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

REPORT BY DIRECTIVE: DIRECTIVE 98/24/EC ON THE PROTECTION OF WORKERS FROM THE RISKS RELATED TO CHEMICAL AGENTS AT WORK
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<td>Advisory Committee on Safety, Hygiene and Health Work</td>
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<td>CAD</td>
<td>Chemical Agents Directive</td>
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<td>CLP</td>
<td>Classification, Labelling and Packaging</td>
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<td>CMD</td>
<td>Carcinogens or Mutagens Directive</td>
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<td>Chronic Obstructive Pulmonary Disease</td>
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<td>Common processes and mechanisms</td>
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<td>DALY</td>
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<td>EQC</td>
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<td>ER</td>
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<td>ESAW</td>
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<td>ESENER</td>
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<td>EU</td>
<td>European Union</td>
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<td>EU-OSHA</td>
<td>European Agency for Safety and Health at Work</td>
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<td>European Working Conditions Survey</td>
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<td>ILO</td>
<td>International Labour Organisation</td>
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<td>KPIs</td>
<td>Key Performance Indicators</td>
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<td>Key requirement</td>
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<td>Occupational Contract Dermatitis</td>
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<td>Acronym</td>
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<td>OEL</td>
<td>Occupational Exposure Limit Value</td>
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<td>OLV</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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<td>SCOEL</td>
<td>Scientific Committee on Occupational Exposure Limits for Chemical Agents</td>
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<td>SDS</td>
<td>Safety Data Sheet</td>
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<td>SME</td>
<td>Small and Medium-sized Enterprises</td>
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<td>SLIC</td>
<td>Senior Labour Inspectors Committee</td>
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<tr>
<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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<td>TS</td>
<td>Tender Specifications</td>
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Executive summary

The Chemical Agents Directive (CAD) lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. It places obligations on the employers to determine whether any hazardous chemical agents are present at the workplace and to take steps to assess (and reduce) any risk to the safety and health of workers arising from the presence of those chemical agents.

Exposure to chemical agents can lead to many potential health consequences, ranging from acute effects – such as accidental burns from strongly acidic or alkaline materials – to long-term insidious (long-latency) effects such as silicosis.

The physical nature of the material can also influence its toxicity/harmfulness, for example, inhaling dusts or harmful liquid chemicals being absorbed through the skin. The mode of exposure can also play a role, both in terms of the mode of ingress/impact (dermal, respiratory, ingestion) and the resultant health effects (e.g. occupational asthma or other respiratory sensitisation).

Requirements of the CAD embody the principles of assessment, with a preference for either elimination or substitution of hazardous chemicals:

- Assessment of the risks associated with the use of a given chemical;
- Elimination of the need to use the chemical, or
- Substitution with a different (safer) chemical or
- Substitution with a different physical form of the same chemical.

Where the use of a hazardous chemical is unavoidable, employers are required to adopt protective and preventive measures including (in order of priority):

- design of appropriate work processes and engineering controls;
- application of collective protection measures at the source of the risk;
• application of individual protection measures including personal protective equipment.

Methodology

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.

Objectives

As noted above, the objective of the CAD is to protect workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents in the workplace or as a result of any work activity involving chemical agents.

Provisions

The CAD requires employers to comply with a number of provisions relating to:

• Assessment of the risks associated with the use of a given chemical;
• Elimination of the need to use the chemical;
• Substitution with a different (safer) chemical;
• Substitution with a different physical form of the same chemical.

Where the use of a hazardous chemical cannot be avoided, then employers are required to adopt protective and preventive measures to eliminate or reduce to a minimum any risks arising from its use including, (in order of priority):

• Changing the design and organisation of systems of work at the workplace;
• Providing suitable equipment (and maintenance procedures) for work with chemical agents;
• Reducing the number of workers exposed or likely to be exposed;
• Reducing the duration and intensity of exposure;
• Implementing appropriate hygiene measures;
• Reducing the quantity of chemical agents present at the workplace;
• Ensuring suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents.

