most other Directives.

Current relevance

Estimates based on employment within appropriate industrial sectors suggest that the CMD is potentially relevant to 12.3% of the EU workforce.

One study identified estimated that overall, 8010 (5.3%) total cancer deaths in Britain (6073 excluding mesothelioma), and 13,598 cancer registrations (11,661 excluding mesothelioma) were attributable to occupation in 2005 and 2004, respectively. Any extrapolation of these figures to the EU-27, as well as the other studies reported, gives a strong indication that this Directive remains relevant.

Data from the individual NIRs show varying levels of occupational cancer (deaths and incident cases) with much missing data and suggestions of under-recording.

Future relevance

One key issue discussed which relates to the future relevance of this Directive is the latency effects of relevant exposures. As discussed by SLIC the full impact of the Directive may still not be known for 15-20 years due to the length of time it can take for exposure to some carcinogens or mutagens to display effects, and thus to be able to measure whether the controls are protecting the workers. Therefore, it could be argued that the Directive remains relevant until such time that the data allows the controls to be assessed.

From the national expert interviews there was a complete consensus on the continued future relevance of the Directive. Some stakeholders at national and EU level advocated the merger of the CAD and CMD, a suggestion which is discussed in the CAD report.

Several stakeholders considered the need to incorporate the prevention of potential risks of exposure to nanomaterials in the provisions of this Directive. The issue of nanoparticles is again discussed at greater length in the CAD report. However, it is noted that there are uncertainties regarding the health effects of nanoparticles and nanomaterials. One consequence of this is that some advocate their inclusion in the CAD, some in the CMD, some in both and some in a separate Directive.

From the NIRs three explicit recommendations were offered to ensure the future relevance of the Directive. Germany ‘urgently’ recommended a reduction in the number of Directives. Austria recommends that the scope of the Directive should be extended to substances and compounds toxic to reproduction whilst Slovakia makes reference to a need to supplement the range of limits for carcinogens for genotoxic carcinogens. Also, Greece recommends that the Directive be supplemented on the basis of more recent Regulations (1272/2008/EC and 1907/2006/EC) already in force although changes reflecting 1272/2008/EC (CLP) have already been adopted and they give no specific recommendations in respect of REACH (1907/2006/EC).

The issue of the inclusion of reprotoxins (not all of which are mutagenic) within a widened scope of the CMD was reviewed. It was noted that over a third of MSs
already accommodate them within their equivalent legislation suggesting a degree of tacit support for such a measure. However, it is suggested that including consideration of reprotoxins and how best to control the risks they present within a wider debate over the future of the CAD and CMD provides the best option given the current lack of detailed data.

The CMD currently assumes that thresholds limits can be identified for carcinogens and mutagens below which there is no risk to health. Hence, there is a strong focus on measures such as substitution and the use of closed systems (as well as an explicit requirement for exposure levels to be reduced as low as technically possible). However, the prospect of identifying some carcinogens or mutagens for which an evidence-based safe threshold can be established would generate additional pressures to revise the CMD.

The issue of simplifying the regulation of chemicals (including carcinogens and mutagens) by merging the CMD and CAD was discussed amongst stakeholders attending a seminar held to discuss some of the findings of this study ("validation seminar"). There was no consensus on this at the seminar (which mainly included employer and worker representatives with some government stakeholders). The issue is discussed further in the CAD report.

There was little objective data relating to the influence of the CMD on workers’ safety and health and none regarding the activities of workers’ representatives, and the behaviour of establishments. There is therefore no objective data at EU level on which to base any assessment of the effectiveness of the CMD.

Subjectively, among EU stakeholders, there was the view that the CMD has had a moderate effect on the safety and health of EU workers. Employers and experts rated the effect higher than workers organisations.

Data on the impact of the CMD on health outcomes was not available because of the long latency period for most cancers. However, some insight can be gained from estimates of exposures to carcinogens. Collated data at EU level relies on the dated CAREX database and the fact that this is the most recent data illustrates the paucity of information on this important topic and the need for concerted action.

Some national data are available. For example, data from Finland suggests that the proportion of the workforce exposed to most chemical agents, including some carcinogens (and including benzene and wood dust covered by the CMD) has decreased substantially across a period from 1970 – 2008 and predicts that exposures on 2020 will remain low – or decrease further. Data from the UK also suggests continuing downward trends in the UK for many exposures (although not all fall under the scope of the CMD). However, all such researchers counsel against extrapolation of such figures to the whole EU because of national differences in factors such as the level and nature of technology and the occupational structure of the labour force.

In such cases however, indications are that the discernible trends commenced well before the adoption of the CMD and cannot therefore be attributed to its effects or effectiveness.
Data reported in the NIRs present a limited and mixed picture of trends in outcomes (deaths/cases) with some showing upward tendencies and others little consistent change in recent years.

Subjective opinions on effectiveness of CPMs

There was no objective data available which may have enabled the effectiveness of individual CPMs to be explored. However, subjective views were gathered from four national stakeholders from four MSs. National stakeholders are of the view that training and risk assessment are the most important factors contributing to the effectiveness of the Directive. They gave some importance to information, and relatively little importance to worker consultation and health surveillance. Given the limited numbers providing such an assessment care should be taken in extrapolating these and other subjective ratings to the wider EU-27.

Additionally no objective data was available which may have enabled the effectiveness of individual enforcement activities to be explored for the CMD. Interview responses from stakeholders were again analysed as a source of subjective opinion. The responses from those interviews, however, offered nothing in the way of a consensus as to how effective the enforcement activities related to this Directive has been in terms of SMEs and larger enterprises. Having said that, the overall opinion on how effective the enforcement activities have been across the industry types was that they have had an effect slightly greater than the midpoint (average 3.6) in terms of a 1-5 rating scale.

Internal and external coherence

With regard to internal coherence, this report focused primarily on coherence between the CMD and the other two chemical directives, the CAD and the Asbestos Directive. No major internal coherence issues were identified. However, there were a number of provisions identified under the CMD that could potentially be applied to all hazardous chemical agents. ‘Preliminary conclusions’ make suggestions for rectifying these inconsistencies of approach although, in most cases, the alternative suggestion is made that merging the two directives would provide a more coherent legal framework for the management of all chemical substances.

Concerning external coherence, the main issues identified related to the interfaces between REACH and the CMD.

Overall discussion

As with the CAD evaluation, a key issue concerning the CMD would seem to be that of merging the CAD and CMD. This topic has been raised through a variety of avenues referred to in the report, including the NIRs, interviews with stakeholders at EU and national level and the seminar held as part of the study. From a legal perspective (assessed in Section 6.1 internal coherence) there would, as noted above, be some rationale for doing so as, in terms of legal obligations, this would provide for more coherent and consistent requirements for the use of chemical substances.

As noted in section 4.2, discussions at the seminar revealed that there was no clear consensus amongst the stakeholders present. Although there was some variation within stakeholder groups it seemed that the main differences of opinion reflected a worker-employer split, with employers mostly favouring a merger but workers preferring to retain the two Directives. There was a suggestion that
merging the two might make compliance and risk management easier for SMEs and it was argued that merging of directives would be beneficial, reducing duplication and removing confusion amongst employers.

Others argued that there is no need to merge the directives as it is open to MSs to implement their provisions within a single legislative instrument; and that any such changes would be burdensome for MSs in having to alter legislation. It was noted that some MSs (e.g. UK) had already adopted such a course.

Given the clear lack of consensus on this issue it would seem unlikely that any agreement could be reached for a merger, despite the apparent legal clarification which could ensue. In any case combined legislation would need to contain the same provisions as currently found in the CAD/CMD to ensure adequate worker protection. Some were of the opinion that the greater hazard associated with carcinogens justified a separate Directive. In this context concerns were expressed that merging the Directives would, in some way, lead to a downgrading of the importance to be placed on carcinogens. This issue, of the possible merging of the CMD and CAD, is examined further in the CAD report.

It has also been recommended in two NIRs, that the scope of the CMD should be amended to include all substances of very high concern such as reprotoxins. This issue was also raised in discussions with EU stakeholders and is believed to have been the subject of a Commission review. From the CSRs, it appears that ten MSs already include some if not all CLP R1A and 1B substances within their transposition of the provisions of the CMD. This suggests that there is already a considerable favourable view towards extending the scope of the CMD (although not a majority).

Another key issue, shared with a great many of the other Directives is the absence of data relating either to implementation of the provisions of the CMD or its impact in terms of reduction in occupational cancers. Article 6 of the Directive provides for the collation by employers of information for the competent authority which is to be made available in request. As this information has to be collected, making it a requirement for this to be transmitted to the competent authority (rather than on request) would not place a large additional burden on employers but, collated at national and EU levels, such information would be of great value in future impact evaluations. Given the existing wording, such a move would not require the Directive to be amended subject to an agreement by MSs to exercise their existing right to request that the information be provided as employers are already required to collect it.

Similarly, Article 14(8) requires all cases of cancer identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen or mutagen to be notified to the competent authority. From the returns provided in the NIRs it is not clear to what extent this is currently happening. Again, this provides an opportunity within the existing provisions of the CMD to generate a valuable source of data for the future. Clearly, as a corollary to this, increased consensus over the definition and diagnosis of cancers as occupational will be
beneficial but the absence of such consensus should not necessarily be a barrier to action.

Although there are legal rationales for doing so, described in the main text, there would appear to be no consensus on the idea of merging the CAD and CMD. This suggestion is discussed further in the CAD report.

The report suggests that, either separately, or as part of any wider discussions, consideration should be given to exploring the scope of the CMD to determine whether or not other substances (e.g. reprotoxins) should be included within it, with evidence that, in more than a third of MSs, this has already been implemented.

Existing provisions within the CMD for providing information to the competent authority and for notifying the competent authority of diagnosed cases of occupational cancer provide a valuable opportunity to collect better data nationally on both exposure and health consequences and collating this at EU-level. The report indicates steps which would apparently enable this without the need for amendment to the CMD as employers are already required to collect it. The current lack of objective data on such an important issue should provide some impetus for such a measure, even if only on a voluntary basis.
1 Introduction

This report is a Directive-specific report which forms part of the reporting of an overall evaluation of 24 Directives on Occupational Safety and Health (OSH) commissioned by DG Employment. The report concerns Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work from here on referred to as the “CMD”.

The evaluation of 24 OSH Directives was initiated in 2013. The evaluation produced cross-cutting findings on the implementation of the 24 Directives, which are documented in the Main Report. Annexed to this main report are Directive-specific reports for each of the 24 Directives (Appendix E) and reports on the implementation of the 24 Directives in the Member States (Appendix G comprising 27 reports as Croatia was excluded from the study).

The objective was to evaluate the practical implementation of EU OSH Directives in the EU Member States with a view to assessing their impacts and with a view to identifying their strengths and weaknesses with the aim of putting forward possible improvements to the regulatory framework. The evaluation was guided by a set of questions and evaluation criteria, which were to be addressed for all Directives and Member States. There are two main sets of questions.

The first set relates to the implementation of the Directives in the Member States:

- **Implementation**: MQ1-MQ7 are mapping questions that as part from addressing the overall implementation of the Directives look into specific implementation issues such as derogations, transitional periods, compliance and enforcement:

  - **MQ1**: Across the Member States, how are the different Common Processes and Mechanisms foreseen by the Directives put in place, and how do they operate and interact with each other?
  - **MQ2**: What derogations and transitional periods are applied or have been used under national law under several of the Directives concerned?
  - **MQ3**: What are the differences in approach to and degree of fulfilment of the requirements of the EU OSH Directives in private undertakings and public-sector bodies, across different sectors of economic activity and across different sizes of companies, especially for SMEs, microenterprises and self-employed?
MQ4: What accompanying actions to OSH legislation have been undertaken by different actors (the Commission, the national authorities, social partners, EU-OSHA, Eurofound, etc.) to improve the level of protection of safety and health at work, and to what extent are they actually used by companies and establishments to pursue the objective of protecting safety and health of workers? Are there any information needs that are not met?

MQ5: What are the enforcement (including sanctions) and other related activities of the competent authorities at national level and how are the priorities set among the subjects covered by the Directives?

MQ6: What are the differences of approach across Member States and across establishments with regard to potentially vulnerable groups of workers depending on gender, age, disability, employment status, migration status, etc., and to what extent are their specificities resulting in particular from their greater unfamiliarity, lack of experience, absence of awareness of existing or potential dangers or their immaturity, addressed by the arrangements under question?

MQ7: What measures have been undertaken by the Member States to support SMEs and microenterprises (e.g. lighter regimes, exemptions, incentives, guidance, etc.)?

The second set addresses the three main evaluation criteria of relevance, effectiveness and coherence (a total of 11 evaluation questions):

› **Relevance:** EQR1-EQR2 relate to the extent to which the provisions of the Directive are relevant for the current as well as future risks and composition of industry sectors:

EQR1: To what extent do the Directives adequately address current occupational risk factors and protect the safety and health of workers?

EQR2: Based on known trends (e.g. new and emerging risks and changes in the labour force and sectoral composition), how might the relevance of the Directives evolve in the future, and stay adapted to the workplaces of the future in light of the horizon of 2020? Does the need for EU level action persist?

› **Effectiveness:** EQE1-EQE7 explore whether the introduction of the Directive has led to changes to enterprise behaviour and the occupational safety and health of workers:

EQE1: To what extent has the Directive influenced workers' safety and health, the activities of workers' representatives, and the behaviour of establishments?

EQE2: What are the effects on the protection of workers' safety and health of the various derogations and transitional periods foreseen in several of the Directives concerned?

EQE3: How and to what extent do the different Common Processes and Mechanisms that were mapped contribute to the effectiveness of the Directives?

EQE4: To what extent do sanctions and other related enforcement activities contribute to the effectiveness of the Directives?

EQE5: What benefits and costs arise for society and employers as a result of fulfilling the requirements of the Directives?

EQE6: To what extent do the Directives generate broader impacts (including side effects) in society and the economy?

EQE7: To what extent are the objectives achieving their aims and, if they are not, what cause could play a role? What factors have particularly contributed to the...
achievement of the objectives?

› **Coherence:** EQC1-EQC2 concern the extent to which the objectives and actions from a given OSH Directive interact or overlap with other OSH Directives and/or with other EU policies:

**EQC1:** What, if any, inconsistencies, overlaps, or synergies can be identified across and between the Directives (for example, any positive interactions improving health and safety outcomes, or negative impact on the burdens of regulation)?

**EQC2:** How is the interrelation of the Directives with other measures and/or policies at European level also covering aspects related to health and safety at work, such as EU legislation in other policy areas (e.g. legislation: REACH, Cosmetics Directive\(^3\), Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?

The overall methodology applied for the evaluation – and thus also for the analysis presented in this report – is presented in detail in Chapter 2 in the Main Report.

The findings in this Directive report are based on the analysis of the OSH legislation in each of the MSs; official statistics at national and EU level; National Implementation Reports (NIRs) submitted to the Commission by each of the MSs by end of 2013 together with scientific articles, existing studies and interviews with both national and EU stakeholders.

The report is structured according to the themes and issues listed above.

› Chapter 2 presents the overall understanding of the Directive, i.e. its rationale, its provisions, and its intervention logic, and introduces the issue of measuring the impacts of the Directive.

› Chapter 3 provides the relevant findings with regard to the implementation of the Directive in the MSs (addressing questions MQ1-MQ7).

› Chapter 4 provides the relevant findings with regard to the relevance of the Directive (addressing questions EQR1-EQR2).

› Chapter 5 provides the relevant findings with regard to the effectiveness of the Directive (addressing questions EQE1-EQE7).

› Chapter 6 provides the relevant findings with regard to the coherence of the Directive (addressing questions EQR1-EQR2).

› Chapter 7 draws the main conclusions emanating from the findings presented in Chapters 3-6

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\(^3\) Now the Cosmetics Regulations (see Section 6.2)
2 The Directive

2.1 Background and objective

Article 137(2) of the Treaty establishing the European Community, since supplanted by Article 153 of the Treaty on the Functioning of the European Union (TFEU), provides that the Council shall adopt, by means of directives, minimum requirements for encouraging improvements, especially in the working environment, to ensure a better level of protection of the safety and health of workers.

Against this general background the Council implemented the introduction of minimum health and safety requirements regarding the exposure of workers to the risks caused by carcinogens and mutagens (although not all carcinogenic or mutagenic agents are covered by its provisions).

From this, a Directive was adopted which lays down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to carcinogens and mutagens during their work. This Directive, the Carcinogens and Mutagens Directive (CMD) is a consolidation Directive that replaces Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work and its subsequent amendments (Directive 90/394/EEC, Directive 97/42/EC and Directive 1999/38/EC). It makes no substantive changes and merely consolidates the body of texts which it replaces.

During the period of this study, which was commenced in 2013, Directive 2014/27/EU was adopted. This sought to align the CMD to the new system for the

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classification and labelling of substances and mixtures laid down in Regulation (EC) No 1272/2008\(^5\).

Directive 2014/27/EU amended the CMD by:

- changing the citation of the asbestos directive in Article 1(4) to reflect the adoption of a revised version;
- revising the definitions of ‘carcinogens’ and ‘mutagens’;
- replacing the use of the term ‘preparation’ (or ‘preparations’) with ‘mixture’ (or ‘mixtures’) in various articles.

It did not therefore result in any substantive changes to the provisions embodied in the CMD (Directive 2004/37/EC). Because the scope of the present study is 2007–2012, and because clearly the changes adopted in this more recent directive had not necessarily come into force (the transposition date being June 2015), the study focussed primarily on the 2004 Directive. However, changes introduced by the 2014 Directive are noted in the text and commented upon where appropriate.

The CMD provides for a three-tiered mechanism to protect workers from these risks, which consists of an obligation for the employer to reduce the use of a carcinogen or mutagen at the workplace, in particular by replacing it so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers’ health or safety; and, where it is not technically possible to replace the carcinogen or mutagen, to ensure that the carcinogen or mutagen is, in so far as possible, manufactured and used in a closed system. When this is not possible, it should be ensured that the level of exposure of workers is reduced to as low a level is technically possible by various measures specified in the Directive. The Directive also provides for binding limit values. Other elements provided in the Directive (unforeseen and foreseeable exposure, access to risk areas, hygiene measures) are complementary provisions to or overlap with core risk management measures.

As regards asbestos, which is dealt with by the Asbestos Directive (2009/148/EC), the provisions of this Directive shall apply whenever they are more favourable to health and safety at work.

2.2 Risks

As is indicated by the title, the CMD seeks to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise

from exposure to carcinogens or mutagens at work. It does not include exposure to ionising radiation or UV radiation.

Many forms of cancer are considered to be at least partly caused by occupational factors. According to Rushton et al (2012) the most important cancer sites for occupational attribution are mesothelioma, sinonasal, lung and bladder cancers and non-melanoma skin cancer for men, and mesothelioma, sinonasal, lung, breast and nasopharyngeal cancers for women. However, not all of these will be caused by exposure to carcinogens or mutagens as defined by the CMD. For example, Rushton and co-workers identified shift work and solar radiation as carcinogenic but neither are encompassed by the CMD.

According to the CMD, “Germ cell mutagens are substances that can cause a permanent change in the amount or structure of the genetic material of a cell resulting in a change in the phenotypic characteristics of that cell, which may be transferred to descendent daughter cells.”

Although such changes at a cellular level in the body may occur as a result of acute exposures to carcinogenic substances, these are not readily observed. The consequences of exposure have an extensive period of latency before they become manifest and, in the case of mutagens, may not become apparent until the next generation. This presents challenges for assessing the effectiveness of the measures adopted by the CMD because of the delay it introduces before any impacts on health can be identified. The same applies to the signs and symptoms which can become apparent as many forms of cancer develop (for example a persistent cough can be indicative of lung cancer). Although information could be collected about the incidence of such signs or symptoms they are rarely specific and cannot therefore be used as early indicators of the effectiveness of measures taken under the CMD.

The Directive is an individual Directive within the meaning of the Framework Directive (Council Directive 89/391/EEC). The Directive should be seen in close relation with the other OSH, especially those relating to other chemical agents and asbestos, and non-OSH Directives and Regulations such as REACH and CLP Regulations.

The coherence with other Directives is analysed further in Chapter 6, providing an analysis of coherence of the Directive with other OSH and non-OSH legislation. Although not applicable during the period formally covered by this evaluation (2007-2012), recent changes introduced by Directive 2014/27/EU have been reflected in this analysis.

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2.3 Provisions

The definitions of carcinogens and mutagens contained within the CMD have been recently amended. Although the original definitions would have been current during the period of this evaluation this is unlikely to have any discernible impact in terms of the evaluation questions and criteria. The definitions given below are therefore those which are current (as of September 2015) not those previously applicable.

For the purposes of this Directive,

‘carcinogen’ means (as modified by Directive 2014/27/EU):

(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council\(^7\);

(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex.

‘mutagen’ means (as modified by Directive 2014/27/EU):

a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008.

Table 2-1 lists the Common Processes and Mechanisms (CPMs) and other Key Requirements (KRs) of the CMD which applies to the protection of workers against risks to their health and safety arise or likely to arise from exposure to carcinogens or mutagens at work. It then lists the provisions of the Directive that during the analysis have been identified as the ones that in particular need to be addressed when assessing the impacts of the Directive. Hence, the assessment focuses on the so-called Common Processes and Mechanisms (CPM) and other KRs:

CPMs are the KRs that derive from the Framework Directive 89/391/EEC and that are included in all or several of the individual Directives (i.e. specific Directives such as the CMD).

Other KRs are the Directive-specific provisions that in addition to the CPMs are considered to be central for generating workplace impacts and safety and health impacts\(^8\), e.g. provisions on limit values.

While Table 2-1 shows that five of the six CPMs are included in the articles in the CMD, the intervention logic figure ((Figure 2-1) illustrates how the CPMs and other KRs are presented in the CMD. For example, with respect to conducting risk


\(^8\) Workplace impacts and health impacts defined in chapter 2.4 of this report.
assessments the employer is required to pay attention to workers at particular risk of exposure to carcinogens or mutagens.

The Directive aims to remove and/or reduce such risks through multiple channels. Key requirements of the directive are to reduce the use of carcinogens and mutagens; and to substitute them with safer materials as far as technically possible.

Table 2-1  Key requirements for the CMD

<table>
<thead>
<tr>
<th>Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CM)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key requirement: Scoping</strong></td>
</tr>
<tr>
<td><strong>Scope of application</strong></td>
</tr>
<tr>
<td>Art. 3(1) read in conjunction with Art 2</td>
</tr>
<tr>
<td><strong>Key requirements: Common processes and mechanisms</strong></td>
</tr>
<tr>
<td><strong>CPM</strong> Conducting a risk assessment Preventive and protective services Information for workers Training of workers Health surveillance Consultation of workers</td>
</tr>
<tr>
<td>Relevant Articles</td>
</tr>
<tr>
<td><strong>Key requirements: Directive-specific provisions</strong></td>
</tr>
<tr>
<td><strong>Three tiered approach</strong> Arts. 4, 5(2)-5(4)</td>
</tr>
<tr>
<td><strong>Measures limiting worker exposure</strong> Arts. 5(5), 7(2) and 10(1)</td>
</tr>
<tr>
<td><strong>Information to competent authorities</strong> Art. 6</td>
</tr>
<tr>
<td><strong>Non-key Directive-specific provisions</strong></td>
</tr>
<tr>
<td>The following Directive-specific provisions are not considered to constitute key requirements in the context of the evaluation:</td>
</tr>
</tbody>
</table>
2.4 Intervention logic

Impact logic

Figure 2-1 illustrates the logical steps of how the CMD – represented by its KRs – leads to impacts, i.e.:

› **CPMs and other KRs** are, as discussed above, the provisions of the Directive that during the analysis have been identified as the ones that in particular need to be addressed when assessing impacts. The figure tries to illustrate that, because of the multifaceted nature of the Directive, it is not possible to identify how each of the KRs in themselves will impacts. In other words, the KRs work in tandem to produce impacts and so they are analysed as such.

› **Workplace impacts** constitute the direct changes/improvements that occur at the workplace as a result of implementing the KRs. For instance, better safety and health surveillance, organizational changes, higher awareness among workers about potential safety and health issues, etc. These changes come at a cost to the workplace, but are also the drivers by which the safety and health impacts occur.

› **Safety and health impacts** constitute the actual removal and/or reduction in safety and health risks arising from exposure to mechanical vibration. These impacts occur as a result of the Directive (KRs) through the above-mentioned workplace impacts.

› **Broader impacts** constitute the impacts that may occur more broadly speaking as a result of the above mentioned safety and health impacts.

Impact outline

While the assessments of the impacts of the Directive are presented in the following chapter – in particular in Chapter 5 – this assessment has taken a starting point in an impact outline. This means that the OSH experts within the evaluation team have made initial hypotheses for the intervention logics, i.e. specified the expected impacts of implementing the Directives. These expected impacts are then examined via the analysis of data gathered from statistics, studies and interviews.

Figure 2-1 shows that the CMD is expected to first lead to increased evidence of a number of workplace impacts: risk assessments, provision of information, training, consultation, health surveillance, substitution, risk management actions, reports to authorities. Furthermore there is expected to be evidence of reduction in use of carcinogens or mutagens by replacement with safer alternatives, as well as an increase in the use of closed control systems.

As a result of these workplace impacts a reduction is expected in the number of workers exposed to carcinogens and mutagens and a reduction in the number of workers suffering from cancer or mutagenic effects related to such exposures.
Key Requirements

**CPMs**
- Conducting a risk assessment
  - Conduct risk assessment with particular attention to workers at particular risk (Art. 3)
- Ensuring internal and/or external prevention and protection measures (R/W/A)
- Information for workers
  - Provide information for workers (Art. 12)
- Training of workers
  - Provide training for workers (Art. 11)
- Health surveillance
  - Provide health surveillance (Art. 14)
- Consultation of workers
  - Consult with workers (Art. 13)

**Other KRs**
- Three lined approach
  - The Directive provides for a three-lined mechanism to protect workers from risks associated with exposure to carcinogens or mutagens at work (Art. 4, 5.2.4)
- Measures limiting worker exposure
  - The Directive requires a number of measures aimed at limiting workers' exposure to carcinogens and mutagens (Art. 5.5, 7.2, 10.2)
- Information to competent authorities
  - The Directive requires that employers, where the result of the risk assessment reveals a risk to worker health or safety, make information specified in the provision available to competent authorities upon request (Art. 6)

Workplace Impacts

**Indicators**
- Workplace impacts are measurable changes that occur when the workplace is a result of the Directive
  - Evidence of risk assessments
  - Evidence of provision of information
  - Evidence of provision of training
  - Evidence of consultation
  - Evidence of health surveillance
  - Evidence of substitution
  - Evidence of other risk management actions
  - Evidence of reports to authorities
  - Evidence of reduction in use of carcinogens and mutagens by replacement with safer alternatives
  - Increased use of closed control systems

Health and safety impacts

**Indicators**
- Health and safety impacts are measurable changes that result from the Directive through workplace changes
  - Reduction in the number of workers exposed to carcinogens or mutagens
  - Reduction in the number of workers suffering from health related to CMD exposure

Broader impacts

**Assessed at acquis level**
- Broader impacts are assessed across all Directives and include areas such as
  - Employment growth
  - Economic growth
  - Increased productivity
  - Improved quality of products and services
  - Improved well-being and job satisfaction

Figure 2.1 CMD Intervention Logic
2.5 Measuring impacts

In continuation of the above impact outline, the assessment of whether the initial impact hypotheses prove to be correct takes place via analysing impacts at three levels; namely (i) workplace impacts; (ii) safety and health impacts; and (iii) broader impacts. There are two important considerations in this regard:

1. While workplace impacts do not necessarily say anything about specific improvements concerning occupational diseases arising from exposure to carcinogens or mutagens, they can provide important indications about these; i.e. relating to the fact that the safety and health impacts from the Directive stem from the associated changes at the workplace.

2. As indicated in the intervention logic, the broader effects of the Directive have been assessed at the acquis level. This analysis will be presented in the Main Report.

Furthermore, the assessment of impacts requires in practice that the addressed impact indicators are quantifiable. A set of indicators has in this context been developed by an OSH expert. This set represents the list of workplace as well as safety and health impacts that ideally should be considered in the evaluation of the Directive (see Table 2-1). However, measuring the impacts of the Directive on this basis requires that the indicators used for the analysis must be quantifiable via available statistics – and this is not always possible.

Note that assessments of the workplace impacts and the safety and health impacts within this evaluation also are based on the results of existing studies and on stakeholder views gathered through interviews.

Table 2-1  Impact indicators

<table>
<thead>
<tr>
<th>Workplace impacts</th>
<th>Safety and health impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of risk assessments</td>
<td>Reduction in the number of workers exposed to carcinogens or mutagens</td>
</tr>
<tr>
<td>Evidence of provision of information</td>
<td>Reduction in the intensity and duration of such exposures.</td>
</tr>
<tr>
<td>Evidence of provision of training</td>
<td>Reduction in the number of workers suffering from diseases related to CM exposure</td>
</tr>
<tr>
<td>Evidence of consultation</td>
<td></td>
</tr>
<tr>
<td>Evidence of health surveillance</td>
<td></td>
</tr>
<tr>
<td>Evidence of substitution</td>
<td></td>
</tr>
<tr>
<td>Evidence of other risk management actions</td>
<td></td>
</tr>
<tr>
<td>Evidence of reports to authorities</td>
<td></td>
</tr>
<tr>
<td>Evidence of increased use of closed control systems</td>
<td></td>
</tr>
</tbody>
</table>

It should also be noted that the fact that an indicator is potentially quantifiable does not necessarily mean that there exists data which can fully quantify the indicator. Hence, Table 2-1, derived from Figure 2-1, should therefore be seen as a list of indicators for which potential statistical sources could exist.
Based on Table 2-1, Table 2-2 provides an overview of identified data variables and statistical sources that are expected to provide useful information in the evaluation of the Directive. It will be noted that very little specific data is available relating to exposure to carcinogens and mutagens.

**Table 2-2  Available statistics**

<table>
<thead>
<tr>
<th>Safety and health impacts</th>
<th>Variable</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in the number of workers exposed to carcinogens or mutagens</td>
<td>Exposure to carcinogens or mutagens</td>
<td>CAREX*, Scientific publications and NIRs</td>
</tr>
<tr>
<td>Reduction in the number of workers suffering from ill-health related to CM exposure</td>
<td>Cancer morbidity or mortality attributable to occupational exposures</td>
<td>Scientific publications and national registries</td>
</tr>
</tbody>
</table>

* Whilst this is acknowledged as out of date (and other more recent material is used where available) it does possibly provide the most comprehensive overview of exposures to carcinogens across the EU.

**Data challenges**

One of the largest challenges identified with respect to the effects of exposure to carcinogens and mutagens and resultant cancer lies in the extremely long latency for the emergence of signs and symptoms of disease and subsequent diagnosis. This has been put as up to 50 years\(^\text{10}\) although 20-30 years might be more typical. This creates an extensive hiatus between the implementation of any change and any tangible benefits from that change. This is reflected in details of current levels of reported cases linked to exposure to carcinogens and mutagens. This issue is discussed further later in the report.

**Additional data**

As mentioned above, in addition to the statistical data sources referred to above, qualitative information from studies and interviews was used to inform the analysis. This included, for example, information from the NIRs on the KR of substitution. For a complete overview of published sources, see the list of references in Appendix A.

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\(^9\) Excluding asbestos

3 Implementation in Member States

For the purpose of the evaluation, a mapping exercise of the implementation of the 24 Directives in the Member States has been conducted. Each Directive, including the CMD, has been mapped according to seven mapping questions. This chapter provides a summary of the findings of the mapping exercise for the CMD.

The National Implementation Reports have constituted an important data source for the mapping, but other sources of data have also been consulted. Additional information on implementation in the individual Member States can be found in the individual country summary reports available in the Main Report. It should be noted that this chapter reflects only the Directive-specific data collected. For an overview of cross-Directive data, please refer to the main evaluation report.

The chapter is structured in accordance with the seven mapping questions and presents data collected through the country-specific data collection. Data is presented across Member States. For the purpose of presenting information across Member States, country codes are used in the tables in this chapter.

3.1 MQ1: Common Processes and Mechanisms

Table 3-1 shows an overview of data collected in the national studies regarding the CPMs and their transposition into national legislation. It should be noted that the publication of Directive 2014/27/EU, which includes some amendments to the CMD, post-dates the period of this work and such changes are not therefore reflected in this section.

11 Eurostat country codes: Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), United Kingdom (UK)
### Table 3-1  CPM implementation

<table>
<thead>
<tr>
<th>Member State</th>
<th>One (O) or several laws (S)</th>
<th>Observed discrepancies (Y/N)</th>
<th>More detailed requirements (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE</td>
<td>O</td>
<td>N</td>
<td>Y (Art. 3, 12-14)</td>
</tr>
<tr>
<td>BG</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 11, 14, 16, Annex II, III)</td>
</tr>
<tr>
<td>CZ</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 16, Annex III)</td>
</tr>
<tr>
<td>DK</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 11, 14, 16, Annex III)</td>
</tr>
<tr>
<td>DE</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 11, 14, Annex II)</td>
</tr>
<tr>
<td>EE</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 11, 14, Annex II)</td>
</tr>
<tr>
<td>IE</td>
<td>O</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>EL</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 12, 14, Annex II)</td>
</tr>
<tr>
<td>ES</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 14, Annex II)</td>
</tr>
<tr>
<td>FR</td>
<td>O</td>
<td>N</td>
<td>Y (Art. 3, 12, 14)</td>
</tr>
<tr>
<td>IT</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 12, 14)</td>
</tr>
<tr>
<td>CY</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3)</td>
</tr>
<tr>
<td>LV</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 11, 12, 14, Annex II)</td>
</tr>
<tr>
<td>LT</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 14, Annex II)</td>
</tr>
<tr>
<td>LU</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 14, 16, Annex II, III)</td>
</tr>
<tr>
<td>HU</td>
<td>O</td>
<td>Y</td>
<td>Y (Art. 3, 11, 13, 14, Annex II)</td>
</tr>
<tr>
<td>MT</td>
<td>O</td>
<td>N</td>
<td>Y (Art. 14)</td>
</tr>
<tr>
<td>NL</td>
<td>O</td>
<td>N</td>
<td>Y (Art. 3, 11, 13, 14, Annex II)</td>
</tr>
<tr>
<td>AT</td>
<td>S</td>
<td>N</td>
<td>Y (3, 12, 14, Annex II)</td>
</tr>
<tr>
<td>PL</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 14, 16, Annex II, III)</td>
</tr>
<tr>
<td>PT</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 12, 14, Annex II)</td>
</tr>
<tr>
<td>RO</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 14, 16, Annex II, III)</td>
</tr>
<tr>
<td>SI</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 16, Annex III)</td>
</tr>
<tr>
<td>SK</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 12, 14, Annex II)</td>
</tr>
<tr>
<td>FI</td>
<td>O</td>
<td>N</td>
<td>Y (Art. 14, Annex II)</td>
</tr>
<tr>
<td>SE</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 12, 16, Annex III)</td>
</tr>
<tr>
<td>UK</td>
<td>S</td>
<td>N</td>
<td>Y (Art. 3, 14)</td>
</tr>
<tr>
<td><strong>Sums</strong></td>
<td>S= 20</td>
<td>Y= 1</td>
<td>Y= 26</td>
</tr>
<tr>
<td></td>
<td>O= 7</td>
<td>N= 26</td>
<td>N= 1</td>
</tr>
</tbody>
</table>

*Source: Country Summary Reports on each Member State*

Table 3-1 shows that most of the Member States have chosen to implement the CMD in several pieces, with fewer member states choosing to implement it in one piece of legislation. There have been no infringement proceedings initiated for non-
communication of transposing measures for any Member State and so this data has not been presented in Table 3-1.

As identified in Table 3-1, the country summary reports indicate that in one Member State there was an observed discrepancy between the Directive and national legislation. Hungarian legislation does not include limit values for benzene and hardwood dusts.

The majority of the Member States have implemented more detailed requirements. This is in particular in regard to CPM-related Articles. These are of potential importance in indicating which provisions MSs have seen fit to add to and might inform a need to amend the Directive to apply such additional requirements to all MSs. As shown in Table 3-1 well over half of the MS implemented more detailed requirements for Article 3 (risk assessment) and Article 14 (health surveillance). Fifteen of the MS implemented more detailed requirements for Annex II (practical recommendations for the health surveillance of workers). After these the following Articles and Annexes were implemented with more detailed requirements by less than half the MS; Article 2 (definitions), Article 11 (training for workers), Article 12 (information for workers), Article 13 (consultation with workers), Article 16 (limit values), and Annex III (limit values and other directly related provisions).

Article 14 (health surveillance) is the primary Article for which the MSs have implemented more detailed requirements – Furthermore, more detailed requirements in the transposition of annex II (practical recommendations for the health surveillance of workers) is only ever implemented if more detailed requirements are implemented for Article 14 in the same MS. These additional details were the following: the requirement to continue or make available health surveillance after exposure has finished\(^{12}\), as well additional requirements to the provision that medical records must be kept and doctors must propose any protective or preventive measures to be taken in respect of any individual worker\(^{13}\). A number of the MSs included specific requirements regarding the provision where workers/employers may request a review of the results of the health surveillance\(^{14}\).

For Article 3 (risk assessment) the MS included a number of more detailed requirements. The most common additional details to Article 3 implemented by the MS relate to describing the risks to be taken into account during risk assessment in more detail (AT, BE, BG, CZ, DE, LV, SE). Requirements include that Austria explicitly require specific attention be paid to the risks from mixtures of substances, Bulgaria requires consideration be given to the additional needs (or risks) of those with impaired health status; and Belgium, the Czech Republic and Latvia have specific requirements for annual revisions rather than the less specific regular in the CMD (every five years would be regular). In two MSs, the risk assessment has to be performed by a knowledgeable (DE) or authorised (CZ) person. Sweden specifies a requirement of requiring specific places in which substances may be

\(^{12}\) AT, BE, DE, DK, EE, ES, FR, LT, MT, NL, PL, PT, RO

\(^{13}\) AT, BE, BG, DE, DK, EE, EL, ES, FI, FR, IT, LT, LV, MT, NL, PL, PT, SK

\(^{14}\) BG, DE, EE, FR, HU, IT, LT, LU, LV, NL, PL, UK
placed to be defined as well as measures taken to ensure that only those persons that have to be in these places have access to them.

A number of MS included more specific methodology for risk assessment provided in the legislation (DE, HU, IT). In the case of Germany these details primarily relate to aligning the requirements with more general national legislation on risk assessments.

Legislation in Hungary includes the specific requirements for the risk assessment to include:

- identifying the carcinogenic material,
- measuring the concentration of the carcinogenic material in the respiratory zone (personal, full time sampling)
- defining by estimation the quantity of the carcinogenic material absorbed into the employee’s skin or into her/his organism through her/his skin,
- defining, in the case of materials included in special legal regulations on completion of biological monitoring (estimation of the quantity of the carcinogenic material absorbed into the human organism, and the estimation of the employee’s loading by chemical materials)

That in Italy includes requirements to record:

- reasons why carcinogens are used;
- the quantities of carcinogenic or mutagenic substances or preparations manufactured or used;
- the number of workers exposed or likely to be exposed to carcinogens or mutagens;
- where known, the exposure of such workers, and the level of this exposure;
- the preventive and protective measures applied and the type of personal protective equipment used;
- the investigations carried out to identify replacement substances.

Three MS (AT, IT, PL) require the risks assessment to be automatically supplied to the authorities, rather than on request.

The following Articles and Annex were implemented with more detailed requirements by fewer than half of the MSs, as identifiable in Table 3-1.

The provisions of Article 11 on sufficient and appropriate training on the basis of all available information on: potential risks to health including the additional risks due to tobacco consumption and precautions to be taken to prevent exposure was implemented with additional requirements in eight MS (BG, DK, DE, EE, LV, HU, NL).
In several MSs (DK, EE, LV, NL) the additional requirements related to indicating requirements for the competence of trainers. In Belgium and Germany training shall encompass emergency measures in the event of an incident.

In Hungary, in addition to references to smoking, training is also required to reflect on alcohol consumption and other lifestyle factors.

Finally, in Bulgaria, the requirement to include ‘precautions’ is expanded to encompass some of the precautionary measures to be taken including those relating to the sanitation requirements for equipment and personal hygiene; and the wearing and using of personal protective means and clothes.

With regard to Article 12 - information for workers, a number of MSs have more detailed provisions (AT, BE, EL, FR, IT, LV, PT, SK, SE).

Two MSs (BE & SK) have the same provision, namely that information shall take the form of an individual briefing document containing all information and instructions. Greece and Sweden also require information to be provided in writing.

In Austria it is specified that, in respect of such training external workers have the same right as staff.

Several MSs include specific content so that, in France, the information to workers focuses on the potentially harmful effects of chemical exposure on fertility, in particular upon the embryo during early pregnancy as well as on the foetus and on the child during breastfeeding; in Italy employers are required to provide information on studies conducted to identify replacement substances; in Latvia information is also provided on labelling; whilst, in Portugal it is a requirement to inform workers about annexed installations and warehouses that contain carcinogens or mutagens agents.

In addition to the general requirement for Consultation (Article 13), reflecting the provision in the Framework Directive, three MSs (BE, HU, NL) provide more detail.

Thus, Belgium includes more detail regarding the issues to be consulted over, such as: the risk assessment, measures aimed at reducing exposure; training and information programmes for workers; labelling of containers, packaging and installations; and delimitation of the risk zones.

Hungary includes provisions relating to the election of the OSH representative, their responsibilities and the scope of their tasks, together with general instructions on the regulation of the OSH committee.

In the Netherlands there is a specific provision reflecting the requirement to provide the results of the occupational health medical examination (in a statistical form which cannot be traced back to the individual, together with an explanation. This can be inspected by or presented to the works council or the staff representation body or interested workers.
On Article 16 - limit values and Annex III - limit values and other directly related provisions several MSs (BG, CZ, DK, LU, PL, RO, SI, SE) report having more stringent limit values for the three substances named in the Directive. Generally speaking, no details are given regarding the derivation of these lower limits.

Benzene limits range from 1.6 mg.m\(^{-3}\) to 3 mg.m\(^{-3}\); vinyl chloride monomer limits range from 3 mg.m\(^{-3}\) to 7.5 mg.m\(^{-3}\); hardwood dust limits range from 1 mg.m\(^{-3}\) to 2 mg.m\(^{-3}\).

The Czech Republic indicates that their transposing legislation sets direct limit values on all carcinogens and mutagens. Poland and Romania indicate they have 'others'.

According to the Slovenian Country Summary Report, derived from the NIR:

Slovenia has exceeded the requirements of the Directive with regard to limit values.

“Slovenia has prescribed binding limit values for 158 carcinogens or mutagens (Annex III of the Rules); this contrasts with the Directive, where only three carcinogens (benzene, vinyl chloride monomer and hardwood dusts) have limit values applied to them. All the prescribed limit values are also binding in Slovenia. An IARC classification is also applied to every individual substance, in addition to the classification under Council Directive 67/548/EEC.

The reason for determining binding limit values for more carcinogens or mutagens than are determined in the Directive is that we believe that it is not possible to determine an appropriate level of health and safety for workers exposed to carcinogens or mutagens merely on the basis of three limit values.

We believe that more limit values should be adopted at the EU level for carcinogens or mutagens.”

It appears that in Slovakia, Government Regulation No 356/2006 was supplemented to include limits (technical guide values) for 32 chemicals – carcinogens and mutagens in addition to those in the CMD.

Finally, in its NIR, Austria refers to the Advisory Committee on Safety and Health at Work recommendation made to the Commission on 5 December 2012 that a further 10 substances, including crystalline silica, hardwood dust, chromium IV, fireproof ceramic fibre and trichloroethylene, should be included in the Directive or in the list of carcinogens and mutagens, together with a binding limit value for each. The Austrian authority (ÖGB) considers that the Commission needs to take urgent action here and is strongly in favour of extending the scope of the Directive so that it includes carcinogens, mutagens and substances toxic to reproduction. It notes that workers in Austria using carcinogens, mutagens and substances toxic to reproduction are already subject to the same strict rules and that all workers in the EU should be protected against such substances and enjoy the same level of protection.
This Directive and CPMs have been transposed into multiple pieces of legislation in the vast majority of the 27 MSs, with only seven of the MS transposing it into one piece of legislation. Examination of the country summary reports shows that no infringement proceedings for non-communication of transposing measures were initiated in any of the MSs. There was one instance of an observed discrepancy in the transposed MS legislation.

In terms of transposing more detailed requirements 26 of the 27 MSs did this, the vast majority of which were CPMs. Over half of the MSs implemented more detailed requirements for Article 3 (risk assessment) and Article 14 (health surveillance). Fifteen of the MSs implemented more detailed requirements for Annex II (practical recommendations for the health surveillance of workers).