As appropriate, priority shall be given to the design of appropriate work processes and engineering controls and the application of collective protection measures at the source of the risk, over the application of individual protection measures including personal protective equipment.
Implementation

Most MSs have implemented the CAD in one rather than several pieces of legislation. Although there are some minor variations in detail in implementing the separate CPMs (and KR) they appear generally to function as a coherent legal entity.

Evaluation of the transposition of the CAD into national legislation showed that a number of Member States had some apparent discrepancies between the Directive and national legislation. However, in most cases, this related to the setting of Occupational Exposure Limit (OEL) values which differed from the EU indicative OEL. However, indicative OELs are not binding and therefore these differences do not constitute a failure in transposition.

All MSs have some more stringent requirements than those set out by the Directive, again mainly relating to limit values.

There are considerable variations in the number of OELs adopted by different MSs. This appears to be a function, at least in part, of the evolving knowledge regarding the potential harmfulness of such substances and the relative ease with which individual MSs can introduce new limits compared to the protracted process of such change at the EU level. The transmission from MSs of the rationale for any differences in limit values should aid the SCOEL in determining where new limits are justified.

Some MSs also provide a more detailed specification for the risk assessment, embodying features which, in other MSs, might be included within guidance material. These include: specifying that all potential channels for exposure must be considered (e.g. inhalation, skin absorption, ingestion); indicating the nature of the person or persons who should carry out an assessment (including the involvement of a physician in certain circumstances); and references to the need, in particular, to consider mixtures of chemicals.

Compliance

Data on levels of compliance with the requirements of the Directive is quite scarce. In some instances, national experts provided an estimate of compliance based on their own knowledge and experience. In some such cases they felt unable to differentiate degrees of compliance with individual provisions, providing an overall estimate of compliance. For those Member States where data are available, the level of compliance with the common processes and mechanisms (CPM) appears very variable, ranging from 10% to 93% across different CPMs. This suggests an effective range from almost no compliance to almost complete compliance in different MSs. This finding would appear in general terms to echo those of an earlier directive-specific study which found poor levels of compliance and poor quality of risk prevention amongst those who had complied.

Although no numerical data are available, subjective opinion from national experts seemed to suggest that compliance was generally related to employer size (increasing with increasing size). This view was supported by national implementation reports. However, it is not clear to what extent these opinions are based on directive-specific appraisals or general views of OSH compliance. However, it is a view supported by other sources.
Opinions are divided as to the extent to which SMEs had problems with complying. However, it should be noted that no evidence of a problem (as reported in a number of NIRs) is different from evidence of no problem. No information is available regarding differences in compliance between sectors or between public or private enterprises.

On substitution, responses varied from substitution being difficult and constituting an extremely rare or one-off event to it not being difficult – but with room for improvement. A number of MSs indicated that it seemed to be more common in certain sub-sectors or product groups.

Guidance documents are by far the most common action undertaken by Member States to support the implementation of the legislation transposing the CAD, although awareness campaigns and support tools are both commonly actioned.

Extensive guidance material is also available at EU level including six different guidance/guideline documents from the Commission and over 25 E-facts, over 20 Reports, over 15 factsheets and up to 20 reviews and summaries from EU-OSHA which includes some material for employers and health and safety practitioners along with separate guidance for workers.

Generally, the Member States consider that available information and guidance is sufficient. However, some national implementation reports which highlight challenges to SMEs also mention lack of knowledge about measurement, risk assessment and risk reduction methods, etc. which could indicate a need for additional accompanying actions in this area. However, the extensive amount of material already available, including that at EU level, suggests that the problem might be more one of adequate communication rather than a need for additional material. No evidence is available over the usage of such material or how beneficial it was found to be in practice.

Few Member States have designated a specific authority responsible for the enforcement of the CAD with enforcement typically coming under the general authority responsible for OSH inspections/enforcement. Also, Member States seldom have criminal or administrative sanctions, which are specific to offences which are committed under the legislation concerning chemical agents.

The findings from the national studies show that most Member States have general approaches to vulnerable groups, which are not targeted at specific Directives (except the following Directives, which are specifically designed to address vulnerable groups: Temporary Workers Directive; Pregnant Workers Directive; Young People Directive).

Estimates based on employment within appropriate industrial sectors suggest that the CAD is potentially relevant to 45.2% of the EU workforce, with the addition of an estimated 10% self-employed workers making a total of 50%.

ESAW statistics on fatal and non-fatal accidents at work do not give any indications as to whether any of the injuries recorded arose from exposure to chemicals. To some extent, this appears to arise from differences in defining and reporting such
accidents between MSs, making collation of disparate sources at an EU level problematic.

However, statistics are recorded for accidents arising from contact with “chemical, explosive, radioactive, biological substances - not specified”. Although not exclusively concerning chemicals this database records that, in 2005 there were 40,411 such accidents (representing an incidence rate of 36.9 injuries resulting in more than three days lost per 100,000 employed), or 0.6% of the total.

There are also limitations in the data available relating to health problems arising from chemical exposures. LFS (2007) data indicates that 3.6% of respondents reported experiencing work-related pulmonary disorders in the last 12 months whilst 1.8% reported occupational skin problems. Whilst chemical agents were not necessarily responsible for these problems they are common causes of such problems. This would seem to illustrate the ongoing relevance of controlling chemical exposures in the workplace and therefore of the Chemical Agents Directive. However, LFS surveys only record what is regarded as the most serious health problem experienced by a respondent so these values should be regarded as indicating a minimum affected.

EWCS 2010 data shows that 16.5% of respondents reported breathing in smoke, fumes, powder or dust, doing so at least a quarter of the time. For breathing in vapours such as solvents and thinners, and handling or being in skin contact with chemical products or substances the equivalent values were 10.4% and 14.7% respectively. Plotting the reported duration of such factors against those reporting breathing difficulties and skin problems shows a trend for increasing likelihood of reporting such problems with increasing daily duration of exposure.

Data on the production of chemicals in the EU indicate a gradual decline in the production of chemicals classified as toxic from 2007-2013, largely in line with an overall reduction in chemicals production in the EU.

One difficulty in interpreting any data sources is that many of the health problems related to chemical exposures are of a long-latency and might not be apparent until some time has elapsed, possibly after the work has left the employment or when exposure has ceased. However, the need for better data is a common issue across many of the safety and health issues covered by the 24 OSH directives and is discussed in more detail elsewhere.

National data is available to support the ongoing relevance of this Directive. For example, data from one MS (France) identifies the six highest risk occupations for occupational asthma as car painters, hairdressers, woodworkers, cleaners, and healthcare workers. The most often implicated agents were isocyanates, latex, alkaline persulphates and aldehydes.

Another significant health problem related to chemical exposures is chronic obstructive pulmonary disease (COPD). In one MS (UK) it is estimated that over a million individuals currently have the disease in Britain with over 25 000 deaths each year. Although the most important cause of COPD is smoking, past exposures to fumes, chemicals and dusts at work will have also contributed to
causing many currently occurring cases and it is estimated that about 15% of COPD is likely to be work-related. Workplace exposures likely to contribute to this COPD burden include various dusts (including, coal, grain, and silica) as well as certain fumes and chemicals (including welding fume, isocyanates, and polycyclic aromatic hydrocarbons).

Thus it is clear that exposure to chemicals makes a significant contribution to respiratory health, reinforcing the view that the CAD is and is likely to remain of considerable relevance.

New and emerging risks

In 2008, EU-OSHA stated that skin diseases were one of the most important emerging risks related to the exposure to, and extensive use of, chemicals. As noted above, almost 2% of the EU workforce reports such problems, although it is not apparent what proportion of these attribute such problems to exposure to chemicals.

Future relevance issues

In terms of future relevance, a number of issues raised in respect of the future relevance of the CAD. The first were those of the possible merging of the CAD and CMD and the question of how best to deal with nanoparticles and other nanomaterials. A third issue related to setting of limit values and, related to this, the issue of dealing with the risks associated with chemical mixtures. A related topic of the distinction between OELs and DNELs is also examined within the report. The question of combining the CAD and CMD is addressed as a coherence issue.