In their NIRs, Austria recommend the inclusion of limit values for further chemicals and extending the provisions of the CMD to cover substances toxic to reproduction whilst Slovakia makes reference to including genotoxic carcinogens.

3.2 MQ2: Derogations and transitional periods

MQ2: “What derogations and transitional periods are applied or have been used under national law under several of the Directives concerned?”

The CMD does not contain any provisions for extended deadlines. Furthermore, it does not contain any possibilities for derogations.

3.3 MQ3: Compliance

MQ3: What are the differences in approach to and degree of fulfilment of the requirements of the EU OSH Directives in private undertakings and public-sector bodies, across different sectors of economic activity and across different sizes of companies, especially for SMEs, microenterprises and self-employed?

Table 3-2 summarises the information available in terms of percent of establishments which comply with the common requirements of the Directive (CPMs). As part of the national studies, carried out as part of this evaluation, all national experts were asked to provide measures of compliance. For brevity, only those MS where statistics have been found are included. Note that some of the numbers given are estimates provided by national experts who sometimes found it difficult themselves to differentiate between the different specific provisions of the Directive, leading to a single figure for all CPMs.
Table 3-2: Compliance with CPMs in Member States (% of establishments)

<table>
<thead>
<tr>
<th>Member State</th>
<th>Perform regular risk assessment</th>
<th>Information to workers</th>
<th>Training of workers</th>
<th>Health surveillance</th>
<th>Consultation of workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>DK</td>
<td>55%</td>
<td>-</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>EE</td>
<td>93%</td>
<td>81%</td>
<td>63%</td>
<td>82%</td>
<td>-</td>
</tr>
<tr>
<td>ES</td>
<td>69.7%</td>
<td>81.5%</td>
<td>81.5%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LT</td>
<td>52%</td>
<td>48%</td>
<td>51%</td>
<td>56%</td>
<td>42%</td>
</tr>
<tr>
<td>NL</td>
<td>38%</td>
<td>27%</td>
<td>27%</td>
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<tr>
<td>PL</td>
<td>79%</td>
<td>53%</td>
<td>46%</td>
<td>84%</td>
<td>40%</td>
</tr>
<tr>
<td>RO</td>
<td>40%</td>
<td>40%</td>
<td>40%</td>
<td>40%</td>
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<tr>
<td>SK</td>
<td>40%</td>
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<td>40%</td>
<td>40%</td>
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</table>

Source: Country Summary Reports on each Member State

Table 3-2 gives rise to two main findings. The first is that data on levels of compliance with the requirements of the Directive is scarce. The experience from conducting the studies at the national levels is that national authorities do not keep account of levels of compliance in respect of specific requirements of individual directives and, further, national stakeholders were reluctant to make concrete statements about levels of compliance during interviews as they consider their knowledge on these specificities to be limited (most have a general idea about levels of compliance across all or groups of directives – but not down to the individual Directive level).

The second finding is that for those Member States where data is available, the level of compliance with the CPMs is assessed as varied – ranging from 14% to 93%. No data were available relating this compliance data to different sectors of activity. As these data are only available from a minority of MSs care should be taken in applying the findings to the wider EU-27.

The national studies also sought to establish whether there are differences in levels of compliance depending on size of establishments. The data indicates that the level of compliance increases with the size of establishment. This is also supported by national implementation reports, where a number of Member States highlight the difficulties faced by SMEs and microenterprises in complying with the requirements. Lack of knowledge, specialised personnel and financial resources, are common explanations to the challenges in implementation. Some examples are given in Box 3-1 below. However, some Member States also indicate that SMEs have no difficulties to implement the Directive (Austria, Czech, Finland, Latvia, Lithuania, Luxembourg, Slovenia, United Kingdom).

No information was identified regarding differences in compliance between different sectors including, in particular, differences between the public and private sectors.

The template for the NIRs included a specific question on one specific KR (substitution), asking specifically about the practical experience of substituting carcinogens and mutagens for less hazardous materials in the workplace.
A small number of MSs provided quantitative data. In Bulgaria, data from the inspection activity show that around 18% of the inspected undertakings using carcinogenic and mutagenic chemical substances are taking efficient measures to replace the carcinogenic substances with analogues that meet the contemporary hygienic and ecological criteria. The NIR includes a number of specific examples.

In Estonia the comment is that 25% of enterprises implementing the REACH Regulation have substituted hazardous chemicals with less hazardous ones, 12% have tried to do that, 40% have not tried to do that. The enterprises who remarked in the questionnaire that they had tried substitution but had not been successful were asked what the reasons for the failure had been. All the respondents remarked that this proved technically impossible and two of them added that it was too expensive for the enterprise. However, it is not clear from this what proportion of the ‘hazardous’ chemicals were carcinogens.

In the same vein, the NIR from Romania reports that the participants in a survey said that they have made substitutions, 26% of the representatives of micro enterprises, 29% of the representatives of small and medium enterprises, and 81% of those of large enterprises. Again, it is not clear what proportion related to carcinogens or mutagens.

In Ireland the use of carcinogens or mutagens was identified in 20% of inspections. In 10% of these, substitution was recommended by the inspector.

Austria indicated that use of confirmed carcinogens in products or formulations in the workplace is declining, although no statistics were included. In part this impact was attributed to the influence of procedures under REACH.

In contrast, Belgium described substitutions following risk assessment as extremely rare, usually occurring as the result of initiatives by suppliers/producers. This was attributed largely to doubts as to the long-term performance of the ‘new’ substance in comparison with the original substance.

Commenting on the difficulties associated with substitution, the UK indicated that they had found no rising trends in the application of the substitution principle.

Others indicate that it happens, but give no statistics (e.g. Slovakia), although some do give examples of particular chemicals which have been substituted (e.g. Portugal, Spain).

The difficulties of substitution form the main focus of the response from several MSs (Denmark, Finland, Germany, Malta).

In some MS (e.g. the Czech Republic, Latvia) the response is limited to indicating that substitution is a requirement in national legislation.

France describes the foundation of a website ‘dedicated to the aim of improving the effectiveness of substitution efforts’. The site now catalogues 1 047 uses and 355 substitution examples.
In Greece, the substitution of less hazardous materials for carcinogens and mutagens is ‘considered satisfactory’. As with Austria they refer to the influence of requirements under REACH which enhance the replacement of certain chemicals by making them harder to use.

In Hungary it is stated that employers give priority to the replacement of carcinogens and mutagens although they cite financial, knowledge and technical barriers to doing so.

Poland and Slovenia indicate that they have no data regarding substituting less hazardous materials for carcinogens and mutagens in the workplace.

One provision of the CMD is for MSs to implement arrangements whereby employers:

 “…shall, when requested, make available to the competent authority appropriate information on: (a) the activities and/or industrial processes carried out, including the reasons for which carcinogens or mutagens are used; (b) the quantities of substances or preparations manufactured or used which contain carcinogens or mutagens; and (c) the number of workers exposed”. (Article 6).

According to a recent European Risk Observatory report only a few MSs have implemented this provision and, even in those that have implemented it and created exposure registers, the registers cover only a small proportion of the workers potentially exposed.
Examples of difficulties related to compliance for SMEs and microenterprises (from NIRs)

- SMEs often lack the expertise to take effective action against risks (Belgium)
- Inadequate awareness of the risks for health and safety of workers exposed to carcinogens and mutagens and the rights, obligations and responsibilities of employers and employees has been noted in micro and small enterprises (Bulgaria)
- Many small undertakings are run to act ‘here and now’, and lack resources such as time and knowledge to familiarise themselves with the rules on the working environment and to solve any working-environment problems (Denmark)
- Due to the employer’s low awareness and minimal use of preventive measures, the workers as a whole are probably in a less protected situation than the staff of large enterprises (Estonia)
- Small and medium-sized enterprises do tend to have less ability to assimilate changes in the laws and regulations regarding health and safety at work because of the absence of internal competence in these matters (France)
- SMEs have serious difficulties, especially in generating exposure data and correctly managing exposure (Germany)
- SMEs and micro enterprises seem to lag behind in the issue of health surveillance (Greece)
- Recording and documenting obligations present difficulties to SMEs as they lack experts with the required qualifications (Hungary)
- SMEs and micro-industries have difficulties due to their lack of resources and seek practical (paper based and online) tools for compliance such as simplified guidance, risk assessment templates etc. (Ireland)
- Limited technical capacity, lack of access to competent dedicated persons and external cost-effective support on health and safety (Malta)
- Overlapping complicates the SME’s overview as provisions are not formulated any differently and are included in the implementation (Netherlands)
- SMEs have greater difficulty in complying with requirements (Portugal)
- Employers have little knowledge of the simplified methods for assessing chemical risks that can be found on the website of the Labour Inspection or on other sites (Romania)
- Small and medium-sized enterprises have staffing and financial problems (Slovakia)
- Workplaces that do not have specialist knowledge of chemical risks find it harder to follow the requirements (Sweden)

The data from the MSs used to assess the degree of fulfilment was quite sparse. Only nine of the 27 MS presented any degree of compliance data for the CPMs, for all establishments. Furthermore, the MSs reported degrees of compliance ranging from 20% up to 93% across all the CPMs. When considering size of establishment, no data or estimates were available reflecting any differences in compliance. However, SMEs were discussed by the MSs in their NIRs. 15 of the 27 MSs discussed specific issues SMEs or micro enterprises have had when trying to comply with the provisions of the legislation. No data were available to allow the separate consideration of public and private sectors or the various industrial sectors within this.

Additional information on compliance with one specific requirement, substitution, was available from the NIRs. This indicates a similarly patchy picture with only limited quantitative data, some qualitative information and many MSs unable to
provide any formal indication of compliance. As with other material, data on the extent of implementation of substitution gives little insight into the proportion of those instances where substitution was possible but not implemented.

3.4 MQ4: Accompanying actions

**MQ4**: What accompanying actions to OSH legislation have been undertaken by different actors (the Commission, the national authorities, social partners, EU-OSHA, Eurofound, etc.) to improve the level of protection of safety and health at work, and to what extent are they actually used by companies and establishments to pursue the objective of protecting safety and health of workers? Are there any information needs that are not met?

In this section, we distinguish between actions at the Member State level (data collected through the national studies) and actions at the EU level (data collected through desk research and interviews with EU level stakeholders).

3.4.1 Actions at Member State level

Table 3-3 shows the type and number of actions undertaken in each Member State. Emphasis is on key documents and actions. In many Member States additional items, such as leaflets etc., may have been produced. No gaps were identified during interviews with stakeholders and therefore this column has been omitted. One shortcoming of this information is that the scope of the enquiry was restricted to 2007-2012. Particularly in some of the more established MSs, some material might predate this period and therefore not be reported. The details reported below should therefore be regarded as a minimum estimate.

Table 3-3 Type and number of accompanying actions in Member States

<table>
<thead>
<tr>
<th>Member State</th>
<th>Guidance documents</th>
<th>Awareness raising campaigns</th>
<th>Support tools (possibly IT)</th>
<th>Financial incentives</th>
<th>Education and training</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE</td>
<td>1</td>
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<td>BG</td>
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<td>CZ</td>
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<tr>
<td>DK</td>
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<tr>
<td>DE</td>
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<td>EE</td>
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<tr>
<td>IE</td>
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<td>ES</td>
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<td>FR</td>
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<td>PL</td>
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</table>
Table 3-3 indicates that guidance documents are the most common action undertaken by Member States in respect to supporting the implementation of the legislation transposing the CMD. Awareness campaigns and support tools are both quite common actions. The remaining actions are adopted considerably less frequently.

Information on the nature of this material is presented in the Country Summary Reports. However, most of the guidance is not specific to carcinogens and mutagens but are more general and addressing wider chemical hazards. In a few instances however, guidance on specific hazards is available, such as that on wood dusts prepared in Austria and guides on reprotoxins (male and female) in Spain. In some MSs (e.g. Belgium, Italy) guidance on best practice in relation to specific applications is included. A limited number of campaigns are listed, including one on prevention in Lithuania and training, again usually of a general nature in respect of chemicals. Support tools are frequently databases of carcinogenic substances but also generic tools such as ‘Stoffenmanager’ tool prepared in the Netherlands which was developed as a control banding tool for hazardous chemicals. Similarly, the ‘Chemiguide’ online tool prepared in Sweden is not specific to carcinogens and mutagens, although some at least of the information and guidance contained in it would be of benefit.

From interviews it appears that the Member States consider that available information and guidance is generally sufficient. No quantitative or qualitative information is available regarding usage of this material.

When asked directly about whether there are gaps, no stakeholders answered yes. However, as already mentioned above under compliance, some national implementation reports which highlight challenges to SMEs also mention lack of knowledge about hazard awareness and risk management, etc., which could indicate a need for additional accompanying actions in this area.

### 3.4.2 Actions at EU level

No information could be found regarding the extent to which employers in MSs made use of EU level information sources.
EU-OSHA:

The EU-OSHA website lists many guides and other documents relating to dangerous substances. However, although carcinogens feature in a number of these (e.g. in relation to substitution) none seem to have a particular focus on carcinogens or mutagens. For example, guidance on forestry refers to many hazards, but those relating to wood dusts do not feature. A selection of the more relevant titles is shown below.

**Factsheet 33 - An introduction to dangerous substances in the workplace**

Dangerous substances are found in many workplaces. This factsheet introduces the key issues on this topic.

**Factsheet 34 - Elimination and substitution of dangerous substances**

This factsheet introduces the process of eliminating or substituting dangerous substances. It gives hints on how to set priorities for substances and processes to substitute.

**Factsheet 35 - Communicating information about dangerous substances**

Effective communication about the risks to workers’ health and their management in the workplace is a common challenge for employers, workers, and their representatives. This factsheet presents points to consider for successful communication and checklists for workers and employers.

**Factsheet 44 - How to convey OSH information effectively: the case of dangerous substances**

Accurate, comprehensive and exhaustive information is not only an employer’s duty towards workers but also a prerequisite for carrying out the compulsory risk assessment and laying down preventive and protective measures against these risks. This report describes 19 initiatives addressing the existing information gap.

**E-fact 66**: Maintenance and hazardous substances

Maintenance workers come into close contact with a broad variety of often hazardous chemicals. Depending on the specific type, these chemicals may not only cause diseases like skin sores or cancer, but many of them are highly flammable and explosive. This e-facts focuses on the specific risks related to various dangerous substances that maintenance workers in general are exposed

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to, and gives some basic recommendations on how these risks can be tackled, including some best practice examples.

E-fact 67: Maintenance and hazardous substances – Maintenance in the chemical industry

This e-fact focuses on the specific risks related to various dangerous substances that maintenance workers in chemical plants are exposed to, and gives some basic recommendations on how these risks can be tackled, including some good practice examples.

ECHA

The European Chemicals Agency (ECHA) also includes guidance material on its website (referred to in some NIRs) although it is noted that the focus is on the supply of chemicals. Thus the page on legislation makes no reference to either the CMD or CAD. Although it can be argued that this listing only includes legislation within the remit of the ECHA this is not apparent from the website, which includes “advances the safe use of chemicals” amongst the ECHA’s remit.

No information is available regarding the use of this material in MSs.

Of the five types of actions described at least four of them were employed by at least four of the MSs. Guidance documents were by far the most employed action. At the EU level a considerable number of accompanying actions were identified relating to dangerous substances although none appeared to focus specifically on carcinogens and mutagens. None of the MSs answered yes when asked directly regarding any gaps. Furthermore, there were no data on the extent to which establishments used the available accompanying actions at national or EU level.

3.5 MQ5: Enforcement

MQ5: What are the enforcement (including sanctions) and other related activities of the competent authorities at national level and how are the priorities set among the subjects covered by the Directives?

The data from the national analysis show that the Member States typically have a general enforcement authority responsible for OSH enforcement and inspections related to all OSH matters including enforcement strategies. But there are exceptions. Table 3-4 indicates whether there are:

› specific authorities (different from the general OSH enforcement authority) involved in relation to enforcement of the legislation transposing the Directive (column 1)

Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States

› specific enforcement strategies, elements of strategies or procedures covering the implementation of the Directive (column 2)

› specific criminal or administrative sanctions which can be applied in cases of non-compliance with the Directive (column 3)

In the case where the answer to the questions is no, reference is made to the Directive report on the Framework Directive, which provides a summary of the general systems in force.

Table 3-4 Enforcement of the Carcinogens and Mutagens Directive

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<td>FI</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>SE</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>UK</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

| Sums         | Y= 9 N= 18                                    | Y=13 N= 14                                |

Source: Country Summary Reports on each Member State

Table 3-4 shows that only three Member States have designated a specific authority responsible for the enforcement of the CMD. For the remainder, the enforcement of the Directive comes under the general authority responsible for OSH inspections/enforcement. Also, thirteen Member States have criminal or administrative sanctions, which are specific to the offences which are committed under the legislation concerning carcinogens and mutagens less often – rather the standard sanctions applicable in the OSH area apply in most Member States.

In general, strategies for OSH are set on the basis of specific perceived priorities; usually it appears on an annual basis. This may be as the result of feedback from Inspectors (e.g. concerns about specific safety hazards), targeting particular
sectors where OSH statistics give cause for concern, or addressing specific issues prompted by national or EU developments (e.g. priorities on MSDs during the EU campaign on this subject).

Nine of the 27 MSs have specific enforcements strategies or procedures for the implementation of this Directive. Furthermore, twelve of the MSs have specific criminal or specific sanctions for this Directive. However, only three of the MSs have a specific authority responsible for the enforcement of this Directive. For the remainder the enforcement of the CMD is the responsibility of the general authority for inspections/enforcement.

3.6 MQ6: Vulnerable groups

The findings from the national studies show that most MSs have general approaches to vulnerable groups, which are not targeted at specific Directives (except for the specific provisions of the following Directives, which are designed to address vulnerable groups: Temporary Workers Directive; Pregnant/breastfeeding Workers Directive; Young People Directive). For the purposes of this report vulnerable groups include women (pregnant or breastfeeding), ageing workers, workers with disabilities, young workers, migrant workers, temporary workers and low-qualified workers. The needs for SMEs are addressed separately (section 3.7).

Typically, there are no specific tools or approaches which focus in particular on these vulnerable groups and the risks associated with the CMD. It would seem that, where risks to one or more of these groups are identified, they are addressed within general guidance on the topic. In respect of young people, their employment in work involving harmful exposure to agents which are 'toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child' is prohibited under the provisions of the Young People Directive and so no specific approach would be required. None of the NIRs make any reference to needs for vulnerable groups in respect of this Directive. However, the following MS specific provisions have been found:

France - Art. R 1225-4 of the Labour Code, phytosanitary products which may cause health issues for pregnant women, or classified as carcinogenic or mutagenic for breastfeeding workers.

MQ5: Answer

MQ6: What are the differences of approach across Member States and across establishments with regard to potentially vulnerable groups of workers depending on gender, age, disability, employment status, migration status, etc., and to what extent are their specificities resulting in particular from their greater unfamiliarity, lack of experience, absence of awareness of existing or potential dangers or their immaturity, addressed by the arrangements under question?

MQ6 Answer

The findings from the national studies show that most MSs have general approaches to vulnerable groups, which are not targeted at specific Directives (except for the specific provisions of the following Directives, which are designed to address vulnerable groups: Temporary Workers Directive; Pregnant/breastfeeding Workers Directive; Young People Directive). For the purposes of this report vulnerable groups include women (pregnant or breastfeeding), ageing workers, workers with disabilities, young workers, migrant workers, temporary workers and low-qualified workers. The needs for SMEs are addressed separately (section 3.7).

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France - Art. R 1225-4 of the Labour Code, phytosanitary products which may cause health issues for pregnant women, or classified as carcinogenic or mutagenic for breastfeeding workers.

21 Vulnerable groups as defined within the report: Occupational health and safety risks for the most vulnerable workers

Netherlands - Special dossier on carcinogens and mutagens on Arboportaal\textsuperscript{22} (pregnant workers).

In addition, as noted earlier, one MS made a specific recommendation in its NIR for extending the provisions of the CMD to cover substances toxic to reproduction (which could be seen as relating to vulnerable groups). This issue is discussed in Section 4.2 (Future relevance).

### 3.7 MQ7: SMEs and microenterprises

No Member States have developed particular measures to support SMEs and microenterprises in the implementation of the legislation transposing the CMD in respect of lighter regimes, exemptions, incentives. However, many Member States have developed various accompanying actions targeted at SMEs, which are typically of a more general nature, see e.g. Directive report on the Framework Directive (89/391/EEC). Thus, size of the enterprise is taken into account in the Czech Republic in determining particular duties and, in the case of microenterprises, exempting them from duties relating to topics such as information and consultation.

In isolated cases, some financial incentives are available. For example, Estonia has put in place financial incentives relating to risk assessments and health surveillance for SMEs (<45 workers) with the support of the European Social Funds.

The template for the NIRs included a question relating to any specific measures taken to support SMEs in implementing the CMD and to describe any such measures taken. Details are available within the individual NIRs. In general however, the majority of MSs report either that they have taken no action (BE, CY, CZ, EA, HU, IT, LT) or report actions which are not specific to carcinogens and mutagens (SE, DK, FI, IE, NL, PT, SL), either relating to OSH in general or to hazardous substances. In a few MSs the reported actions appear to not be SME-specific (AT, BG, EE) although this is not always clear from the response.

In a few instances, details are given which make it clear that actions specific to carcinogens and mutagens focussed on SMEs have been taken, including extensive actions in the autonomous regions of Spain, dedicated webpages in MSs such as Romania and the UK, and training activities in France and Germany.

\textsuperscript{22} \url{http://www.arboportaal.nl/}
4 Assessment of relevance

In this section, the relevance of the Directive in relation to the coverage of workforce and Member States, and the severity and extent of risks covered is investigated. The conclusions from the five parameters used to assess relevance are summarised in the table below.

<table>
<thead>
<tr>
<th>Coverage of Workforce and Member States</th>
<th>Fatalities and health problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of MS where the Directive is potentially relevant</td>
<td>Proportion of EU workforce to whom the Directive is potentially relevant</td>
</tr>
<tr>
<td>27</td>
<td>12.3%</td>
</tr>
</tbody>
</table>

The Directive has been transposed into national legislation in all MSs according to evidence from the NIRs\textsuperscript{23}. The possibility of exposure to potential carcinogenic substances covered by the CMD can be identified in each MS. On this basis the Directive can be regarded as relevant in all MSs.