A need for a nanoparticles directive?

There was a divergence of opinion apparent from interviewing various stakeholder groups at EU and national level over the issue of nanoparticles etc. Some stakeholders considered that such material were adequately addressed under the provisions of the CAD (and possibly also the CMD given that some were at least suspected of having carcinogenic properties) whilst others took the opposing view that what they saw as the novel risks associated with nanoparticles warranted a new Directive. Discussions specifically with subject matter experts tended to the view that nanomaterials should be considered under the CAD (or CMD where they are carcinogenic or mutagenic), as they are like any other chemical agents and could therefore be included in this Directive.

MSs were specifically asked in the NIR template whether the CAD adequately addresses the risks from nanomaterials. Most did not provide an unequivocal answer although the majority appear to indicate that the provisions of the Directive should be adequate. Nevertheless, some other MSs gave a clear response that they considered a new Directive to be required (although they did not generally indicate reasons for this view).

In addition to the question responses, some MSs saw fit to include specific formal recommendations on this issue. Denmark recommended that “it should be clarified that some nanomaterials are hazardous chemical substances”. Slovakia recommended specifying in more detail the requirements on “the protection of the health and safety of workers from the risks related to chemical agents at work concerning nanoparticles and ultrafine particles, fibres, aerosols, etc.” Greece however was a little more circumspect recommending that “With regard to the use
of nanomaterials, further research is required in order to determine the need to extend the legal framework and the scope of Directive 98/24/EC."

The issue of how best to manage the risks from nanomaterials was also discussed at the seminar held to consult stakeholders on issues arising from the review ("validation seminar"). A number of delegates, mostly representing employers, felt that nanoparticles could be handled under the provisions of the CAD (or CMD, if appropriate), although not all employer stakeholders shared that view. They argued that the same types of industrial processes apply to this material as to other fine powders; and that what was needed is clear guidance for employers and workers from producers and suppliers. In contrast other delegates, mostly from organisations representing workers, argued that special precautions are required for nanoparticles and that a specific directive was needed.

The view that the CAD is applicable seems to be reflected in the Commission guidance on nanomaterials.

On balance, it would seem that nanoparticles/materials are adequately addressed by the existing legislation at EU level, although more guidance might be required at EU and national level to educate stakeholders and others of this fact and to provide guidance on the selection and implementation of control measures appropriate for the risks presented by nanomaterial use. It of course remains open to MSs, if they take a contrary view, or if the nature of their national legislation entails a more prescriptive approach, to adopt amendments to their own legislation to accommodate any specific measures considered necessary.

A further factor mentioned in a number of interviews with stakeholders was the issue of the complexities of determining the extent of risk from mixtures of chemicals and that the rate of introduction of new chemicals into the workplace tended to move faster than the level of knowledge and awareness of those in authority could keep pace with. However, it is not immediately apparent whether this reflects any need to amend the Directive to maintain its future relevance, or a challenge relating to its implementation and enforcement. On limit values a view was expressed that setting limits at an unrealistic level would lead to work being directed towards other countries where higher or no limits existed. This was easier to counter where limits values were evidence-based as the decision to allow their workers to be put at risk was one for the other countries to determine. It perhaps becomes harder where the limit is based on the precautionary principle where evidence of actual harm is not available.

The Commission procedural steps required for the adoption of limit values is laid down in section 6.1. This complex (and time-consuming) process is seen by some as part of the problem in that, compared to national systems, it takes too long for new OELs to be adopted.

Many MSs have implemented additional Limit Values for chemicals not covered by the Chemical Agents Directive and those supplementary lists issued since. Some have also implemented lower limits than those established under the Directive. This is usually considered to reflect the relatively slow rate with which limits for new substances can be incorporated into legislation at an EU-level.
The complexities and lack of consistency in respect of national limit values was explored in some detail in a previous report on the CAD which commented on the marked differences between MS in the numbers of national OELs, as well as other issues such as the challenges of addressing mixtures of chemicals and, moving into the workplace, the contrasting levels of knowledge about OELs amongst employers and the tendency, in some quarters at least, to regard the whole exercise of compliance as one of getting exposures below the OEL rather than managing risk. In their conclusions, the authors question the focus on OELs, drawing attention to other means of communicating risk and risk management to employers. In this context, they refer (amongst other approaches) to the control banding approach (discussed in this report). Whilst scientific studies would suggest that this approach is not perfect, it does appear to offer some merit for consideration as a more accessible approach to risk management and, as such, one which is likely to achieve better levels of compliance and therefore better effective, practical control of workplace risks.