Turning to the labour market, determination of the proportion of the labour market covered by the provisions of this Directive is therefore a matter of establishing the number of persons employed within the appropriate sectors. The Directive is relevant to all such workers. There are a variety of sectors and occupations where exposure to carcinogenic substances is possible, usually for small, select sub-groups of the workforce. However, many of these tend to represent a specialist sub-group within a sector, making it difficult to establish the numbers of workers potentially exposed. In order to provide an approximate estimate of the proportion of the EU-27 workforce possibly exposed to carcinogenic substances, without estimating numbers in such subsectors, a procedure was adopted whereby the whole employment figure was adopted for those sectors where the majority can be assumed to be at risk of exposure (not necessarily exposed) and to omit those in

\textsuperscript{23} Individual NIRs
relatively small subsectors. This will clearly result in, on the one hand, an overestimate of those potentially at risk and, on the other hand, an underestimate. However, it was considered that this provided a reasonably accurate overall estimate where the intention was to provide a broad view of the proportion of the workforce covered, rather than any detailed calculation.”

Professional OSH expert consideration of NACE coding of economic sectors suggests that the following sectors are relevant to this Directive: mining and quarrying (NACE B); Construction (NACE F); selected subcategories of manufacturing (NACE C), manufacture of wood and of products of wood and cork, except furniture (NACE C16), manufacture of coke and refined petroleum products (NACE 19), manufacture of chemicals and chemical products (NACE C20), manufacture of other non-metallic mineral products (NACE C23). Finally, a selected sector within the transporting and storage sector (NACE H); land transport and transport via pipelines (NACE H49).

LFS data\textsuperscript{24} documents that in 2012, a total of 215,678,600 people were employed within the EU-27 (15-74 years). Of these, 841,000 were employed within the mining and quarrying sector (NACE B); 15,438,900 were employed within the construction sector (NACE F). Turning to the subcategories of NACE C the SBS database\textsuperscript{25} indicates that there were 3,680,400 workers in the relevant subsections out of a total of 30,000,000 workers employed in the manufacturing sector (12.3%) in 2010. Applying this percentage to the 33,632,500 workers in the same manufacturing sector according to the LFS data yields a total of 4,136,797 workers.

Turning to the subcategory of NACE H the SBS database\textsuperscript{26} indicates that there were 5,623,000 workers in 2009 in the relevant subsection out of a total of 10,000,000 workers employed in the transporting and storage sector (56%) in 2010. Due to an issue with access to the data for the subcategory of NACE H49 for the year 2010 data was taken from 2009 for this category\textsuperscript{27}. Applying this percentage to the 10,948,400 workers in the same (transporting and storage) sector to the LFS data yields a total of 6,131,104 workers.

Combining the total workers from each relevant sector gives a total of 26,547,801 workers or 12.3% of the EU workforce to whom this Directive is relevant.

\textsuperscript{24} Employment by sex, age and economic activity (from 2008 onwards, NACE Rev. 2) - 1 000 lfsa_egan2
\textsuperscript{25} Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) [sbs_sc_sca_r2]
\textsuperscript{26} Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) [sbs_sc_sca_r2]
\textsuperscript{27} http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/File:Key_indicators,_land_transport_and_transport_via_pipelines_(NACE_Division_49),_EU-27,_2010.png
This can be compared to the estimated figure of 32,000,000 suggested by Kauppinen et al (2000) during the period 1990–1993. It is not known to what extent such employment figures will have changed in the intervening ten years although it is noted that, according to LFS figures employment within the manufacturing sector across the EU-27 has fallen by approximately 12% in the five years from 2008 suggesting that, allowing for this, the two estimates are not dissimilar.

4.1 EQR1: Current relevance

**EQR1: To what extent do the Directives adequately address current occupational risk factors and protect the safety and health of workers?**

As explored and documented in the report on the Chemical Agents Directive, some information on exposures to chemicals is available from EU database resources such as Eurostat. However, none of these sources record the nature of the chemicals to which exposure has occurred and, in particular, none record whether any of these exposures were to substances which can be considered to be potentially carcinogenic or mutagenic. Eurostat statistics, detailed in Chapter 5 (effectiveness) show that chemicals considered to be carcinogens, mutagens or reprotoxins (the data doesn’t differentiate these) continue to be produced in considerable quantities within the EU-28 although there has been a decline in recent years. However, although production figures give some limited insight into what might be regarded as the potential for exposure they give no direct picture of levels of exposure of the number of workers potentially at risk.

However, a variety of published reports and papers were identified which do provide some useful insights into the number of workers potentially exposed if not the levels of exposure.

The SHEcan report (Cherrie et al, 2011) collected available published information about the uses and/or circumstances of exposure for each of 25 occupational carcinogenic substances. In summary it indicated that for six of these substances (Benzo[a]pyrene, Diesel engine exhaust emissions, Hard wood dust, Hydrazine, Mineral oils as used engine oil, 4, 4’ methylenedianiline (MDA)) there are probably more than a million workers in the EU currently exposed and for six substances (o-Toluidine, 1, 2-Dibromoethane, 4,4’-Methylene bis 2-chloroaniline (MbOCA), 1, 2-Dichloroethane, 1, 2-Epoxypropane, Bromoethylene) there are less than 10,000 exposed workers. The other substances gave intermediate estimates with the

29 Employment by sex, age and economic activity (from 2008 onwards, NACE Rev. 2) - 1 000 [lfsa_egan2]
30 Cherrie et al. (2011) Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work: Summary report.
exception of Hexachlorobenzene for which the extent of exposure could not be determined.

As a further development, the project identified OELs for each substance from a variety of EU and national sources (43 OELs in total). Calculations suggested that, for 14 substance-OEL combinations less than 1% of workers were exposed above the suggested limit value. The authors interpreted this as representing current full compliance with the OEL in question.

In a further development the report includes projected incident cancer cases and deaths taking a forward projection to 2069. The report includes projections for seven substances where the introduction and implementation of an OEL would have a clear health benefit in terms of avoided cancer cases.

Van Tongeren et al (2012) estimated that, in the UK alone, there were more than half a million workers exposed to each of six carcinogens including crystalline silica, mineral oils, non-arsenical insecticides and 2,3,7,8-tetrachlorodibenzop-dioxin.

Some data on exposures to carcinogens can be found in national registries although some, such as that in Germany, only provide information on the number of workers registered as exposed (around 50,000) with no details on the substances in question. Others include details of substances which are not covered by the CMD. Summary details of this material have been published in the European Risk Observatory Report “Exposure to carcinogens and work-related cancer: A review of assessment methods”. As this review notes:

“From the point of view of prevention, it would be beneficial to estimate the effects of present exposure on future risk, evaluating the potential short- and long-term health effects and how often they may occur in workers. This would require information on the numbers of exposed workers and their levels of exposure over time and on the health effects of the exposures. Unfortunately, quantitative estimates of this type of data are not usually available.”

According to this source, the register in Finland (ASA Register of Workers Exposed to Carcinogens) includes environmental tobacco smoke and asbestos but excludes silica. Notifications to the Register in 2010 indicated that approximately 16,000 workers (0.6% of the workforce) are exposed to selected carcinogens.

The SIREP information system in Italy is noted to have recorded about 37,000 workers exposed to selected carcinogens between 1996 and 2005 (about 0.2% of the employed labour force). The most common exposures were hardwood dust, PAHs, chromium VI compounds and various chemicals to which chemical processing plant workers may have been exposed (for example benzene, butadiene, acrylonitrile, dichloroethane, vinyl chloride, ethylene oxide and propylene oxide).

The Polish Central Register of Carcinogenic or Mutagenic Agents records exposures to more than 300 carcinogenic or mutagenic chemical substances. The

Register shows that approximately 2,500 plants reported more than 150,000 person-exposures annually. Again, hardwood dusts (about 660 companies; 11,000–13,000 exposed workers per year) and exposure to polycyclic aromatic hydrocarbons (PAHs) (117–125 plants, 3,000 exposed per year) feature highly.

Finally, Kauppinen et al (2006) published findings in relation to one carcinogenic substance, wood dust, across 25 of the EU MSs. The findings, summarised in Table 4.2, demonstrate the considerable extent of continuing exposure even for this one substance affecting an estimated 2% of the EU workforce.

Although the evidence is patchy and uneven, collectively it would appear to support the ongoing relevance of the CMD in terms of workers apparently continuing to be exposed to carcinogens and mutagens.

Table 4.2 Numbers of workers exposed to inhalable wood dust, and distribution of exposed workers (%) by country in 25 member states of the European Union (EU-25) in 2000–2003

<table>
<thead>
<tr>
<th>Country</th>
<th>Employed (thousand)</th>
<th>Exposed (thousand)</th>
<th>Exposed (% of employed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>3008</td>
<td>84</td>
<td>2.8</td>
</tr>
<tr>
<td>Belgium</td>
<td>4197</td>
<td>51</td>
<td>1.2</td>
</tr>
<tr>
<td>Cyprus</td>
<td>315</td>
<td>8.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>4751</td>
<td>148</td>
<td>3.1</td>
</tr>
<tr>
<td>Denmark</td>
<td>2170</td>
<td>72</td>
<td>3.3</td>
</tr>
<tr>
<td>Estonia</td>
<td>586</td>
<td>27</td>
<td>4.6</td>
</tr>
<tr>
<td>Finland</td>
<td>2372</td>
<td>65</td>
<td>2.7</td>
</tr>
<tr>
<td>France</td>
<td>22855</td>
<td>308</td>
<td>1.3</td>
</tr>
<tr>
<td>Germany</td>
<td>36536</td>
<td>704</td>
<td>1.9</td>
</tr>
<tr>
<td>Greece</td>
<td>4092</td>
<td>70</td>
<td>1.7</td>
</tr>
<tr>
<td>Hungary</td>
<td>3847</td>
<td>62</td>
<td>1.6</td>
</tr>
<tr>
<td>Ireland</td>
<td>1836</td>
<td>44</td>
<td>2.4</td>
</tr>
<tr>
<td>Italy</td>
<td>18785</td>
<td>351</td>
<td>1.9</td>
</tr>
<tr>
<td>Latvia</td>
<td>990</td>
<td>45</td>
<td>4.5</td>
</tr>
<tr>
<td>Lithuania</td>
<td>1403</td>
<td>41</td>
<td>2.9</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>186</td>
<td>2.7</td>
<td>1.5</td>
</tr>
<tr>
<td>Malta</td>
<td>148</td>
<td>2.9</td>
<td>2.0</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>7510</td>
<td>116</td>
<td>1.5</td>
</tr>
<tr>
<td>Poland</td>
<td>13709</td>
<td>310</td>
<td>2.3</td>
</tr>
<tr>
<td>Portugal</td>
<td>4013</td>
<td>110</td>
<td>2.7</td>
</tr>
<tr>
<td>Slovakia</td>
<td>2129</td>
<td>42</td>
<td>2.0</td>
</tr>
</tbody>
</table>

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Work-related health problems

With many of the OSH Directives, EU databases and surveys of work-related health problems can be of use in assessing the ongoing relevance of the provisions of directives. However, this was not possible in respect of early signs or symptoms of cancer.

As an additional complication, the long period of latency of many cancers and the delay before many mutagenic changes become manifest makes it difficult to establish the current level of problem. However, Rushton et al (2012) have estimated that, of all cancer deaths in Britain in 2005, 8010 (5.3%) could be attributed to past occupational exposures (6073 excluding mesothelioma), with 13,598 of all cancer registrations in 2004 attributable to occupation (11,661 excluding mesothelioma).

Even with the exclusion of mesothelioma cases, any extrapolation of such figures to the EU-27 gives a strong indication that this Directive remains relevant.

In addition, the template to the NIRs asked two specific questions relating directly to cases of occupational cancer:

What proportion of current annual cancer deaths is attributable to occupational exposure to carcinogens and how many deaths per year does this equate to?

What proportion of annual incident cases (newly occurring cases each year) is attributable to occupational exposure to carcinogens and how many cases per year does this equate to?

As with many of the other questions asked, responses to these were patchy and varied widely in detail. Because of the perceived importance of this issue the responses are all summarised below. In most cases it is not clear whether the figures include those relating to asbestos exposure, or whether they relate to exposures to carcinogens not covered by the CMD.

**Austria** provided the following two tables, suggesting an increasing trend in both deaths and incident cases over the period 2007-2012 (although it is possible that this is due to an increased recognition of cases as occupational rather than an actual increase in cases).

<table>
<thead>
<tr>
<th>Country</th>
<th>Deaths</th>
<th>Incident Cases</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slovenia</td>
<td>925</td>
<td>29</td>
<td>3.1</td>
</tr>
<tr>
<td>Spain</td>
<td>16258</td>
<td>433</td>
<td>2.7</td>
</tr>
<tr>
<td>Sweden</td>
<td>3975</td>
<td>58</td>
<td>1.5</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>22843</td>
<td>384</td>
<td>1.7</td>
</tr>
<tr>
<td>EU-25</td>
<td>179400</td>
<td>3600</td>
<td>2.0</td>
</tr>
</tbody>
</table>

---

Belgium had no data.

Bulgaria reported that, in the period 2007—2012, the National Social Security Institute had no officially reported cases of cancer or occupational diseases attributable to occupational exposure to carcinogens or deaths from such exposures.

Cyprus and the Czech Republic had no data.

Denmark could report no statistics on deaths from occupationally-related cancer. However, in respect of suspected and confirmed work-related cancerous diseases the land authorities reported the following data over the 2007-11 period:

2007: suspected 563; confirmed 153
2008: suspected 715; confirmed 187
2009: suspected 701; confirmed 166;
2010: suspected 587; confirmed 172;
2011: suspected 478; confirmed 160.

In a footnote to the suspected work-related cancers it is recorded that approximately a third of reported cancer cases are due to the effects of asbestos. It is not known whether the second set are therefore predominantly attributable to asbestos exposures or if these represent cases relating to other carcinogens.

Additionally, the authorities from the aviation sector reported that between five and ten cases of occupational disease are reported each year that are attributable to the designation of ‘cancerous diseases’.

Estonia had no statistic but estimated that 200 cases a year could be attributable directly to work and the working environment.
Finland cited published research which estimated that the proportion of cancer deaths attributable to occupational exposure (malignant neoplasms) ‘a few years ago’ was eight per cent. They had no data on incident cases.

France could offer no data on cancer deaths from their registry. However, on incident cases they reported that:

“The number of cancer cases with recognised occupational causes amounted to 1,902 in 2012, which represents a year-on-year increase of 5%. Historical exposures to asbestos were still responsible for the bulk of cases of recognised occupational cancer, accounting in 2012 for 1,579 recognised cases, or 83% of the total, far ahead of cancers caused by any other carcinogen. After asbestos, coal tar remained the main causal agent, with compensation being paid for 76 outbreaks of cancer. Wood dust came next, with compensation payable in 72 cases, followed by aromatic amines, with 71 cases.”

Germany and Greece were unable to provide any data.

Hungary reported that tumours and cancer-related deaths in Hungary (too). In the absence of registration, the estimated number of deaths by occupational-related cancer is between 3,200 and 3,300 cases per year. However, nearly all of these have been lung cancer following exposure to asbestos or to ionising radiation, and asbestos-induced mesothelioma, neither of which are covered by the CMD.

Data presented on annual incident cases is confusing but indicates fluctuating proportions over the five-year period with an average of 36% of cases apparently related to carcinogenic chemical substances.

Ireland estimate that 4% of deaths (300/7500) are ‘occupationally derived’ with the assumption that a similar percentage applies to incident cases. However, this assumes that all forms of cancer result in a similar proportion of fatalities, which is not necessarily the case as some are more ‘survivable’ than others.

Italy could provide no data.

Latvia could provide no data on cancer deaths. On incident cases they note:

“According to statistics, the group of malignant tumours and pre-cancer diseases in 2012 contained one case of occupational disease, in 2011 – seven; 2020 – four; 2009 – three and 2008 – eight. It is, however, possible that malignant tumours are not always associated with the use of carcinogens at work, and thus these data may not be representative of the actual situation and in reality the number of such cases could be notably higher.”

Lithuania, Luxembourg and Malta could provide no data.

Netherlands estimates that the contribution of substance exposure at work to the total number of cancer cases in the Netherlands is 8% for men and 1.5% for women. They provide a table of specific forms of cancer presented below.
The report indicates that the extent of incident cases is not known.

**Poland** state that:

“According to data made available by the Central Register of Occupational Diseases in Poland, 96 cases of cancer resulting from occupational exposure to carcinogenic or mutagenic agents were noted in 2011, and 61 cases were noted in 2013. However, there are no data concerning the proportion of cancer deaths attributable to occupational exposure to carcinogens in the total number of deaths.”

On incident cases central registry data are reported as follows:

a) in 2007, 113 tumour cases were recorded, including 100 classified as group 17 (malignant tumours resulting from occupational exposure to agents recognised as carcinogens in humans). Among these, the most frequently mentioned causal agents were asbestos (55 cases), and polycyclic aromatic hydrocarbons (PAH) (24 cases), while the most frequent locations were the lungs (47 cases) and the pleura (25 cases);

b) in 2008, 100 tumour cases were recorded, including 85 classified as group 17. Among these, the most frequently mentioned causal agents were asbestos (45 cases), and polycyclic aromatic hydrocarbons (PAH) (17 cases), while the most frequent disease were lung cancer (43 cases) and mesothelioma of the pleura (14 cases). Two locations for malignant tumours resulting from hazards created by ionizing radiation were noted: the lungs (14 cases) and female breast (1 case);

c) in 2009, 95 tumour cases were recorded (3% of all diseases), including 87 classified as group 17. Among these, the most frequently mentioned causal agents were asbestos (54 cases), and polycyclic aromatic hydrocarbons (PAH) (11 cases), while the most frequent disease were lung cancer (49 cases) and mesothelioma of the pleura (17 cases). Two locations for malignant tumours resulting from hazards created by ionizing radiation were noted: the lungs (7 cases) and the body of the uterus (1 case);

d) in 2010, 100 tumour diseases were recorded (3.4% of all diseases). The main causal agents mentioned were asbestos (61 cases) and ionizing radiation (12 cases). The most frequent were lung cancers (50 cases) and mesothelioma (32 cases, including 31 in the pleura and 1 in the peritoneum);
e) in 2011, 96 tumour diseases were recorded (3.8% of all diseases). The main causal agents mentioned were asbestos (44 cases), polycyclic aromatic hydrocarbons (PAH) (17 cases), and ionizing radiation (16 cases). The most frequent were lung tumours (64 cases) and mesothelioma of the pleura (17 cases);

f) in 2012, 61 tumour diseases were recorded (2.5% of all diseases). The main causal agents mentioned were asbestos (38 cases), polycyclic aromatic hydrocarbons (PAH) (8 cases), and ionizing radiation (6 cases). The most frequent were lung tumours (29 cases) and mesothelioma of the pleura (19 cases).

In Portugal only four deaths from cancer were reported over the five year period representing less than 1% of the total deaths. It is also indicated that, in terms of cancer registrations, 16 new cases of occupational cancer were recorded in the period between 2005 and 2012. However, the report notes that ‘it can be argued’ that the current statistical system may not be able to fully address all active cases of occupational diseases.

The report from Romania includes two tables reproduced below. The first shows reports from family doctors (presumed to be deaths). The second shows incident cases attributable to occupational exposure to carcinogens

<table>
<thead>
<tr>
<th>Year</th>
<th>Occupational disease</th>
<th>Cause</th>
<th>No of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>Bladder cancer</td>
<td>Organo-chlorinated pesticides</td>
<td>1</td>
</tr>
<tr>
<td>2008</td>
<td>Testicular carcinoma</td>
<td>X-ray</td>
<td>1</td>
</tr>
<tr>
<td>2008</td>
<td>Uterine carcinoma</td>
<td>Ionizing radiation</td>
<td>1</td>
</tr>
<tr>
<td>2008</td>
<td>Bladder tumor</td>
<td>Benzene, tar</td>
<td>1</td>
</tr>
<tr>
<td>2009</td>
<td>Lung cancer</td>
<td>Free crystalline silica, arsenic trioxide</td>
<td>1</td>
</tr>
<tr>
<td>2009</td>
<td>Larynx Cancer</td>
<td>Free crystalline silica</td>
<td>1</td>
</tr>
<tr>
<td>2010</td>
<td>Lung cancer</td>
<td>Free crystalline silica</td>
<td>2</td>
</tr>
<tr>
<td>2010</td>
<td>Larynx Cancer</td>
<td>Asbestos</td>
<td>1</td>
</tr>
<tr>
<td>2010</td>
<td>Acute lymphoblastic leukemia</td>
<td>Ionizing radiation</td>
<td>1</td>
</tr>
<tr>
<td>2010</td>
<td>Lung Adenocarcinoma</td>
<td>Asbestos, aromatic hydrocarbons (of soot, tar)</td>
<td>1</td>
</tr>
<tr>
<td>2010</td>
<td>Lung cancer</td>
<td>Chromium salts, lead chromate</td>
<td>1</td>
</tr>
<tr>
<td>2010</td>
<td>Lung Adenocarcinoma</td>
<td>Asbestos</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>Pleural Mesothelioma</td>
<td>Asbestos</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>Digestive tract cancer</td>
<td>Pharmaceutical products</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>Bladder cancer</td>
<td>Organic Solvents</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>Lung cancer</td>
<td>Free crystalline silica</td>
<td>2</td>
</tr>
<tr>
<td>2011</td>
<td>Lung cancer</td>
<td>Hexavalent chromium</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>Breast cancer</td>
<td>Chemical industry carcinogens</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>Pleural Mesothelioma</td>
<td>Asbestos</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>Cancer of the digestive tract</td>
<td>Carcinogens and potential carcinogens</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>Bladder cancer</td>
<td>Organic Solvents</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>Lung cancer</td>
<td>Silicon dioxide</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>Lung cancer</td>
<td>Hexavalent chromium</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>Lung cancer</td>
<td>Silicon dioxide</td>
<td>1</td>
</tr>
</tbody>
</table>


Slovenia were unable to provide any data.
According to the NIR from **Spain**:

“The vast majority of researchers and assessment agencies are of the view that approximately 5% of all cancers may be attributed directly to exposure regarded as occupational in nature.”


**Sweden** estimate the number of deaths from cancer related to occupational exposure to be 1%, i.e. approximately 500 per annum and an estimate of 1-2% of incident cases, equivalent to 550-1 100 per annum.

Finally, the **UK** cite the work of Rushton and co-workers which suggests that approximately 8,000 cancer deaths could be due to work activities (Although not all are caused by substances covered by the CMD. This equates to 5.3% of current all cancer deaths each year with incident cases at 4% or 13,500 new cases of cancer which could be attributable to occupational exposure.

EQR1: Answer

Estimates based on employment within appropriate industrial sectors suggest that the CMD is potentially relevant to 12.3% of the EU workforce.

No comprehensive data on current exposure to carcinogenic and mutagenic substances across the EU-27 are available. Carcinogens, mutagens (or reprotoxins) continue to be produced in considerable quantities within the EU-28, although there has been a decline in recent years. However, production figures give no direct picture of levels of exposure, or the number of workers potentially at risk.

Despite the shortcomings in the data it is clear from a variety of sources that workers in the EU-27 continue to be potentially at risk from exposures to carcinogenic or mutagenic substances and that there is therefore an ongoing need to control such exposures to remove or reduce the risks.

It is difficult to gain a clear picture of the current health impacts of such exposures. The long period of latency of many cancers and the delay before many mutagenic changes become manifest makes it difficult to establish the current level of problems in terms of registered cases or deaths, and early signs or symptoms are not considered a viable surrogate. However, Rushton et al (2012)\(^{35}\) have estimated that, in Britain in 2005 and 2004, 8,010 (5.3%) of all cancer deaths (6,073 excluding mesothelioma) and 13,598 of cancer registrations (11,661 excluding mesothelioma) were attributable to occupation.

Data from the individual NIRs show varying levels of occupational cancer (deaths and incident cases) with much missing data and suggestions of under-recording.

This material, as well as the substance specific studies identified, gives a strong indication that this Directive remains relevant.

4.2 EQR2: Future relevance

**EQR2**: Based on known trends (e.g. new and emerging risks and changes in the labour force and sectoral composition), how might the relevance of the Directives evolve in the future, and stay adapted to the workplaces of the future in light of the horizon of 2020? Does the need for EU level action persist?

Using lung cancer and exposure to crystalline silica as an example, Hutchings and Rushton (2011)\(^{36}\) have estimated that, without any interventions, lung cancer registrations attributable to crystalline silica exposure at work will remain little changed by 2060 but that, with various workplace interventions in place, the level of such cancers could be reduced considerably.

In an editorial commenting on the estimates of levels of occupational cancers presented by Rushton et al reported in the previous section, Cherrie writes of the need for action to reduce the risks of such cancers continuing:

“We must take ownership of the cancer burden from workplace chemicals and make sure that in another 20 years from now, occupational cancer does not continue to be a problem waiting for a solution. The key is to ensure that exposures to the main contributing carcinogens are being adequately controlled and that the level of control is increasingly being tightened in the future.”\(^{37}\)

As noted earlier, the report by Cherrie and co-workers\(^{38}\) includes projections of future incident cancers in the EU and the expected deaths arising from exposures to a number of chemicals without any appropriate action being taken to reduce risk, together with further projections of the reductions possible with appropriate action to reduce exposures to selected carcinogenic substances below possible OEL levels.

This provides a strong argument for the continuing relevance of the Directive and the control provisions contained within it.

Interviews with EU stakeholders included a number of comments regarding the relevance of the Directive. One key issue with understanding who the Directive is protecting is latency periods. As discussed by the SLIC interviewee, the full impact of the Directive may still not be known for 15-20 years due to the length of time it

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\(^{37}\) Cherrie (2008) Editorial: We can eliminate occupational cancer from chemicals

\(^{38}\) Cherrie et al. (2011) Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work: Summary report.
can take for exposure to some carcinogens or mutagens to display effects, and thus to be able to measure whether the controls are protecting the workers. However, in the opinion of the ETUI stakeholder interviewed, due to the extremely high numbers of people dying from cancers the CMD remains (and will remain) highly relevant. In both cases, these are the opinions of potentially influential stakeholders although they did not provide documentary evidence to support those views.

In terms of potential new or emerging risks the Eurometaux interviewee considered risks including reproductive influence, pregnancy effects and fertility of men. To some extent this reflects earlier comments and suggestions regarding reprotoxins. The FIEC interviewee indicated the belief there are new risks from nanotechnology. Nanoparticles are already used for a variety of uses. They (FIEC) believe that it is not possible to measure whether bad or neutral nanoparticles are in the air we breathe. They were also concerned that current protective equipment does not completely cover the risks.

The subject of OELs was mentioned by several stakeholders. For example the Euromines interviewee indicated that they consider the CMD to be one of the most problematic Directives. They expressed the belief that the subject area is not well enough understood and therefore questioned whether the OELs were based on sound information. This was echoed by the IMA interviewee who went on to suggest that OELs are not appropriate for the CMD and that limit values should be implemented through the Chemical Agents Directive. The rationale for this is not known. They explained that many of the IMA members find the CMD OELs hard to understand. Again, the reason for this is not known as they are presented in the same format and can be seen to some extent as comparable to the Binding Limit Values within the Chemical Agents Directive, with the additional provision for exposure to be as low as technically possible. Finally, they indicated that they support the Commission’s thoughts on merging the CAD and CMD.

Two additional comments by EU stakeholders considered the impact on SMEs. FIEC specifically considered concerns over considerations on introducing silica dust in the CMD. They believe that a lot of companies, and particularly small ones, will struggle to adhere to this as there is no alternative material. UEAPME commented on the effects of the CMD on SMEs more directly. They explain that its members noted that the application of this directive is particularly heavy for SME craftsman, in that they are required to document exposure to certain materials. However, they added that this comment does not reflect the situation across the EU, but rather offers a reflection of the situation at national level (Germany).

A number of the national stakeholder interviews included comments considering the relevance of the Directive. The general consensus of the national stakeholder and expert interviews is that the CMD remains relevant and will continue to be so, with no comments to the contrary. However, there were several comments regarding the absence of specific requirements for controlling nanotechnologies. One stakeholder expressed that there are a number of new or emerging risk factors possible (technological progress, composition, mobility and availability of skilled workforce, on-going automation of work processes, etc.), however, it is not possible to accurately predict how these factors will affect the Directive. However,
one other stakeholder expressed that there are no new or emerging risks relevant to this Directive.

The confusion caused by the limit values and classifications was discussed by several national stakeholders and experts. Concerns were expressed that the combined limit value and classification requirements of the CAD and the CMD can be difficult for employers to implement, especially smaller business with limited resources (it is possible that the stakeholders were confusing requirements within the CMD and CAD with those of the CLP Regulation 2008/1272). One stakeholder expanded on this by discussing the need for clearer coherence between this and other Directives (i.e. the CAD) to reduce the bureaucratic and administrative burden upon employers and those responsible for enforcement.

A further issue raised was the current requirement of the CMD (Article 5(3) for the exposure of workers to be reduced to as low a level as is technically possible. This was raised in the context that REACH provides for both threshold and non-threshold carcinogens. At the time of publication of the CMD it was considered that “current scientific knowledge is not such that a level can be established below which risks to health cease to exist” (Preamble, paragraph 11). However, published scientific studies since then suggest that scientific knowledge does now allow the identification of safe thresholds for certain carcinogens. For example, Bolt and Huici-Montagud (2008)\(^{39}\) suggest four categories of classifying carcinogens and mutagens which include threshold-based limits for both genotoxic and non-genotoxic carcinogens, with the default assumption (for chemicals with carcinogenic or mutagenic activity) remaining that they have linear dose-response relationships without any threshold for effects, known as non-threshold (i.e. there is no ‘safe’ level of exposure).

Clearly this is an issue for the SCOEL to consider and to reflect in any future recommendations. However, given the current requirements, for the prioritisation of substitution, and the use of a closed system where technically possible (Article 5(2)), as well as the requirement from Article 5(3), the CMD might require amendment should SCOEL consider a threshold to be identifiable for any substances, making a permissible safe level appropriate. Again, this issue is probably best addressed in the context of a wide-ranging review of the CAD and CMD and their possible merging.

In terms of legal coherence it seems that there might be some merit in merging the CAD and CMD (see section 6). Opinions appear to be divided on this issue. When it was discussed amongst stakeholders attending the seminar held to consult them on issues arising from the review (“validation seminar”) it was apparent that there was no clear consensus amongst the stakeholders present. Although there was some variation within stakeholder groups it seemed that the main differences of opinion reflected a worker-employer split, with most (but not all) employers favouring a merger but workers preferring to retain the two Directives. There was a

suggestion that merging the two might make compliance and risk management easier for SMEs, and it was argued that merging of the Directives would be beneficial, reducing duplication and removing confusion amongst employers. It was noted that some MS already implement the CAD and CMD within a single legislative instrument, e.g. UK. However, others expressed the opinion that merging the two Directives would, in some way, downgrade the special status accorded to carcinogens and result in a reduction in protection.

There are relatively few specific comments in the NIRs regarding the relevance of the CMD, although they do comment on other aspects of its provisions and their implementation which could be regarded as relating to this. As noted earlier, the NIR from Austria includes strong support from the ÖGB in favour of extending the scope of the Directive so that it includes carcinogens, mutagens and substances toxic to reproduction. The Danish Working Environment Authority has set new limit values and has, among other things, lowered the limit value for inhalable timber dust. The shipping authorities introduced a ban for some carcinogens (unspecified), and several (carcinogenic) substances have been regulated, including all IARC-classified substances. Danish employers indicated a need for better coordination between the requirements of the REACH Regulations and those of both the CMD and CAD. To avoid duplication, the issue of the relationship between the provisions of the CMD and CAD and other legislation such as REACH is discussed in the CAD report.

According to the German NIR the scope of the national transposition (Hazardous Substances Regulation) has been extended to apply to workers and to pupils, students and the self-employed. Hungary requires information to the authorities to be retained for a period of 50 years (as opposed to 40 years specified in the Directive). The NIR from the Netherlands reports in some detail measures predicated on a long-standing ‘target risk’ of $1 \times 10^{-6}$. Poland reports having set maximum levels for concentrations were set for 49 chemical substances and 3 types of dust (dust containing asbestos, dusts of artificial mineral fibres, and dusts of hardwood) classified as carcinogenic or mutagenic.

The Polish NIR comments extensively on the problems and confusion caused for some employers by the plethora of Regulations and legislation covering chemicals (including carcinogens). This would seem to implicitly support suggestions from elsewhere for a rationalisation of the Directives.

Slovenia report that they have reduced the working time of workers who work with proven chemical carcinogens or in work processes with a risk of chemical carcinogenicity to a maximum of 33½ hours per week (from the normal 40 hours). They have also included the prohibition of the use of carcinogens and mutagens in teaching at primary and secondary schools; and that the use of carcinogens and mutagens at higher-education institutions and research institutions is permitted only on the basis of an assessment by a public health body.

They also comment that SMEs in particular would find the requirements of the CMD easier to follow if they more closely reflected the provisions of REACH and CLP (although the provisions of Directive 2014/27/EU, which had not been adopted at the time of interview, might help to at least partly resolve this issue).
Commenting on the complexity of the Regulations and Directives covering chemicals, one of the Autonomous Regions of Spain suggested that this would be easier if the legislation in its entirety was simplified (which could again be seen as implicitly supporting merging the CMD and CAD).

Whilst clearly these MSs consider that these changes render the legislation more relevant to the risks as they see them they don't appear to indicate a general consensus for change.

As well as these observations on national practices, the NIRs do however include some specific recommendations.

Germany ‘urgently recommended’ that the number of [chemicals] Directives be reduced. In this context they also referred to REACH and the ‘GHS’ (presumably the UN Globally Harmonised System). On this issue it is noted that, according to the NIR from Portugal, the majority of SMEs take the legislation on chemical products as a whole, without distinguishing between those measures applied to carcinogens or mutagens and those applied to chemical agents. This latter comment appears to offer tacit support to suggestions of merging the CMD and CAD.

The German DGB also called for the scope of the Directive to be extended to ‘hazardous substances toxic to reproduction’. This same explicit recommendation for amendment was also offered by Austria:

- ‘The scope of the Carcinogens Directive (2004/37/EC) should be extended to substances and compounds toxic to reproduction.’

One explicit recommendation for amendment was offered by Greece:

- ‘Directives 98/24/EC and 2004/37/EC on chemical agents and carcinogens, respectively, should be supplemented on the basis of the more recent Regulations 1272/2008/EC and 1907/2006/EC, which are already in force.’

It should be noted that amendments to reflect 1272/2008/EC (CLP) have already been adopted and that the recommendation gave no specific indication of specific recommendations in respect of REACH (1907/2006/EC)

- man-made mineral fibres ‘We propose supplementing the range of limits for carcinogens so that they respect current scientific knowledge about the possibility of setting limits (non-genotoxic and genotoxic carcinogens in group C).

- We also recommend that uniform limits for carcinogens and mutagens also be set and applied for other chemical agents in the European Union, because the adoption of differing national limits deforms risk assessment results (in each state, there are different limits for the same substances). Instead of various national limits for the same substances, we recommend reacting more quickly to technological progress and scientific knowledge
and issuing binding uniform limits or expert guidelines applicable to the entire European Union."

The recommendations in the NIRs from some MSs relating to reprotoxic and genotoxic substances reflect concerns on this issue reported in interviews with some stakeholders (e.g. Eurometaux).

Mutagens which have genotoxic properties are of course covered by the CMD but those substances which are genotoxic but not mutagenic are not. However, they are included within the scope of the CAD, which lays down minimum requirements for the protection of workers from risks to their safety and health referenced to the specific nature of those risks. In addition to their labelling under CLP they can also be addressed within REACH as Substances of Very High Concern (SVHCs).

To give some idea of the scale of the issue, there are 151 substances classified under Annex VI of CLP as R1A and 1B. Of these, 97 are reprotoxic substances only and therefore fall outside the scope of the CMD. In addition, there are a further nine substances recognised by the European Chemicals Agency of which eight are reprotoxic substances only and again fall outside the scope of the CMD.

From the CSRs, it appears that ten MSs (AT, BG, CZ, DE, FI, FR, LV, NL, PL, SE) already include some if not all CLP R1A and 1B substances within their transposition of the provisions of the CMD. For one other, although they do not specifically include them, there are additional provisions made relating to such substances to extend their legal provisions. This suggests that there is already a considerable favourable view towards extending the scope of the CMD (although not a majority).

Clearly, if the CAD and CMD are combined then the revised Directive can promote the use of whatever measures are considered appropriate for the level and nature of the risk – which would overcome any apparent lack of coherence in approach.

To counter this view, consideration must be given to whether the stringent controls defined within the CMD are necessary in respect of work with such substances, or whether measures adopted in the context of the CAD are sufficient. However, the lack of suitable data (as to the number, age, sex, etc. of workers actually exposed to each substance and level of exposure, including existing control measures) makes such judgements impossible. Imposing specific constraints on ways of working as included in the CMD, (rather than the more goal-oriented approach of the CAD) might also be considered to hinder the development of innovative solutions.

With the current (limited) level of knowledge, the best solution would seem to be to include consideration of reprotoxins and how best to control the risks they present within a wider debate over the future of the CAD and CMD.

One other key issue discussed which relates to the future relevance of this Directive is the latency effects of relevant exposures. As discussed by SLIC the full impact of the Directive may still not be known for 15-20 years, due to the length of time it can take for exposure to some carcinogens or mutagens to display effects, and thus to be able to measure whether the controls are protecting the workers.
Therefore, it could be argued that the Directive remains relevant until such time that the data allows the controls to be assessed.

However, rather than the absence of evidence due to latency, published projections of future incident cancers in the EU and the expected deaths arising with or without any appropriate action being taken to reduce risk, provides a strong evidence-based argument for the continuing relevance of the Directive and the control provisions contained within it.

Confusion caused by the OELs provisioned by this Directive were discussed by the stakeholders. It was expressed that the knowledge base for setting the OELs may be questionable and needs to be developed to ensure the accuracy of OELs. Furthermore, a stakeholder confirmed support for the notion of merging this Directive with the Chemical Agents Directive. Wider issues relating to different indices of risk or limits to exposure are presented in the CAD report.

From the national expert interviews there was a complete consensus on the continued future relevance of the Directive. Some stakeholders at national and EU level advocated the merger of the CAD and CMD, a suggestion which is discussed in the CAD report.

Several stakeholders considered the need to incorporate the prevention of potential risks of exposure to nanomaterials in the provisions of this Directive. The issue of nanoparticles is again discussed at greater length in the CAD report. However, it is noted that there are uncertainties regarding the health effects of nanoparticles and nanomaterials. One consequence of this is that some advocate their inclusion in the CAD, some in the CMD, some in both and some in a separate Directive. Again, this issue is discussed in the CAD report.

From the NIRs three explicit recommendations were offered to ensure the future relevance of the Directive. Germany ‘urgently’ recommended a reduction in the number of Directives. Austria recommends that the scope of the Directive should be extended to substances and compounds toxic to reproduction whilst Slovakia makes reference to genotoxic carcinogens. Also, Greece recommends that the Directive be supplemented on the basis of more recent Regulations already in force (1272/2008/EC and 1907/2006/EC).

The issue of the inclusion of reprotoxins (not all of which are mutagenic) within a widened scope of the CMD was reviewed. It was noted that over a third of MSs already accommodate them within their equivalent legislation suggesting a degree of tacit support for such a measure. However, it is suggested that including consideration of reprotoxins and how best to control the risks they present within a wider debate over the future of the CAD and CMD provides the best option given the current lack of detailed data.

As a further issue, the prospect of identifying some carcinogens or mutagens for which an evidence-based safe threshold can be established would generate additional pressures to revise the CMD. At present, CMD includes the assumption that such thresholds cannot be identified and adopts a focus on measures such as substitution and the use of closed systems (as well as an explicit requirement for exposure levels to be reduced as low as technically possible).
The issue of simplifying the regulation of chemicals (including carcinogens and mutagens) by merging the CMD and CAD was discussed amongst stakeholders attending a seminar held as part of the evaluation project to discuss some of the preliminary findings from the study (“validation seminar”). There was no consensus on this at the seminar (which mainly included employer and worker representatives with some government stakeholders). The issue is discussed further in the CAD report.
5 Assessment of effectiveness

Impact assessment

As noted in Chapter 2, there are very few EU collated statistics available from which to assess the effectiveness of the CMD. What few resources there are can be analysed in conjunction with analysing stakeholder assessments of the effectiveness of the Directive.

As a reservation, there are few, if any, substantial sources available that uniquely address occupational carcinogens across all EU-27. The available EU-27 data of relevance can also be related to other directives, in particular the CAD and, partly, to the Directive on Asbestos. An additional constraint has also been that the database CAREX (financed by EC) has not been updated for the EU-15 countries since 1990-3. It has only been updated once, where it included four new EU countries, namely the Czech Republic and the three Baltic countries (in 1997). The European Risk Observatory report on assessment methods relating to exposure to carcinogens and work-related cancer comments:

“On the whole, the information on occupational exposure to carcinogens in Europe is outdated and incomplete. Yet occupational exposure data are the basis for assessing risks, estimating the burdens of diseases and other consequences of exposure, identifying high-risk worker groups and setting prevention priorities. The CAREX estimates from the early 1990s should be updated.”

To our knowledge, CAREX is the only database that provides information, albeit outdated, on exposure to occupational carcinogens at EU level. Whilst CAREX is clearly outdated it will therefore be referred to below to complement other sources such as national databases.

5.1 EQE1: Effect on occupational safety and health

EQE1: To what extent has the Directive influenced workers’ safety and health, the activities of workers’ representatives, and the behaviour of establishments?

5.1.1 Workplace impacts

According to information from EU stakeholder interviews, legislation on Carcinogens or Mutagens has been most successful for large enterprises (eight out of nine who had an opinion expressed this view) and most challenging for SMEs (all nine expressed this view).

The EU stakeholders interviewed considered that the CMD has, to a medium to high extent, positively affected the safety and health of workers. Employers and experts (e.g. from research institutions) rated the effect slightly higher than workers organisations, although all group scores were between 3.0 and 4.0.

To the extent that the actions did not occur before the introduction of the CMD, the material on compliance reported in section 3.3 provides some insight into the workplace impacts of the CMD. As noted there, there are only patchy and uneven statistics some of which are based solely on the expert opinion of the national expert rather than any formal survey material. This, together with the data on substitution derived from the NIRs, also in section 3.3, offers the only real insight into the impact of the provisions of the CMD at the workplace.

It might be considered that one impact of the CMD, specifically the requirement to substitute carcinogens or mutagens for safer substances would be to see a reduction in the overall use of such substances. Whilst not specifically ‘use’ data, information on the production of carcinogens, mutagens and reprotoxic chemicals is available from the European Environment Agency.

This data is presented graphically below. Looking at the bottom of each bar (CMR chemicals), although there is possibly a slight dip in 2008 and 2009, there is clearly no overall downward trend in the production of such materials over the nine years shown. Even the marked overall downturn in chemical production in 2009 had very little apparent impact on CMR production. Clearly these figures give no indication of exposure.
Production data from other (Eurostat) sources show a slightly different picture. Figure 5-3 shows a graph from an alternative source which seems to show a slight reduction in CMRs in the most recent years (to 2013).

The accompanying narrative text states:

“EU-28 production of the most toxic chemicals — carcinogenic, mutagenic and reprotoxic (CMR) chemicals — fluctuated between 34 and 36 million tonnes over the period from 2004 to 2007. Output fell by 5.3 million tonnes (or 14.8 %) between 2007 and 2008 to stand at 30.6 million tonnes. There was a recovery in the level of production in 2009 and 2010, as the output of CMR chemicals rose to 34.7 million tonnes — back to a level of output that was similar to that recorded prior to the financial and economic crisis. From 2010, the level of production of CMR chemicals declined once more at a relatively steady rate to reach 30.7 million tonnes by 2013.”

A further note indicates that:

"The relative share of CMR chemicals in total EU-28 chemical production fell from 9.9% in 2004 to 9.0% by 2008. After a jump to 10.9% in 2009 the relative share decreased to 9.5% by 2013."

**Figure 5-3: EU-28 production of toxic chemicals by toxicity class 2004-2013**

Again, these figures clearly give no direct indication of worker exposure. However, the fact that they are continuing to be produced indicates that those workers involved in their production could be regarded as remaining at risk. Although the apparent downward trend in recent years might suggest some progress, the figures could be regarded as reflecting the reported problems that employers have in making substitutions.

### 5.1.2 Safety and health impact

According to 1990-3 figures based on CAREX, there were about 32 million workers in 15 EU countries exposed to 85 agents registered by CAREX. They constituted 23% of the work force. The exposed workers had altogether 42 million exposures, equal to 1.3 mean exposures for each exposed worker. As noted above, although outdated this source does appear to provide the most comprehensive picture relating to change in exposure. The age of this source illustrates the need for better collection and collation of relevant data across the EU.