The modelling of risks usually implicit in the development of such approaches would also offer a possible solution to the growing number and complexity of chemicals and chemical mixtures otherwise requiring OELs to be established.

Interviewees at EU and MS level were asked to provide an assessment (on a scale of 1-5) of the extent to which the CAD has been successful in achieving its objectives (indicating ratings from ‘very low’ to ‘very high’). Stakeholders representing employers and ‘other’ stakeholders at MS level, in the five MSs where such ratings were provided, gave relatively high average scores of 3.9. Worker organisations were markedly more positive and provided an average score as high as 4.3. These can be compared to the mean rating amongst EU stakeholders of 3.4, with no separate EU stakeholder groups giving ratings higher than 4.0.

Exploring changes in workplace exposures, European Working Conditions Survey (EWCS) data shows the extent to which workers reported being exposed to breathing in smoke, fumes, powder or dust. It shows that the proportion of workers who reported exposure has remained relatively unchanged from 2005 to 2010, although small decreases were apparent amongst those reporting higher levels of exposure throughout all of the working time or almost all of the time. Similar data for the proportion of workers who reported being exposed breathing in vapours, such as solvents and thinners, have remained steady for all categories from 2005 to 2010. In a third category, the proportions of workers who reported exposure to handling or being in skin contact with chemical products or substances have remained stable for all categories from 2005 to 2010.

These data appear to suggest only a minor change in chemical exposures over the years and therefore only a modest impact of the CAD. However, as noted above, the data provide no insight into the nature of the chemicals exposures or whether or not they presented any risk to health or safety. However, quantitative data from

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one high-risk industry sector regarding exposures to crystalline silica dust indicates considerable progress, which can be related to concerted efforts by employers at the EU level to improve workers health.

A potential misleading aspect of the EWCS data is that, if exposure is reduced (to below harmful levels) or a substance replaced with a less toxic material, the workers will still report themselves as ‘exposed’. Therefore the apparent lack of change in the EWCS statistics does not necessarily indicate a lack of effectiveness.

EWCS data for the proportion of workers who experience respiratory problems or skin problems believed to have been caused by their work shows increases from 1995 to 2005. These figures could, at least in part, reflect an increased awareness (i.e. greater reporting), but they clearly do not indicate any obvious downward trends.

Subjective opinions on effectiveness

In interviews, EU employer organisations generally assessed the CAD to have had a higher impact on the overall safety and health of workers (3.75), compared to worker organisations, who considered the effectiveness of the CAD to be markedly lower (2.75). In contrast, stakeholders in the ‘others’ category (SLIC and OSHA) responded that the CAD has had a high impact (4) on the safety and health of workers.

Coherence

An analysis of legal coherence identified a number of different individual areas of legal inconsistency or a lack of coherence between the CAD and CMD. One solution suggested was that of merging the two directives.

Combining the CAD and CMD?

There have been numerous comments and suggestions made from a variety of different sources both for and against any suggestion of merging the CAD and CMD. Both EU and national stakeholders offered a mixture of opinions. As there were differences in the numbers of stakeholders from different groups interviewed care must be taken in assigning any numerical ‘score’ to those expressing either view and the ratings given are weighted accordingly.