Based on CAREX material Table 5-2 shows the ten most common exposures in 1990-3 compared to 1999. The highest level of exposure came from solar radiation.

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42 Occupational exposure to carcinogens in the European Union, Occup Environ Med 2000;57:10-18
and environmental tobacco smoke that it is assumed that 7.5 million workers were exposed to at least 75% of the working time. Next in line came crystalline silica, diesel exhaust, radon, wood dust, lead and inorganic compounds, benzene, asbestos, and ethylene. As an aside it is worth noting that exposures to some of these agents are not currently included in the CMD. However, many are included on a list of carcinogens which the Advisory Committee on Safety and Health proposes adding to Annex III of the CMD.43

These figures represent a change from the EU-15 (1990) to EU-19 (1999) and cannot therefore be used to determine any detailed trends. However, the slight decrease in the total exposures (700,000) could be taken to imply that the addition of additional MSs masks a larger fall within the EU-15. Although dated, this data is retained as the only collated material providing any degree of overview of the EU-wide situation. If nothing else, the material serves illustrate the paucity of information.

It should be noted that the figures for exposure are not equivalent to figures for registrations and attributable deaths referred to later in this chapter. Also, figures for most common exposures vary from country to country in the EU-19.

Table 5-2: The ten most common exposures by Agent and number of persons exposed in EU-15 (1990-3) compared to EU-19 in 1999

<table>
<thead>
<tr>
<th>Ten most common exposures by Agents in EU-15</th>
<th>Estimates (000)</th>
<th>Estimates (000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU-15 1990-93; EU-19 1999</td>
<td>1990-93</td>
<td>1999</td>
</tr>
<tr>
<td>Solar radiation (at least 75% of working time)</td>
<td>9.100</td>
<td>8.900</td>
</tr>
<tr>
<td>Tobacco smoke, environmental (at least 75% of working time)</td>
<td>7.500</td>
<td>7.300</td>
</tr>
<tr>
<td>Silica</td>
<td>3.200</td>
<td>3.100</td>
</tr>
<tr>
<td>Diesel engine exhaust</td>
<td>3.000</td>
<td>3.000</td>
</tr>
<tr>
<td>Radon</td>
<td>2.700</td>
<td>2.600</td>
</tr>
<tr>
<td>Wood dust</td>
<td>2.600</td>
<td>2.500</td>
</tr>
<tr>
<td>Lead and lead compounds, inorganic</td>
<td>1.500</td>
<td>1.500</td>
</tr>
<tr>
<td>Benzene</td>
<td>1.400</td>
<td>1.400</td>
</tr>
<tr>
<td>Asbestos</td>
<td>1.200</td>
<td>1.200</td>
</tr>
<tr>
<td>Ethylene</td>
<td>1.200</td>
<td>1.200</td>
</tr>
<tr>
<td>Total persons exposed in EU</td>
<td>33.400</td>
<td>32.700</td>
</tr>
</tbody>
</table>


As there are no updated or comparative figures on occupational cancer for all EU-27 available, it is not possible to assess the overall impact of the Directive at EU-level.

The Risk Observatory Report cited earlier includes data from Finland relating to trend in exposure to crystalline silica (quartz dust) which suggest declining exposure but a slight increase in the numbers exposed. Figure 5-4 reproduces this data.

43 The Advisory Committee on Safety and Health at Work. Opinion. Doc. 2011/12 Opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace

Kauppinen and co-workers (2013) reported that, in Finland, the proportion of the workforce exposed to most chemical agents, including some carcinogens (and including benzene and wood dust, covered by the CMD) has decreased substantially across a period from 1970-2008 (although exposures to some others such as diesel exhaust has not decreased greatly). The paper also predicts that exposures on 2020 will remain low – or decrease further. The authors caution against generalising these findings to other countries given national differences in factors such as the level and nature of technology and the occupational structure of the labour force.

National data from NIRs, reported in section 4.1, suggests a mixed picture with some MSs presenting data suggesting an increase in deaths and cases, whilst others indicate a more static picture. However, it appears that some of these (at least) include deaths from asbestos exposure and, in other cases increases in numbers might reflect changes in classifications. Great care should therefore be used in interpreting any of this material.

According to a study in UK, 5.3% (8,010) of total cancer deaths in 2005 were attributable to occupational causes. A number of these were attributable to substances such as asbestos (1937 deaths) not covered by the CMD. In all, men accounted for 79% and women for 21% of these deaths. In 2004, 4% (13,598) of the total of cancer registrations were due to occupational causes (again not all attributable to substances covered by the CMD. In all, cancer registrations attributable to occupation amongst men accounted for 5.7% of all registrations and women for 2.1% of these. It should be noted that, although figures may vary between the EU-15 countries, similar results were found in Denmark (estimated 4-
5% annual registrations) and Finland (3% annual registrations); both of these
countries have some of the best cancer registration systems.\textsuperscript{47}

Table 5-3 shows that there is only one type of cancer (mesothelioma) that can be
regarded as almost hundred percent occupational, with an attributable fraction of
94.9%. Next come sinonasal and lung cancers, with attributable fractions of 32.7%
and 14.5%, respectively. Other attributable fractions for occupational cancer are
nasopharynx (8%), bladder (5.3%), breast (4.6%), non-melanoma skin cancer
(4.5%), oesophagus (2.5%), stomach (1.9%) and non-Hodgkin’s lymphoma (1.7%).

Table 5-3: Occupational Cancer in Great Britain: Top-ten attributable fractions (%), based on
2004 and 2005 figures.

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>ICD-10 code</th>
<th>Attributable fraction (%) (95% confidence interval)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesothelioma</td>
<td>C45</td>
<td>97.0\textsuperscript{b} (96.0, 98.0)\textsuperscript{b}</td>
<td>82.5\textsuperscript{b} (75.0, 90.0)\textsuperscript{b}</td>
<td>94.9\textsuperscript{b} (93.0, 96.9)\textsuperscript{b}</td>
<td></td>
</tr>
<tr>
<td>Sinonasal</td>
<td>C30-C31</td>
<td>43.3 (27.3, 74.0)</td>
<td>19.8 (14.4, 31.6)</td>
<td>32.7 (21.5, 54.8)</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>C33-C34</td>
<td>21.1 (19.2, 24.7)</td>
<td>5.3 (4.3, 6.9)</td>
<td>14.5 (13.0, 17.2)</td>
<td></td>
</tr>
<tr>
<td>Nasopharynx</td>
<td>C11</td>
<td>10.8 (2.3, 47.9)</td>
<td>2.4 (0.6, 6.8)</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>C67</td>
<td>7.1 (4.6, 9.7)</td>
<td>1.9 (1.3, 3.9)</td>
<td>5.3 (3.4, 7.7)</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>C50</td>
<td></td>
<td>4.6 (3.3, 6.0)</td>
<td>4.6 (3.3, 6.0)</td>
<td></td>
</tr>
<tr>
<td>Non-melanoma skin cancer</td>
<td>C44</td>
<td>6.9 (1.3, 15.0)</td>
<td>1.1 (0.0, 2.9)</td>
<td>4.5 (0.8, 9.9)</td>
<td></td>
</tr>
<tr>
<td>Oesophagus</td>
<td>C15</td>
<td>3.3 (1.5, 7.5)</td>
<td>1.1 (0.3, 2.8)</td>
<td>2.5 (1.1, 5.9)</td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>C16</td>
<td>3.0 (1.5, 5.1)</td>
<td>0.3 (0.1, 0.5)</td>
<td>1.9 (1.0, 3.4)</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkin’s lymphoma</td>
<td>C82-C85</td>
<td>2.1 (0.6, 9.9)</td>
<td>1.1 (0.1, 2.9)</td>
<td>1.7 (0.5, 4.5)</td>
<td></td>
</tr>
</tbody>
</table>

Source: Rushton et al, (2012) British Journal of Cancer 107, S3-S7\textsuperscript{48}


\textsuperscript{48} ICD = International Classification of Diseases; b Taken as equal to attributable deaths for this short survival cancer. Based on registrations.
Looking at the total numbers of attributable occupational deaths (2005 figures), lung cancer counted for the highest number, namely 4,745 incidences, followed by mesothelioma with 1,937, breast with 555, bladder with 245, oesophagus with 184, stomach with 108, non-Hodgkin's lymphoma with 57, sinonasal with 38, non-melanoma skin cancer with 23 and nasopharynx with 8 incidences (Table 5-4).

Table 5-4: Top-ten attributable numbers, deaths (2005)

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Attributable numbers (95% confidence interval)</th>
<th>Deaths (2005)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICD-10 code</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C33-C34</td>
<td>4020</td>
<td>725</td>
<td>4745</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(3659, 4696)</td>
<td>(592, 946)</td>
<td>(4251, 5643)</td>
<td></td>
</tr>
<tr>
<td>Mesothelioma</td>
<td>C45</td>
<td>1699</td>
<td>238</td>
<td>1937</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1681, 1717)</td>
<td>(216, 260)</td>
<td>(1898, 1976)</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>C50</td>
<td>215</td>
<td>30</td>
<td>245</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(139, 296)</td>
<td>(21, 62)</td>
<td>(159, 358)</td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>C67</td>
<td>156</td>
<td>28</td>
<td>184</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(70, 358)</td>
<td>(8, 70)</td>
<td>(78, 429)</td>
<td></td>
</tr>
<tr>
<td>Oesophagus</td>
<td>C15</td>
<td>101</td>
<td>6</td>
<td>108</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(52, 176)</td>
<td>(3, 11)</td>
<td>(55, 187)</td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>C16</td>
<td>43</td>
<td>14</td>
<td>57</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(0, 138)</td>
<td>(1, 37)</td>
<td>(1, 176)</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkin's lymphoma</td>
<td>C82-C85</td>
<td>27</td>
<td>10</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(17, 47)</td>
<td>(8, 16)</td>
<td>(25, 63)</td>
<td></td>
</tr>
<tr>
<td>Sinonasal</td>
<td>C30-C31</td>
<td>20</td>
<td>2</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4, 44)</td>
<td>(0, 6)</td>
<td>(4, 50)</td>
<td></td>
</tr>
<tr>
<td>Non-melanoma skin cancer</td>
<td>C44</td>
<td>7</td>
<td>1</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2, 31)</td>
<td>(0, 2)</td>
<td>(2, 33)</td>
<td></td>
</tr>
</tbody>
</table>


Table 5-5 shows that the attributable numbers of registrations (2004) in total differ from the number of deaths. This is mainly due to differences in survival rates for different cancers. Registrations are highest for lung cancer (5442), then non-melanoma skin cancer (2862), breast (1969), mesothelioma (1397), bladder (550), oesophagus (188), stomach (157), non-Hodgkin's lymphoma (140), sinonasal (126) and nasopharynx (15).

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49 Attributable fraction applicable to all leukaemias
With regard to mesothelioma and lung cancer, registrations are 100% and 40.8% related to asbestos.\(^{50}\) For breast cancer, this relates only to women. Although men are susceptible to breast cancer the incidence is generally much lower although, possibly because of less awareness, the relative mortality tends to be higher.

Overall, the conclusions are similar to earlier studies based on CAREX and national registers.\(^{51}\)

\textit{Table 5-5 Attributable numbers of registrations (2004)}

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Attributable numbers</th>
<th>Related to asbestos</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICD-10 code</td>
<td>Registrations (2004)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
</tr>
<tr>
<td>Lung</td>
<td>C33-C34</td>
<td>(4212, 5406)</td>
</tr>
<tr>
<td>Non-melanoma skin cancer</td>
<td>C44</td>
<td>(478, 5447)</td>
</tr>
<tr>
<td>Breast</td>
<td>C50</td>
<td>1699</td>
</tr>
<tr>
<td>Mesothelioma</td>
<td>C45</td>
<td>(1681, 1717)</td>
</tr>
<tr>
<td>Bladder</td>
<td>C67</td>
<td>(321, 684)</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>C15</td>
<td>159 (71, 365)</td>
</tr>
<tr>
<td>Stomach</td>
<td>C16</td>
<td>149 (77, 258)</td>
</tr>
<tr>
<td>Non-Hodgkin's lumphoma</td>
<td>C82-C85</td>
<td>102 (0, 328)</td>
</tr>
<tr>
<td>Sinonasal</td>
<td>C30-C31</td>
<td>95 (60, 162)</td>
</tr>
<tr>
<td>Nasopharynx</td>
<td>C11</td>
<td>14 (3, 61)</td>
</tr>
</tbody>
</table>


Table 5-6 shows the agents that are most commonly referred to as being responsible for occupationally-attributable cancers. The top ten are asbestos (4,216), shift work, including flight personnel (1,957), mineral oils (1,730), solar radiation (1,541), silica (907), diesel engine exhaust (801), PAHs from coal tar and pitches (475), paints (359), dioxins (316), and passive smoking (284). Altogether, the list includes 41 agents responsible for occupationally-attributable cancers.

\(^{50}\) As regards asbestos, which is dealt with in the Asbestos Directive, the provisions of the Carcinogens or Mutagens Directive shall apply whenever they are more favorable to health and safety at work (chapter 1, art. 1.4). However, in practice, follow-up to this directive does not include asbestos related occupational cancers.

\(^{51}\) See e.g. British Journal of Cancer, Occupation and Cancer in Britain, April 2010.
Table 5-6 Top-ten cancer registrations related to occupation

<table>
<thead>
<tr>
<th>Occupational agent</th>
<th>2004 Registrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos</td>
<td>4,216</td>
</tr>
<tr>
<td>Shift work (including flight personnel)</td>
<td>1,957</td>
</tr>
<tr>
<td>Mineral oils</td>
<td>1,730</td>
</tr>
<tr>
<td>Solar radiation</td>
<td>1,541</td>
</tr>
<tr>
<td>Silica</td>
<td>907</td>
</tr>
<tr>
<td>Diesel engine exhaust</td>
<td>801</td>
</tr>
<tr>
<td>PAHs from coal tar and pitches</td>
<td>475</td>
</tr>
<tr>
<td>Paints (Painters)</td>
<td>359</td>
</tr>
<tr>
<td>Dioxins</td>
<td>316</td>
</tr>
<tr>
<td>Passive smoking</td>
<td>284</td>
</tr>
<tr>
<td>Total registrations attributable to occupation</td>
<td>13,598</td>
</tr>
<tr>
<td>Total cancer registrations in UK (2004)</td>
<td>339,156</td>
</tr>
</tbody>
</table>

Source: Rushton et al.,(2012) Occupation and cancer in Britain, British Journal of Cancer, 102, 1428-1437

An attempt to list industry sectors and occupations with an estimate of a total of at least 50 attributable registrations show that occupational cancer can be attributed to 29 industry sectors in the UK. The main ten industries are listed in Table 5-7. The five industries with an estimate over five hundred are construction (5692), shift work, including flight personnel (1971), metal workers (1250), personal and household services (804), and land transport (505).

Except for shift work, including flight personnel (predominantly female), personal and household, and wholesale, retail, restaurants and hotels, men are far more exposed than women.

Table 5-7: The 10 most exposed industry sectors (2010)

<table>
<thead>
<tr>
<th>10 most exposed industry sectors (UK)</th>
<th>Attributable registrations</th>
<th>Cancer sites (with at least 10 attributable registrations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construction, incl. roofers, roadmen and painters</td>
<td>5621 Men, 71 Women, 5692 Total</td>
<td>Bladder, lung, mesothelioma, oesophagus, non-melanoma skin cancer (NMSC), sinonasal, stomach</td>
</tr>
<tr>
<td>Shift work, including flight personnel</td>
<td>1 Men, 1970 Women, 1971 Total</td>
<td>Breast</td>
</tr>
<tr>
<td>Metal workers</td>
<td>1081 Men, 169 Women, 1250 Total</td>
<td>Bladder, lung, NMSC, sinonasal</td>
</tr>
<tr>
<td>Personal and household services</td>
<td>274 Men, 530 Women, 804 Total</td>
<td>Bladder, cervix, lung, mesothelioma, Non-Hodgkin’s lymphoma, NMSC, oesophagus, ovary</td>
</tr>
<tr>
<td>Land transport</td>
<td>463 Men, 42 Women, 505 Total</td>
<td>Bladder, leukaemia, lung, mesothelioma</td>
</tr>
<tr>
<td>Mining</td>
<td>285 Men, 17 Women, 302 Total</td>
<td>Lung, mesothelioma</td>
</tr>
<tr>
<td>Printing, publishing etc.</td>
<td>235 Men, 51 Women, 286 Total</td>
<td>Lung</td>
</tr>
<tr>
<td>Public admin and defence</td>
<td>239 Men, 34 Women, 273 Total</td>
<td>Lung, NMSC</td>
</tr>
<tr>
<td>Wholesale, retail, restaurants and hotels</td>
<td>110 Men, 159 Women, 269 Total</td>
<td>Lung, mesothelioma</td>
</tr>
<tr>
<td>Farming</td>
<td>180 Men, 39 Women, 219 Total</td>
<td>Leukaemia, lung, Non-Hodgkin’s lymphoma, NMSC, STS</td>
</tr>
</tbody>
</table>

There is little objective data relating to the influence of the CMD on workers' health and none regarding the activities of workers' representatives, and the behaviour of establishments.

Data on the impact of the CMD on health outcomes are not available because of the long latency period for most cancers. However, some insight can be gained from estimates of exposures to carcinogens. A study based on the update of the outdated CAREX database, making comparisons between estimates for 1990-3 of the numbers exposed to the ten most common carcinogens against similar estimates for 1999 (updated in 2010), suggests that there has been only a slight decrease in the total prevalence of exposures implying little or no change in the risk of exposure. Although both periods predate the adoption of the CMD and therefore offer little insight into its impact the fact that this is the most recent data illustrates the paucity of information.

Some limited national data, drawn from published studies and the NIRs present a mixed picture of trends in both exposures and outcomes (cases/deaths).

Subjectively, among EU stakeholders, there is the view that the CMD has had a moderate effect on the safety and health of EU workers. Employers and experts rate the effect higher than workers organisations.

5.2 EQE2: Effect of derogations and transitional periods

As mentioned in Section 3.2, the CMD does not contain any provisions for extended deadlines. Furthermore, it does not contain any possibilities for derogations.

5.3 EQE3: Effect of Common Processes and Mechanisms

The CPMs are introduced by the Framework Directive, although some of them have more stringent requirements added in respect of the CMD. It cannot therefore necessarily be determined to what extent any changes can be attributed to either Directive. However, the debate is largely academic as no objective data are

52 Note that these estimates include agents such as solar radiation and environmental tobacco smoke which are not covered by the CMD, although this makes little difference to the overall conclusion.
available which enable the effectiveness of individual CPMs to be explored. Thus, although sections on compliance give some (limited) details of the extent to which different CPM and KR provisions have been implemented there is no way of determining attribution.

12 EU stakeholders were interviewed on the CMD and four of those gave their perceptions of the influence of individual CPMs on its effectiveness of the CMD. These stakeholders are of the view that training and risk assessment are the most important factors contributing to the effectiveness of the Directive. They give some importance to information, relatively little importance to worker consultation and health surveillance. Employers put most emphasis on risk assessment and, to some extent on training and workers consultation whereas workers put more emphasis on training and information.

Turning to the KRs, the exception to this general lack of information is the limited amount of data and qualitative material on the specific KR of substitution drawn from the NIRs where there is limited and uneven information summarised in the compliance section on the extent to which this has occurred.

5.4 EQE4: Effect of enforcement

**EQE4: To what extent do sanctions and other related enforcement activities contribute to the effectiveness of the Directive?**

No objective data are available which enable the effectiveness of individual enforcement activities to be explored for the CMD.

Section 3.3 contains material from the NIRs relating to the degree of compliance with the CMD. This section summarises some national stakeholder views on the variation in compliance with size of enterprise and the impact enforcement has on compliance.

According to the 16 national stakeholders interviewed regarding the CMD, there are differences of opinion between employers, workers, and others as to the degree of compliance in larger enterprises and SMEs. Overall, slightly fewer than half (7) consider that compliance is high in larger companies, whereas eleven think that compliance is low in SMEs. However, employers think that compliance is higher for larger enterprises than workers and others who think that compliance is medium. The opposite is the case with regard to SMEs. Here employers find that compliance is low / problematic, compared to workers and others who find that compliance is medium.

EU stakeholders were asked to score the extent to which effective enforcement plays a role in relation to achieving a high degree of compliance with the key KR’s in the Directive. The average score (3.6) is a little over medium and higher for employers (3.8) than for workers (3.3). Although positive, the score suggests that more efforts could be made to implement the Directive.
5.5 EQE5: Benefits and costs

EQE5: What benefits and costs arise for society and employers as a result of fulfilling the requirements of the Directive?

This question is principally addressed in the Main Report in a cross-Directive perspective. However, some limited information has been identified from subjective opinions for the CMD.

The benefits and costs to employers and society arising from fulfilling the Directive are interlinked. In general, 67% of stakeholders think that legislation on the CMD has been most successful for large enterprises, whilst 75% consider it to have been challenging for SMEs.

EU Stakeholders were asked to indicate what benefits they think derive from the implementation of the Directive (issues ranging from improved health and safety to improved company image). However, most of those interviewed did not or were not able to answer this question.

In the view of the interviewed stakeholders, there has been an increase in the compliance costs to implement the Directive. Employers and 'others' think that the increase has been higher than workers. None were able to attribute these costs to individual requirements, regarding them as integral to actions to address carcinogens and mutagens. One respondent also felt that there has been an increase in the administrative burden related to the implementation of the Directive. However, two out of three interviewees had no comments to this question.

Interviewees also considered that SMEs and micro enterprises experience a much larger cost/burden in implementing the legislation than larger enterprises.

There was only one response to the question on what obligations are particularly burdensome in implementing the Directive. Thus, one employer stakeholder identified labelling and putting up signs. It is not clear why this should be regarded as a specific issue relating to the CMD.

5.6 EQE6: Broader impacts

EQE6: To what extent does the Directive generate broader impacts (including side effects) in society and the economy?

This question is principally addressed in the Main Report in a cross-Directive perspective. However, some limited data has been identified for the CMD.

Looking at the broader effects in society, there is a general agreement among the eight EU stakeholders interviewed who expressed an opinion (four did not) that the Directive has had a high impact on agenda setting and influencing national priorities (with a total score 4) and on learning/increasing knowledge about
carcinogens or mutagens (3.8). The impact on environmental effects is a little more than medium (3.4) and lower for e.g. motivation of workers (2.8).

5.7 EQE7: Objective achievement

EQE7: To what extent are the objectives achieving their aims and, if they are not, what cause could play a role? What factors have particularly contributed to the achievement of the objectives?