EU stakeholder groups expressed views and opinions regarding the CAD. All regarded the Directive as being of continuing relevance. One (of six) employer stakeholders endorsed the view that this Directive and that for Carcinogens or Mutagens should be merged into a single Directive. However, several others commented that the distinction between the two was not always clear and could lead to some confusion, which could be interpreted as tacitly endorsing a single directive

When this issue of combining the CAD and CMD was discussed amongst stakeholders attending the seminar held to consult them on issues arising from the review (“validation seminar”), views were quite polarised. Some delegates argued that, because of the similarity in approaches, merging the directives would be beneficial, reducing duplication and removing confusion amongst employers. Others argued however that there was no need to merge the directives and that any such changes would be burdensome for MS in having to alter legislation indicating that, in any case, combined legislation would need to contain the same
provisions as currently found in the CAD/CMD to ensure adequate worker protection. A further argument was that the greater hazard associated with carcinogens justified a separate Directive. Thus whilst there might be a clear legal rationale for such a merger it is clear that there are what might be regarded as ideological differences against such a move. In any case, as several stakeholders indicated, merging the Directives without any changes in the effective content would not occasion any need to change legislation at the MS level.

Other than the legal rationalisation, there is no evidence-base on which to argue for or against such a move. The UK is often pointed out as an example of how merged legislation can be adopted – although there is no evidence that it works any better than the separate approach adopted by a number (probably the majority) of other MSs. Although some stakeholder opinion suggests that it would make it easier or less complicated for employers (and therefore presumably improve compliance) there is no evidence to suggest that compliance is any better (or worse) amongst employers using chemicals covered by one or both Directives. In fact no data has been seen even to establish the magnitude of the problem - i.e. how many employers use chemicals covered by both Directives and are therefore required to comply with two sets of provisions?

Given the absence of any coherent evidence-base therefore it is clear that other than acknowledging the issue, no clear conclusions or recommendations can be drawn from this work. It is of course possible (as exemplified by the UK) for individual MSs to rationalise their legislation transposing both Directives under a single instrument.

Concerning external coherence, the main issues identified concern the interface between REACH Regulation and the CAD, more specifically, the potential overlaps and discrepancies between limit values set under the two pieces of legislation.

The origins and methodologies for the derivations of OELs and DNELs are different and comparing the detailed processes involved in their development is beyond the scope of this study on the implementation of the CAD. However, differences between the two in terms of their numeric values, are seen as a source of confusion and complication for employers in endeavouring to comply with the CAD.

The information on the methodologies for the derivation of OELs and DNELs summarized in this study is based on a number of published scientific papers and no critical comparison or assessment between the two methodologies has been performed to date.

On a wider issue, although if achieved combining the OEL and DNEL systems to provide a common indicator of risk would resolve the issue of disparity it would not reduce the burden on manufacturers or downstream users, or address the bigger issue of whether the OEL/DNEL approach is the best way of communicating risk to employers and therefore enhancing compliance and improving the health of workers as a result.

Clearly, there is a need to review the process of establishing risks and risk management measures for workers exposed to chemicals, ideally to formulate a
common understanding approach between the CAD and REACH. The entire subject should be brought into a discussion on the whole approach and methodologies applied so far. To put this into perspective, in addition to the considerable differences between MSs in the number of existing OELs referred to earlier, there are also many thousands of chemicals for which no OEL exists. One paper, written in 2009, summarized the position, stating: “Under REACH the toxicological properties of approximately 30,000 substances need to be assessed in the next 11 years”.

The authors advocate exploring different approaches to communicating risk, such as the Control Banding approach in which chemicals are grouped according to similar physical or chemical characteristics, how the chemical will be handled or processed, and what the anticipated exposure is expected to be. Such an approach was also advocated by other authors who published a description of the process of determining a DNEL for one paint system which they calculated would require the calculation of 35 exposure scenarios.

As noted above, a detailed critique of the various approaches is clearly beyond the scope of the present study. However, the study has identified the considerable potential for confusion and possible inconsistencies in what employers see themselves as having to comply with, a confusion which, it can be suggested, is likely to lead to further poor quality of compliance and implementation of the current EU legislations as suggested by the CADimple study cited earlier.