This question is principally addressed in the Main Report in a cross-Directive perspective. However, some limited subjective information has been identified for the CMD. This indicates that the legislation transposing the CMD only reached its objective to a medium extent (average score 3.2). The score from ‘other’ (EU experts) is approaching ‘high’ (3.8) with that from employers a little over medium, and that from workers is less than medium (2.8).

On average, amongst the five stakeholders who expressed a view, the extent to which the playing field has been levelled was scored close to low (2.2). Within this, worker scores were just under medium (2.7), while other scores were lower, with employers rating it as 1.0 (very low).
6 Assessment of coherence

6.1 EQC1: Coherence and complementarity between the CMD and the other OSH Directives (Internal coherence)

EQC1: What, if any, inconsistencies, overlaps, or synergies can be identified across and between the Directives (for example, any positive interactions improving health and safety outcomes, or negative impact on the burdens of regulation)?

In view of the analysis of internal coherence it is important to mention beforehand the scope of application of the three chemical directives and how they interact one with each other:

Scope of application

The CMD applies to activities in which workers are or are likely to be exposed to carcinogens or mutagens as a result of their work (Article 3(1)). Carcinogens and mutagens are defined by reference to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation)53.

Interaction with other OSH chemical directives

› The provisions of the CAD apply without prejudice to more stringent and/or specific provisions contained in the CMD54.

› The provisions of the CMD apply to asbestos, whenever these provisions are more favourable to health and safety at work. The requirements of the CAD also apply as asbestos fall under the definition of chemical agents.

54 Note that Article 1 of Directive 98/24/EC still refers to the previous carcinogens Directive. This is not a problem as the references to the repealed Directive are to be construed as references to Directive 2004/37/EC (Article 20 Directive 2004/37/EC).
Similar requirements under the risk assessment procedures

All the chemical directives provide that the risk assessment must take into account the nature, degree and duration of worker’s exposure to chemicals agents. Since the CAD contains such provision it is unnecessary for the CMD to replicate it under its risk assessment requirement. Such overlaps however do not lead to double regulation in practice.

Requirements applying to all chemical agents under the CMD

Although at present the CMD by definition only relates to carcinogens and mutagens some provisions from the risk assessment procedure of the CMD could also be applied to all chemical agents under the CAD since they are unlikely to be tailored to the specific hazards and risks derived from carcinogens and mutagens:

› The requirement that the assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers’ exposure does not exist in the risk assessment under the CAD. It could however be argued that the risks derived from exposure to hazardous chemical agents would still require that the assessment is renewed regularly and in any event when any change occurs in the conditions which may affect workers’ exposure. Note that the CAD already provides that the risk assessment shall be kept up-to-date, particularly if there have been significant changes which could render it out-of-date, or when the results of health surveillance show it to be necessary. However this provision does not entail the regular renewal of the risk assessment but only its up-date.

› The requirement that employers must supply the authorities responsible at their request with the information used for making the assessment does not exist under the CAD. It is difficult to justify why this requirement does not apply to all chemical agents independently of the level of risk.

› Unlike the CAD, the CMD, requires that the risk assessment must take into account all other routes of exposure, such as absorption into and/or through the skin. Such criteria to define the risk of exposure are not only valid and pertinent for carcinogens and mutagens but also for certain hazardous chemical agents which exposure route is not inhalation. However, under the CAD employers must take into account in their risk assessment any occupational limit values (OLV) and biological values (e.g. blood content of lead). This would mean that in case that there is an OLV for a chemical agent and if the OLV is based on the other exposure routes employers will have to take it into account in their risk assessment.

Preliminary conclusions:

› Consider the review of the risk assessment procedure under the CMD to include its general elements under the CAD, such as the obligation to renew the risk assessment regularly, to supply the authorities responsible at their request with the information used for making the assessment, take into account all other routes of exposure, such as absorption into and/or through the skin.
The three chemical Directives follow different approaches with regard to the derived risk management measures. This is mainly due to the specificity of the risk covered and the different hazardous properties of these agents (e.g. carcinogens or mutagens/ asbestos/ hazardous chemical agents).

Although the three chemicals Directives do not apply the same risk management approaches and structure, one risk management measure from the CMD could be applied to all hazardous chemical agents under the CAD:

› Measures related to the demarcation of risk areas and use of adequate warning and safety signs including ‘no smoking’ signs in areas where workers are exposed or likely to be exposed. It can however be argued that such requirement could limit worker exposure to hazardous chemical agents and could be replicated under this Directive.

Preliminary conclusions:

› Consider the review of the risk management measures under the CMD to include in the CAD its general requirements applying to all chemical agents such as the demarcation of risk areas and use of adequate warning and safety signs including ‘no smoking’ signs in areas where workers are exposed or likely to be exposed for relevant hazardous chemical agents. This would involve the development of selection criteria as to which hazardous chemical agents should be covered by this management measure.

Substitution requirements

The CMD requires the employer to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers’ health or safety, as the case may be.

The CAD requires that, in order to eliminate or reduce exposure to hazardous chemical agents to a minimum, substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers’ safety and health, as the case may be.

The substitution requirements under the CAD are less stringent. Substitution must be the preferred option, whereas the CMD obliges employers to substitute these agents but sets exceptions (in so far as is technically possible / if the nature of the activity so permits). One could argue that the substitution requirements under the CMD could also be applied to all hazardous substances independently of the level or type of risk, as it is the case in certain countries (e.g. Germany⁵⁵). On the other hand, the more serious potential health outcome from exposure could justify the current setting with more stringent requirements of substitution in relation to hazardous substances.

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⁵⁵ The Federal Ordinance for the Protection against Hazardous Substances of 26 November 2010 applies the substitution requirements of Directive 2004/37/EC to all hazardous substances
carcinogens and mutagens. In addition, any more stringent requirements on substitution could involve a significant compliance cost for employers. This latter view is consistent with the practical experience reported in the NIRs where substitution is often found to be difficult and expensive. In all cases, the outcome of the risk assessment should direct this as, if the risks are adequately removed or controlled without substitution, then there is little justification for requiring it.

Preliminary conclusions:

› Consider the review of the provisions of the CAD on substitution to align them with the provisions of the CMD in order to enhance the substitution of hazardous substances.

› However, this preliminary conclusion should be seen in the light of the implementation of the substitution procedure under REACH (authorisation, restriction), which should drastically reduce the number of hazardous substances workers can be exposed to (see also section 3.1).

Preventive and protective services

The CMD does not include any requirement relevant to the appointment of preventive and protective services. This is the case for all chemicals Directives and does not create any issue of coherence, as the requirement to appoint such services/persons is rather linked with every specific establishment/undertaking and not risk specific. The requirement applies through the Framework Directive and these services carry out their activities with regards to any agents present in the specific workplace, including chemical agents.

Information to workers

In relation to information to be provided to workers, the CMD does not include a ‘without prejudice’ clause referring to the relevant article of the Framework Directive, like the CAD. This does not create a consistency issue because the Framework Directive applies in all cases and, moreover, the CAD also applies in relation to carcinogens or mutagens, without prejudice to more stringent and/or more specific provisions contained in the CMD.

The CMD contains some additional requirements that are more general and could bring an added value to the general principle set in the Framework Directive (see Framework Directive report), as well as some risk specific requirements which are justified by the scope of this particular Directive.

› However some provisions on information from the CMD could also be applied to all chemical agents under the CAD since they are unlikely to be tailored solely to the specific hazards and risks derived from carcinogens and mutagens: The CMD is the only of the three chemicals directives to require that the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the risk assessment reveal a risk to workers health or safety and regulate the access rights to such list (for the doctor and/or competent authority/persons and the exposed workers themselves).

› The CMD is the only of the three chemicals directives to establish access of workers and/or any workers’ representatives to anonymous collective information.
Details concerning information relevant to PPE are provided in the CMD and Asbestos Directive but not in the CAD.

Preliminary conclusions:

› Consider the review of the information to workers requirements under the CAD to include provisions from the CMD on access of workers and/or any workers' representatives to anonymous collective information, on the employers obligation to up-to-date the list of the workers engaged in the activities in respect of which the results of the risk assessment reveal a risk to workers health or safety and regulate the access rights to such list and provisions from the CMD and Asbestos Directive on information relevant to PPE.

Training of workers

In relation to training of workers, the CMD does not include a ‘without prejudice’ clause referring to the relevant article of the Framework Directive, like the CAD. This does not create a consistency issue because the Framework Directive applies in all cases and, moreover, the CAD also applies in relation to carcinogens and mutagens, without prejudice to more stringent and/or more specific provisions contained in the CMD.

However, some provisions on information from the CMD could also be applied to all chemical agents under the CAD since they are unlikely to be tailored to the specific hazards and risks derived from carcinogens and mutagens:

› The CMD includes training requirements relevant to the potential risks/effects to health. Such requirement is also set in the Asbestos Directive but not the CAD.

› Hygiene requirements are a part of training only under the CMD and a similar training requirement is not included in the CAD.

› The CMD refers to training concerning wearing and use of protective equipment and clothing. Details concerning training relevant to PPE are provided in the Asbestos Directive in respect of respiratory equipment, but the CAD does not include any relevant training requirement.

Preliminary conclusions:

› Consider the review of the training provisions under the CAD to include training requirements relevant to the potential risks/effects to health of chemical agents, to hygiene or other similar measures applicable to all chemical agents, to the proper use of PPE.

Health surveillance

The CMD is one of the fourteen Directives that include a health surveillance requirement. As the case with information and training, the health surveillance provision under the CMD does not include a ‘without prejudice’ clause referring to the relevant article of the Framework Directive, like the CAD. This does not create a consistency issue because the Framework Directive applies in all cases and, moreover, the CAD also applies in relation to carcinogens and mutagens, without prejudice to more stringent and/or more specific provisions contained in the CMD. However two provisions on health surveillance from the CMD could also be applied to all chemical agents under the CAD:
The CMD requires that the doctor or the authority responsible for the health surveillance must be familiar with the exposure conditions or circumstances of each worker. The Asbestos Directive includes a similar requirement, whereas the CAD does not.

The CMD provides the possibility by workers concerned or the employer to request a review of the results of health surveillance. This is also foreseen in the Asbestos Directive, but not in the CAD. This is linked to the obligation to set a list of exposed workers, which would facilitate the implementation of this requirement (see under section 2.4 – Information to workers).

**Preliminary conclusions:**

- Consider the review of the health surveillance provisions under the CAD to include a measure requiring that the doctor or the authority responsible for the health surveillance must be familiar with the exposure conditions or circumstances of each worker and the possibility to review the results of the health surveillance, upon request of the worker concerned or the employer.

**Health records**

The Framework Directive does not regulate health records, whereas almost all daughter Directives contain a provision dedicated to health records, including the CMD which contains specific requirements and specifications relevant to health records. The relevant requirements are more detailed in the CAD 98/24/EC than in the CMD and Asbestos Directive but, as previously mentioned, this does not create any coherence issues due to the use of ‘without prejudice’ clauses.

**Consultation of workers**

The CAD, as with a majority of Directives (15) regulating specific risks and categories of workers, does not contain specific worker consultation requirements but mentions that ‘consultation and participation of workers and/or of their representatives shall take place in accordance with Article 11 of Directive 89/391/EEC on the matters covered by this Directive’. No coherence issues were identified in this instance.

Limit values are defined under the CMD as 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 to this Directive.

OELs can be established through either a ‘health based’ approach\(^\text{56}\) or ‘a risk based\(^\text{57}\) approach. The methodology to define OELs under the EU OSH legislation

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\(^{56}\)According to the SCOEL methodology ‘health based’ OELs may be established in those cases where a review of the total available scientific data base leads to the conclusion that it is possible to identify a clear threshold dose/exposure level below which exposure to the substance in question is not expected to lead to adverse effects.

\(^{57}\)According to the SCOEL methodology, on some adverse effects (in particular genotoxicity, carcinogenicity and respiratory sensitisation) it may not be possible on present knowledge to define a threshold of activity. In such cases it must be assumed that any level of exposure, however small, might carry some finite risk and OELs for substances possessing these properties must be established following a risk-based approach. The Commission sets, in such cases, OELs at levels considered to carry a sufficiently low level of risk. A series of
follows in general a 'health based' approach. OELs can either be indicative OELs or binding OELs.

CMD only contains binding limit values for Benzene, Vinyl chloride monomer and Hardwood dusts.

Binding OELs (BOELs) are adopted taking into account socio-economic factors and feasibility factors as well as the factors considered when establishing indicative OELs (IOELs). For any chemical agent for which a BOEL value is established at EU level, Member States have a degree of flexibility in that they must establish a corresponding national binding OEL value which can be stricter, but cannot exceed the Community limit value.

Similarly to the CAD, binding limit values on carcinogens and mutagens must be adopted by the European Parliament and Council in accordance with Article 153(2) of the TFEU on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

Given the similarity between these approaches, no coherence issues are identified related to the adoption of binding limit values under the CMD and CAD. See also section 6.2 (REACH)

The CMD, unlike the CAD, requires employers to give particular attention to any effects concerning the health or safety of workers at particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with chemical agents. As mentioned above this is a potential issue, since this provision could apply to all hazardous chemical substances and not only to carcinogens and mutagens.

Reporting obligations. According to the CMD, the employer must, upon request, submit the findings of his investigations to the relevant authorities concerning the substitution of carcinogens and mutagens. The CAD, which also contains substitution requirements, does not contain such provision. This provision could however be applied to all chemical agents in order to enhance substitution to less dangerous chemicals. The reporting obligations under the Asbestos Directive are very specific to the risks derived from exposure to asbestos (e.g. notification prior demolition work) and cannot be replicated under the CMD.

exposure levels associated with estimated risks might need to be calculated by SCOEL. But it is not the remit of SCOEL to determine the acceptability of such risks. This is the responsibility of the Commission, and requires further consultation with pertinent groups (organisations/bodies).

For further details on the procedure of adoption of limit values please see the analysis under the CAD Specific Report.
Inspection and enforcement measures. The CMD does not include any provisions relating to inspections or penalties. This is also the case with the CAD. Of the three chemicals directives, only the Asbestos Directive provides for adequate penalties to be applicable in the event of infringement of the national transposing legislation. This does not seem to be justified by the scope of this Directive and such requirements should cover the OSH acquis as a whole (see relevant analysis in the Framework Directive report).

EU stakeholders’ views

One stakeholder stressed that the CAD and CMD were full of uncertainties and overlaps, and they had difficulties to clarify the boundaries (areas of application) of each Directive. They suggested that, in consideration of the similarity of objectives and the uncertainty deriving from the numerous overlaps, these Directives could work better if consolidated into a single text. This issue is discussed elsewhere.

One stakeholder identified overlaps between the CMD and that for pregnant workers in relation to lead exposure. However, this does not seem relevant as lead is covered by the CAD (which sets a Biological Limit Value) and not the CMD.

Information from the NIRs

One Member State mentioned that the Asbestos and CMD were supplemented by the CAD. They considered that it was inappropriate to bring the Directives together under one common regulation. They finally flagged that the division was easy to understand and to deal with, and that it supported chemical working-environment management at undertakings in a simple way.

With regard to internal coherence, this section focuses primarily on coherence between the CMD, and the other two chemical directives, CAD and the Asbestos Directive. No major internal coherence issues were identified. However, there were a number of provisions identified under the CMD that could potentially be applied to all hazardous chemical agents. The preliminary conclusions suggest reviewing the CAD to include these CMD provisions.

Findings related to coherence between the CMD and the Framework Directive are described and addressed in the Directive report on the Framework Directive. These findings are limited to some questions of overall coherence of the OSH body of legislation, whereby provisions of a general nature which could be considered as part of a framework have been introduced in the different daughter directives, including the CMD.
6.2 **EQC2: Coherence between the CMD and other EU measures and policies / international instruments (External coherence)**

**EQC2**: How is the interrelation of the Directives with other measures and/or policies at European level also covering aspects related to health and safety at work, such as EU legislation in other policy areas (e.g. legislation: REACH, Cosmetics Directive\(^59\), Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?

<table>
<thead>
<tr>
<th>Other EU non-OSH legal acts</th>
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<tr>
<td>This Directive does not apply to workers exposed only to radiation covered by the Treaty establishing the European Atomic Energy Community(^60).</td>
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**Legal links with other EU legislation**

**REACH and CMD coherence**

- Scope of application of the two pieces of legislation

Article 2(4) of Regulation (EC) No 1907/2006 (REACH) provides that REACH must apply without prejudice to Union workplace legislation, including among others the CMD.

- Reference to the CMD in the safety data sheets

Safety data sheets (SDSs) are the main tool for ensuring that suppliers communicate enough information along the supply chain to allow safe use of their substances and mixtures. Annex II to REACH, which set the requirements for the compilation of SDS, refers several times to the CMD. Those references relate to the use of data from the SDS generated through REACH in the implementation of OSH requirements or, conversely, the use of national exposure limit values established on the basis of EU OELs under the CMD to inform exposure controls and personal protection requirements in the SDS, which would in turn feed into the risk assessment undertaken by the employer:

- Section 7 of Annex II to REACH on handling and storage provides that SDS shall assist employers in devising suitable working procedures and organisational measures related to handling and storage of chemical substances in accordance with Article 5 of the CMD.

- Section 8 of Annex II to REACH on exposure controls and personal protection requires that the national exposure limit values established on the basis of EU OELs under the CMD, including their legal basis, should be provided. It also mentions that the description of appropriate exposure control measures shall be provided and it must relate to the identified

\(^59\) Now the Cosmetics Regulations

\(^60\) See article 1(2) of CMD.
use(s) of the substance or mixture as referred to in subsection 1.2 of this Annex. It adds that this information must be sufficient to enable the employer to carry out an assessment of risk to the safety and health of workers arising from the presence of the substance or mixture in accordance with Articles 3 to 5 of the CMD where appropriate.

Exposure limits: potential overlaps

Under REACH, manufacturers or importers manufacturing or importing more than 10 tonnes of a chemical substance subject to registration must derive levels of exposure to the substance above which humans should not be exposed, known as Derived No Effect Levels (DNELs) in their registration dossier (see Annex I point 1 of REACH). These DNELs must also be included in the SDS together with the national exposure limit values established on the basis of EU OELs under the CMD. The DNELs and OELs applicable to the same chemical may differ. This can raise confusion as to which value must be applied. These inconsistencies are most likely to happen in the case of substances covered under the CAD where a significant number of chemical agents with OELs compared to the CMD (i.e. Benzene, Vinyl chloride monomer). See the Directive Specific Report on CAD for further analysis and recommendations concerning the overlaps between DNELs and OELs.

Substitution requirements under REACH and the CMD

As mentioned above, the CMD provides that the employer must reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers’ health or safety, as the case may be.

Under REACH the substitution principle applies both under the provisions on restriction and authorisation. In the case of restriction, substitution is encouraged by the limitations (which may be a prohibition) imposed on the manufacture, use and/or placing on the market of the substance while the authorisation process puts pressure on companies to move to alternatives

One could argue that REACH will generate more data that will support employers to identify less hazardous chemical substances than the ones previously used.

Wording inconsistency on exposure reduction

Article 60(10) of REACH on the granting of authorisation provides that "notwithstanding any conditions of an authorisation, the holder must ensure that the exposure is reduced to as low a level as is technically and practically possible". However Article 5(3) of the CMD provides a slightly different wording "the employer

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61 Information on currently recommended monitoring procedures must be provided at least for the most relevant substances.
must shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible”.

› Information generated under REACH fed into employer risk assessment

Employers carrying out risk assessment procedures and setting management measures under the CMD must rely on information transmitted down the supply chain through the safety data sheets under REACH (including results of the Chemical Safety Assessment (CSA), such as exposure scenarios, and information on exposure control measures and on handling and storage).

However some employers expressed their concern on the difficulties they encounter to use information from the SDSs. They stress that it is a very complex and burden exercise to use information from SDSs.

Difficulties arise because of the size and level of detail contained within these documents, meaning that some employers find it difficult to locate the information relevant to their assessment. This is a particular issue for SMEs where staff often lack specialist OSH knowledge and need to obtain information in an accessible and quickly understandable form. Lengthy legalistic documents tend to create a barrier to their use.

In situations where SDSs do not match the specific conditions of use of downstream users (e.g. employers) these downstream users should communicate their conditions of use to their chemical supplier, potentially leading to the revision of the SDSs.

Preliminary conclusions:

› To prepare awareness raising campaigns (e.g. through the REACH helpdesks and labour inspections or EU OSHA) to inform employers on how to use the SDSs (e.g. the risk management measures under Annex II Section 8.2.1 of REACH) in order to ensure that they are able to extract relevant information from the SDSs to fulfill their obligations under the CMD.

› To improve the usability and readability of SDSs for OSH purposes

› REACH and CMD: a different approach to threshold for carcinogens and mutagens

Note that, as discussed earlier, the REACH Regulation distinguishes between threshold and non-threshold carcinogens and mutagens whereas the CMD using a more precautionary approach only sets two limit values for carcinogens and is clearly using a non-threshold approach by requiring that occupational exposures are avoided/minimised as far as technically feasible. As discussed previously, the

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62 Derived Minimum Effect Levels (DMELs) must also be set by registrants for substances where no safe threshold can be set (e.g. carcinogenicity).

63 At the time of adoption of the CMD it was considered by the scientific community that no-effect threshold levels could be reliably established for carcinogens and mutagens.
emergence of evidence for a threshold effect for some carcinogens or mutagens would require the provisions of the CMD to be reconsidered.

It is important to note that binding OELs under CMD are adopted through the normal legislative procedure (See Article 16 of the CMD) whereas DNELs are either set by registrants or ECHA’s committee for Risk Assessment. Therefore their adoptions and entry into force are much faster and easier than binding OELs under CMD.

Another point to be considered is the derivation of “practical level” for the non-threshold substances. Currently different methodologies apply under REACH and OSH and this does not help the companies in particular when preparing an authorisation application under REACH or when they are challenged by their assessment on the proper control of the risk by the enforcement Authorities.