In conclusion, determining the effectiveness of the Chemical Agents Directive is challenging. Objectively there is no data on injuries relating to chemicals exposure and limited information on health problems which might be associated with chemicals although the relationship is unclear. Even if there had been clear, unequivocal signs of change, the existence of other legal duties (especially those laid down under REACH) would make it hard to establish whether or not any such changes were attributable to the CAD or to other legislation. Although some scientific studies have examined specific substances (such as respirable silica) the impact of the CAD is otherwise largely indeterminable (although subjective opinions are more positive).

As a result, one clear, strong recommendation to arise from this work is that there is a clear need to explore ways of collecting better data nationally on both exposure and health consequences and collating this at EU-level. One possible option is provided by the proposed development of European Occupational Diseases Statistics collation system. Whilst a pilot study for such a system identified many problems of comparability it concluded that these could be avoided with improvements in data collection. It specifically concluded that such data can be used both in directing prevention and in the evaluation of the impact of the problem (and measures taken to alleviate the prevention).

It is suggested that there is a clear need to explore ways of collecting better data nationally on both exposure and health consequences and collating this at EU-level.
On the issue of nanomaterials, it would seem on balance that the risks to health associated with these are adequately addressed by the existing legislation at EU level, although more guidance might be required at EU and national level (or the better awareness of existing guidance – it is not possible to tell) to educate stakeholders and others of this fact, and to provide guidance on the selection and implementation of control measures appropriate for the risks presented by nanomaterial use.

Other than the legal rationalisation, there is no evidence-base on which to argue for or against merging the CAD and CMD. Given the absence of any coherent evidence-base, it is clear that other than acknowledging the issue, no clear conclusions or recommendations can be drawn from this work.

At present it is open to individual MSs how they implement the CAD and CMD and, if they feel that a unitary approach provides the most effective solution, then it is open to them to do so.

One further suggestion, which does not require amendment of any Directive but which arose from this appraisal, is to prepare awareness-raising campaigns (e.g. through the REACH helpdesks and/or EU-OSHA) to inform employers on how to use the SDSs for their risk assessment in order to ensure that they are able to extract relevant information from the SDSs. This is of particular importance given the potential for confusion which can arise given when the numeric values of the OELs and DNELs are different for the same substance. Moreover it would be beneficial to understand the real difficulties that employers found in using data and information from the SDS in order to perform the risk assessment from exposure of chemicals at the workplace.

Finally, there are considerable practical challenges in keeping on top of the considerable numbers of chemical substances and mixtures requiring the determination of exposure limits of some form under both CAD and REACH. This places a considerable burden on manufacturers (as shown by one paper cited) and has the potential to cause immense confusion amongst employers. There is some evidence from other reports and published material to suggest that this confusion is unhelpful and presents a barrier to compliance. Not only is a better alignment of the OEL and DNEL approaches necessary but it is recommended that other approaches to communicating risk and risk management measures to employers are investigated.
1 Introduction

About this report

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 98/24/EC on the protection of workers from the risks related to chemical agents at work, from here on referred to as the “Chemical Agents Directive” (CAD).

Evaluation of OSH Directives

The evaluation of 24 OSH Directives was initiated in 2013 and finalised in June 2015. 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).

Objective of the evaluation

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 apart 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 current as well as future risks and the 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 in 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
achieved by 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 Directive¹, 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; and 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

¹ Now the Cosmetics Regulation (see Section 6.2)
2 The Directive

2.1 Background and objective

The text of the Chemical Agents Directive (Directive 98/24/EC) refers to Article 118a of the Treaty establishing the European Economic Community, indicating that it 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.

This Treaty has since been supplanted by the Treaty on the Functioning of the European Union (TFEU), Article 153 of which provides for the Union to ‘support and complement the activities of the Member States’ including ‘improvement in particular of the working environment to protect workers’ health and safety’.

Against this general background, a Directive was conceived which laid down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

Very recently, some of the provisions of the Directive have been amended in order to align it to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures. This amending legislation was not in place during the period covered by the evaluation (2007-2012) but the changes therein are noted and will be taken into account in assessing the relevance of the Chemical Agents Directive (CAD).