Preliminary conclusions:
› To review the scientific methods for the determination of binding OELs under CMD to ensure consistency and coordination with DNELs for threshold carcinogens under REACH.
› In the review of the CMD to take into account the existence of threshold and non-threshold carcinogens and mutagens and the adequate risk management measures for these two types of carcinogens and mutagens.
› To find out scientific solution in order to have better understanding of the risk assessment approach and the appropriateness of risk management measures for threshold as well as non-threshold substances.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (hereinafter the CLP Regulation) entered into force on 20 January 2009. The CLP Regulation was adopted to align EU law to the United Nations Globally Harmonised System criteria for classification and labelling of hazards at the global level, in order to facilitate trade while protecting human health and the environment. Title II of CLP Regulation puts in place the procedures for classification. It requires manufacturers, importers and downstream users to identify and examine available information on potential physical, health and environmental hazards of substances and mixtures, and regulates the methods for the generation of new information. The information gathered and generated must then be evaluated by the duty holders for the purpose of classification. Title III provides rules for labelling of substances and mixtures according to any hazard identified. Title IV sets in place requirements for the packaging of hazardous substances or mixtures (design, materials, fastenings). Finally, Title V refers to the harmonised classification and labelling of substances.

The CMD was recently amended by Directive 2014/27/EU in order to align the previous classification and labelling system with the new system laid down in the

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CLP Regulation (CLP). As underlined by the Commission guidance on the new labelling systems, employers will have to apply the provisions of the CLP and/or take into account the information on hazards contained in the labels and in the safety data sheets provided for in REACH Regulation when they carry out the preventive and protection measures in accordance with the CMD (e.g. identification of hazardous chemicals, substitution requirements, risk assessment).

Some EU stakeholders have indicated concerns regarding an apparent inconsistency in that a note in the CLP (Note Q Annex VI) provides conditions for an exclusion from labelling requirements in relation to man-made mineral fibres:

“The classification of a man-made mineral fibre as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:

- a short term biopersistence test by inhalation has shown that the fibres longer than 20 μm have a weighted half-life less than 10 days; or
- a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 μm have a weighted half-life less than 40 days; or
- an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or
- absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.”

This exclusion deals with mineral fibres which have a wide range of possible chemical compositions and physical structure and characteristics. The hazard is mainly thought to be related to the shape and resultant biopersistence of the material. The concern, expressed by some EU stakeholders was that the note, reproduced above, sets out circumstances where classification of mineral fibres as a carcinogen need not apply. This is however consistent with the current scientific evidence which shows that not all MMMFs are equally harmful and is not an example of incoherence between the CLP and CMD. MMMF recognised as carcinogenic still have to be labelled (and treated) as such. Such concerns possibly reveal a need for improved guidance on this issue to clarify the situation. Assuming the recommendation is approved, such guidance could perhaps also reflect and

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65 European Commission, Chemicals at work – a new labelling system, Guidance to help employers and workers to manage the transition to the new classification, labelling and packaging system (February 2013)
explain the (SCOEL 2012 recommendation) assignment of an IOEL to all those fibres not subject to more specific (stricter) provisions.

Apart from this apparent inconsistency, no coherence issues are identified between the CMD and the CLP Regulation.


Other EU Policies

The European Parliament and the Council of the European Union have adopted in November 2013 a general Union action programme in the field of the environment for the period up to 31 December 2020 ('the 7th Environment Action programme' or '7th EAP').

On the EU policy on chemicals it stresses that in order to safeguard the Union’s citizens from environment-related pressures and risks to health and well-being, the 7th EAP must ensure that by 2020:

› the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed in all relevant Union legislation, and risks for the environment and health, in particular in relation to children, associated with the use of hazardous substances, including chemicals in products, are assessed and minimised. Long-term actions with a view to reaching the objective of a non-toxic environment will be identified;

› the use of plant protection products does not have any harmful effects on human health or unacceptable influence on the environment, and such products are used sustainably;

› safety concerns related to nanomaterials and materials with similar properties are effectively addressed as part of a coherent approach in legislation.

The ‘7th EAP’ then provides that to achieve this goal it requires:

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67 Recommendation from the Scientific Committee on Occupational Exposure Limits for man made-mineral fibres (MMMF) with no indication for carcinogenicity and not specified elsewhere. SCOEL/SUM/88 March 2012
Continuing to implement REACH in order to ensure a high level of protection for human health and the environment as well as the free circulation of chemicals within the internal market while enhancing competitiveness and innovation, while being mindful of the specific needs of SMEs. Developing by 2018 a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions, building on horizontal measures to be undertaken by 2015 to ensure: (1) the safety of manufactured nanomaterials and materials with similar properties; (2) the minimisation of exposure to endocrine disruptors; (3) appropriate regulatory approaches to address combination effects of chemicals and (4) the minimisation of exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances;

Monitoring the implementation of Union legislation on the sustainable use of biocidal products and plant protection products and reviewing it, as necessary, to keep it up to date with the latest scientific knowledge.

Finally the 7th EAP mentions that in order to develop a comprehensive approach to minimising exposure to hazardous substances, in particular for vulnerable groups, including children and pregnant women, a chemical exposure and toxicity knowledge base will be established. It stresses that this knowledge base, together with the development of guidance documentation on test methods and risk assessment methodologies will accelerate efficient and appropriate decision-making, which is conducive to innovation and the development of sustainable substitutes including non-chemical solutions.

None of these measures are particularly targeted to workers exposed to hazardous chemical agents. Such measures (e.g. the establishment of a knowledge base, the substitution of hazardous substances) will however have a positive impact on, and potential synergy with, the application and implementation of the CMD.

Although respirable crystalline silica is not included in the CMD, it is worth mentioning the NEPSI Agreement between the social partners on workers' health protection addresses the handling and use of crystalline silica and products containing it⁶⁹. It was signed by 17 industry associations where workers are exposed to crystalline silica which can lead to lung cancers – although notably the construction sector, where a significant proportion of worker exposure to silica occurs, is currently not covered. The aim of this Agreement is:

- to protect the health of employees and other individuals occupationally exposed at the workplace to respirable crystalline silica from materials/products/raw materials containing crystalline silica

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to minimise exposure to respirable crystalline silica at the workplace by applying Good Practices in order to prevent, eliminate or reduce occupational health risks related to respirable crystalline silica.

To increase the knowledge about potential health effects of Respirable crystalline silica and about Good Practices in particular by research and monitoring and dissemination of good practices.

Annex I to this Agreement contains good practices which provide a detailed description of silica and of industrial activities involving occupational exposure to respirable crystalline silica and it potential health effects. These guidelines also contain proposed measures on how to assess whether there is a significant risk from exposure to respirable crystalline silica, how to decide what type of control and prevention measures should be put in place to eliminate or to reduce them to acceptable levels and how to monitor the effectiveness of the control measures and workers health. The guidelines also set recommendation for the information, instruction and training of workers exposed to respirable crystalline silica.

Such guidelines are based on the requirements of the OSH EU legislation and are in line with the CAD and CMD. Overall no coherence issues were identified between the OSH EU chemical legislation and this Agreement.

The 1974 ILO Occupational Cancer Convention (No. 139) has been ratified by 15 EU MS.

The ILO Occupational Cancer Convention requires the State parties to periodically determine the carcinogenic substances and agents to which occupational exposure shall be prohibited or made subject to authorisation or control, and those to which other provisions of the Convention apply. Moreover, according to the Convention, exemptions from prohibition may only be granted subject to a certificate specifying in each case the conditions to be met.

Overall, the ILO Occupational Cancer Convention and the CMD are based on the same principles (replacement and reduction, protective measures and recording, information for workers, medical examinations) and the two instruments follow a consistent approach.

One stakeholder pointed out that REACH does not distinguish between chemicals falling within the scope of the CAD and those falling within the CMD.

Several stakeholders refer to the interfaces between EU OSH legislation and REACH without mentioning the CMD. One stakeholder provided that information within the safety data sheets prepared as per REACH would help the employers to perform risks assessment, to procure personal protective equipment and to train the workers.

Another stakeholder highlighted the interactions between REACH and the CMD and CAD, stressing that all these instruments impose requirements on the use of hazardous chemicals in the workplace, and that employers would find themselves faced with two sets of duties. The stakeholder underlined that although REACH
and these two directives should ultimately complement one another, their requirements were considered to overlap to some extent, which could give rise to inconsistencies in their application.

Information from the NIRs

One Member State mentioned that the requirements on exposure scenarios according to REACH would differ in a number of cases from the requirements imposed under the CMD and CAD.

Another Member State considered that it was challenging, particularly for SMEs, to gain an overview of the various EU rules, for instance the CMD and CAD and REACH and CLP, which regulate the chemicals sector as a whole.

EQC2: Answer

Concerning external coherence, the main issues identified relate to the interfaces between REACH and the CMD.
7 Conclusions and recommendations

7.1 Implementation

This Directive and CPMs have been transposed into multiple pieces of legislation in the vast majority of the 27 MSs, with only seven of the MS transposing it into one piece of legislation. Examination of the country summary reports shows that no infringement proceedings for non-communication of transposing measures were initiated in any of the MSs. There were two instances of observed discrepancies in the transposed MS legislation although one was considered to be relatively minor.

Over half of the MSs implemented more detailed requirements for Article 3 (risk assessment) and Article 14 (health surveillance). Fifteen of the MSs implemented more detailed requirements for Annex II (practical recommendations for the health surveillance of workers).

The CMD does not contain any provisions for extended deadlines or for derogations.

The data from the MSs used to assess the degree of fulfilment was quite sparse. Only nine of the 27 MS presented any degree of compliance data for the CPMs, for all establishments. These reported degrees of compliance ranging from 14% up to 93% across all the CPMs. Because these findings are drawn from a minority of MSs care should be taken in extending them to the wider EU-27.

When considering size of establishment, no data or estimates were available reflecting any differences in compliance between those of different sizes. However, SMEs were discussed in the NIRs. Fifteen of the 27 MSs discussed specific issues SMEs or micro enterprises have had when trying to comply with the provisions of the legislation.

No data were available to allow the separate consideration of public and private sectors or the various industrial sectors.

Additional information on compliance with one specific requirement, substitution, was available from the NIRs. This indicated a patchy picture with only limited
quantitative data, some qualitative information and many MSs unable to provide any formal indication of compliance. As with other material, data on the extent of implementation of substitution gives little insight into the proportion of those instances where substitution was possible but not implemented.

**Supporting actions**

Guidance documents were by far the most employed action within MSs, with sixteen of the 27 MSs having developed at least one guidance document. At the EU level, a considerable number of accompanying actions were identified in relation to dangerous or hazardous substances, although none appeared to focus specifically on carcinogens and mutagens. None of the MSs answered yes when asked directly whether there were any gaps. No data is available on the extent to which establishments used the available accompanying actions.

**Enforcement**

Nine of the 27 MSs have specific enforcements strategies or procedures for the implementation of this Directive. Twelve of the MSs have specific criminal or specific sanctions for this Directive. However, only three of the MSs have a specific authority responsible for the enforcement of this Directive. The enforcement of the CMD is in most cases the responsibility of the general authority for inspections/enforcement.

**Vulnerable groups**

There were only two MSs where specific tools or approaches focussed on particular vulnerable groups were identified. Both France and the Netherlands provided specific provisions for pregnant workers. Otherwise, however, a general approach to vulnerable groups is adopted amongst the MSs.

**SMEs and microenterprises**

In general, MSs have not developed specific measures to support SMEs and microenterprises. Only three of the MSs provide lighter regimes and only three MSs provide financial support for SMEs and microenterprises. Furthermore, only two of the MSs have included specific exemptions for SMEs or microenterprises. It is worth noting here that in comparison to the majority of the OSH 24 Directives this Directive prompted more MSs to develop specific measures for SMEs and microenterprises than most other Directives.

**Current relevance**

The Directive has been transposed into national legislation in all MSs according to evidence from the NIRs. The possibility of exposure to potential carcinogenic substances covered by the CMD can be identified in each MS. On this basis the Directive can be regarded as relevant in all MSs. Estimates based on employment within appropriate industrial sectors suggest that the CMD is potentially relevant to 12.3% of the EU workforce.

Details of the extent to which workers in the EU are potentially exposed to carcinogenic substances are patchy. AN EU-OSHA Risk Observatory report commented that information on the numbers of exposed workers and their levels of exposure over time and on the health effects of the exposures is not usually available. Eurostat data indicates that carcinogens, mutagens (or reprotoxins) continue to be produced in considerable quantities within the EU-28, although there has been a decline in recent years. Such data gives no indication of worker
exposure although it could be regarded as indicating at least the potential for exposure. One study (SHEcan) provided estimates for some substances, suggesting considerable potential for exposure and this, supplemented by estimates from national studies suggests that workers in the EU-27 continue to be potentially at risk from exposures to carcinogenic and mutagenic substances and that there is therefore an ongoing need to control such exposures to remove or reduce the risks.

With many of the OSH Directives, EU databases and surveys of work-related health problems can be of use in assessing the ongoing relevance of the provisions of directives. Given the difficulties due to the long latency of most forms of cancer, consideration was given to whether some insight might be obtained by exploring some of the early signs and symptoms of cancers which might be reflected in such reported problems. However, although some forms of cancer do result in early signs or symptoms such as breathing difficulties, it was recognised that it was not possible to differentiate the proportion of such symptoms attributable to cancer from more benign causes. Furthermore, the long period of latency of many cancers, and the delay before many mutagenic changes become manifest, makes it difficult to establish the current level of problem.

One study has estimated that overall, 8,010 (5.3%) total cancer deaths in Britain and 13,598 cancer registrations were attributable to occupation in 2005 and 2004, respectively. In addition, the NIRs asked two specific questions relating directly to cases of occupational cancer relating to the incidence of deaths and new cases. As with many of the other questions asked in the NIRs, responses to these were patchy and varied widely in detail. In addition, in most cases it is not clear whether the figures include those relating to asbestos exposure, or whether they relate to exposures to carcinogens not covered by the CMD. Nevertheless, collectively, this material, as well as the substance specific studies identified, gives a strong indication that this Directive remains relevant.

Any extrapolation of these figures to the EU-27, as well as the other studies reported, gives a strong indication from health outcomes that this Directive remains relevant.

One key issue discussed which relates to the future relevance of this Directive is the latency effects of relevant exposures. As discussed by SLIC the full impact of the Directive may still not be known for 15-20 years due to the length of time it can take for exposure to some carcinogens or mutagens to display effects, and thus to be able to measure whether the controls are protecting the workers. Therefore, it could be argued that the Directive remains relevant until such time that the data allows the controls to be assessed.

Confusion over OELs was discussed by some EU stakeholders. It was considered that the knowledge base on which OELs are based on may be questionable and needs to be developed to ensure the accuracy of OELs. One stakeholder confirmed support for the notion of merging this Directive with the Chemical Agents Directive.
At the time of publication of the CMD it was considered that “current scientific knowledge is not such that a level can be established below which risks to health cease to exist” (Preamble, paragraph 11). However, there is now evidence that scientific knowledge now does allow the identification of safe thresholds for certain carcinogens. Clearly this is an issue for the SCOEL to consider and to reflect in any future recommendations.

From the national expert interviews there was a complete consensus on the continued future relevance of the Directive. However, several stakeholders considered the need to incorporate potential risks of exposure to nanomaterials in the provisions of this Directive.

From the NIRs two explicit recommendations were offered to ensure the future relevance of the Directive. Austria recommends that the scope of the Directive should be extended to substances and compounds toxic to reproduction. Greece recommends that the Directive be supplemented on the basis of more recent Regulations already in force.

The issue of the inclusion of reprotoxins (not all of which are mutagenic) within a widened scope of the CMD has been explored extensively at EU level and was reviewed. It was noted that over a third of MSs already accommodate many of them (CLP, R1A and 1B) within their equivalent legislation suggesting a degree of tacit support for such a measure. However, it is suggested that including consideration of reprotoxins and how best to control the risks they present within a wider debate over the future of the CAD and CMD provides the best option given the current lack of detailed data.

7.3 Effectiveness

Overall effectiveness

There is little objective data relating to the influence of the CMD on workers’ safety and health and none regarding the activities of workers’ representatives, and the behaviour of establishments.

Subjectively, among EU stakeholders, there is the view that the CMD has had a moderate effect on the safety and health of EU workers. Employers and experts rate the effect higher than workers organisations.

Data from the production of chemicals suggests that there has been a slight reduction in recent years in the production of chemicals grouped as ‘carcinogens, mutagens or reprotoxins’, both in absolute terms and as a proportion of total chemical production. Such data provide no direct insight into worker exposure although they could be regarded as reflecting the ‘potential’ for exposure. However, such changes can be a function of many influences and there is no information to suggest that the provisions of the CMD (for example substitution) have had any discernible impact.

Data on the impact of the CMD on health outcomes is not available because of the long latency period for most cancers. However, some insight can be gained from estimates of exposures to carcinogens. Comparisons between estimates for 1990-3 of the numbers exposed in to the ten most common carcinogens, against similar
estimates for 1999 suggest that there has been only a slight decrease in the total exposures to these ten agents. Although both periods predate the adoption of the CMD, and therefore offer little insight into the impact of the CMD, the fact that this is the most recent data illustrates the paucity of information.

Not all of these are covered by the CMD although many are included on a list of carcinogens which the Advisory Committee on Safety and Health proposes adding to Annex III of the CMD. These figures represent a change from the EU-15 (1990) to EU-19 (1999) and cannot therefore be used to determine any detailed trends. However, the slight decrease in the total exposures (700,000) could be taken to imply that the addition of additional MSs masks a larger fall within the EU-15.

National data presents a mixed picture (with caveats about extrapolating from them to the whole EU).

The Carcinogens or Mutagens Directive does not contain any provisions for extended deadlines or for derogations.

No objective data are available which enable the effectiveness of individual CPMs to be explored. However, subjective views were gathered from four national stakeholders from four MSs. National stakeholders from these MSs at least are of the view that training and risk assessment are the most important factors contributing to the effectiveness of the Directive. They give some importance to information, relatively little importance to worker consultation and health surveillance, and no importance to ensuring prevention services.

No objective data are available which enable the effectiveness to be explored of individual enforcement activities for the CMD. Interview responses from stakeholders were analysed as a source of subjective opinion. The responses from these interviews, however, offered nothing in the way of a consensus as to how effective the enforcement activities related to this Directive has been in terms of SMEs and larger enterprises. Having said that the overall opinion on how effective the enforcement activities have been across the industry types is that they have had a fairly average effect.

### 7.4 Coherence

With regard to internal coherence, this report focused primarily on coherence between the CMD and the other two chemical directives; the CAD and the Asbestos Directive. No major internal coherence issues were identified. However, there were a number of provisions identified under the CMD that could potentially be applied to all hazardous chemical agents. ‘Preliminary conclusions’ make suggestions for rectifying these inconsistencies of approach although, in most cases, the alternative suggestion is made that merging the two directives would provide a more coherent legal framework for the management of all chemical substances.
Concerning external coherence, the main issues identified relate to the interfaces between REACH and the CMD. The debate shares many issues with the parallel debate over REACH and the CAD and the CAD report should be seen for this text.

7.5 Overall discussion

As with the CAD evaluation, a key issue concerning the CMD would seem to be that of merging the CAD and CMD. As noted in the CAD report discussions at the seminar held to discuss some of the main findings emerging from the study ("validation seminar") revealed that there was no clear consensus amongst the stakeholders present. Although there was some variation within stakeholder groups it seemed that the main differences of opinion reflected a worker-employer split, with most (but not all) employers favouring a merger but workers preferring to retain the two Directives. There was a suggestion that merging the two might make compliance and risk management easier for SMEs and it was argued that merging of directives would be beneficial, reducing duplication and removing confusion amongst employers.

Others argued that there is no need to merge the directives as it is open to MSs to implement their provisions within a single legislative instrument (it was noted by some that some MSs e.g. UK, had already done so); and that any such changes would be burdensome for MS in having to alter legislation.

Assessments of legal coherence identified a number of provisions under the CMD that could potentially be applied to all hazardous chemical agents. Preliminary conclusions make suggestions for rectifying these inconsistencies of approach although, in most cases, an alternative suggestion would be the suggestion to merge the two directives. However, although from a legal perspective this would provide a more coherent legal framework (for the management of all chemical substances) there is no clear consensus for such a view and no objective evidence on which to base a firm recommendation one way or the other.

It has also been suggested that the scope of the CMD should be amended to include all substances of very high concern such as reprotoxins, as such substances are often classified with carcinogens and mutagens elsewhere. It would seem that including consideration of reprotoxins (together with other substances classified according to their main effect) and how best to control the risks they present within a wider debate over the future of the CAD and CMD provides the best option given the current lack of detailed data.

In any case combined legislation would need to contain the same provisions as currently found in the CAD/CMD to ensure adequate worker protection. Some were of the opinion that the greater hazard associated with carcinogens justified a separate Directive. In this context concerns were expressed that merging the Directives would, in some way, lead to a downgrading of the importance to be placed on carcinogens.

This issue, of the possible merging of the CMD and CAD, is examined in the CAD report.
Another key issue, shared with a great many of the other Directives is the absence of data relating either to implementation of the provisions of the CMD or its impact in terms of reduction in occupational cancers. Article 6 of the Directive provides for the collation by employers of information for the competent authority which is to be made available in request. Such information should include:

(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens or mutagens are used;
(b) the quantities of substances or preparations manufactured or used which contain carcinogens or mutagens;
(c) the number of workers exposed;
(d) the preventive measures taken;
(e) the type of protective equipment used;
(f) the nature and degree of exposure;
(g) the cases of replacement.

As this information has to be collected by employers, making it a requirement for this to be transmitted to the competent authority (rather than on request) would not place a large additional burden on them but, collated at a national level (and then at an EU level), such information would be of great value in future impact evaluations. Given the existing wording, such a move would not require the Directive to be amended in any way subject to an agreement by MSs to exercise their existing right to request that the information be provided.

Similarly, Article 14(8) requires all cases of cancer identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen or mutagen to be notified to the competent authority. From the returns provided in the NIRs it is not clear to what extent this is currently happening. Again, this provides an opportunity within the existing provisions of the CMD to generate a valuable source of data for the future. Clearly, as a corollary to this, increased consensus over the definition and diagnosis of cancers as occupational will be beneficial.

7.6 Overall Recommendations

Although there are legal rationales for doing so there would appear to be no consensus on the idea of merging the CAD and CMD. This suggestion is discussed further in the CAD report. However, either separately, or as part of any wider discussions, consideration should be given to exploring the scope of the CMD to determine whether or not other substances (e.g. reprotoxins) should be included within it.

Existing provisions within the CMD for providing information to the competent authority and for notifying the competent authority of diagnosed cases of occupational cancer provide a valuable opportunity to collect better data nationally on both exposure and health consequences and collating this at EU-level.
Consideration should be given to encouraging MSs to exercise their right to request the information (and to enforce reporting of cancer cases) to provide the basis of a considerable enhancement of knowledge regarding the impact and effectiveness of the CMD.
Appendix A  References