3 Consolidated version of the Treaty on the Functioning of the European Union (TFEU), OJ C326/47, 26.10.12
The Directive places obligations on the employers to assess the risks to health and safety arising from the presence of any hazardous chemical agents in the workplace and take steps to eliminate or reduce to a minimum any such risks.

As explained in more detail in section 2.3, Article 5 of the CAD outlines the steps necessary.

It also places an obligation on the Commission to evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure, by means of an independent scientific assessment of the latest available scientific data. This assessment is done under the auspices of the Scientific Committee on Occupational Exposure Limits.

The establishment of this Committee has recently been amended by the publication of a new Commission Decision (03.03.2014)\(^5\). This defines the mission of the Committee as being to provide the Commission with Recommendations or Opinions on any matter relating to the toxicological evaluation of chemicals for their effects on the health of workers. As part of its functioning it is to adopt a methodology for the derivation of Occupational Exposure Limits (‘OELs’) and keep it under review; to reflect all relevant scientific factors relating to the setting of OELs. It also has to ensure that this methodology reflects current risk assessment practice. This methodology is to be published by the Commission.

This assessment (by the SCOEL) is to form the basis of indicative occupational exposure limit (OEL) values (Article 3(2)) which are to be taken into account by Member States in establishing national occupational exposure limit values (Article 3(3)).

Member States have to keep workers’ and employers’ organisations informed of indicative occupational exposure limit values set at EU level.

The Directive (Article 3(4)) also provides for the development of binding occupational exposure limit values (Article 3(4)), which are again to be taken into account by Member States. In such cases, the resulting national binding occupational exposure limit values must be based on, but not exceed, the equivalent EU limit value (Article 3(5)).

In a third category, binding biological limit values may also be drawn up (Article 3(6)) following advice (from the SCOEL) and used by MSs to develop national binding biological limit values. These must again be based on, but not exceed, the EU limit values (Article 3(7)).

Binding OELs (Annex I) and binding biological limit values (Annex II) are to be laid down in Annexes to the Directive.

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\(^5\) Commission Decision of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (2014/113/EU)

It also includes a number of further Key Requirements relating to the obligations on Member States and employers to adhere to occupational exposure limit values (plus the limit values themselves – in this and subsequent supplementary directives, e.g. 91/322/EEC, 2000/39/EC, 2006/15/EC); procedures for accidents, incidents, and emergencies; prohibition of production, manufacture, or use of chemical agents laid out in Annex III of the Directive; as well as Directive-specific preventive and protective measures detailed in Section 2.3.

The Chemical Agents Directive has, as its objective, the protection of workers from risks to their safety and health arising (or likely to arise) from the effects of chemical agents that are present at the workplace, or as a result of any work activity involving chemical agents.

### 2.2 Risks

As noted above, the Chemical Agents Directive addresses the risks inherent from exposure to hazardous chemical agents.

The health risks arising from exposure to chemical agents are manifold and can range from acute effects – such as accidental burns from strongly acidic or alkaline materials – to long-term insidious (long-latency) effects such as silicosis and other respiratory diseases. The physical nature of the material can also influence its toxicity/harmfulness, for example inhaling dusts, or absorbing harmful liquid chemicals through the skin. The mode of exposure can also play a role, both in terms of the mode of ingress/impact (dermal, respiratory, ingestion) and the resultant health effects (e.g. occupational asthma or other respiratory sensitisation).

Some chemicals, whilst not directly toxic, can displace (or consume) oxygen in the atmosphere, creating an irrespirable environment. In addition, although the main focus of the Directive would appear to be potential health effects, reference is also made to other hazards, such as to chemicals which are inflammable, ignition of which could lead to fire or explosion (Article 6(6)).

According to the EU-OSHA website:

“Dangerous substances can have many different health effects including:

- acute effects: through poisoning, suffocation, explosion and fire.
- long-term effects, for example:
  - respiratory diseases (reactions in the airways and lungs) such as asthma, rhinitis, asbestosis and silicosis;
- occupational cancers (leukaemia, lung cancer, mesothelioma, cancer of the nasal cavity).

- health effects that can be both acute and long-term:
  - skin diseases
  - reproductive problems and birth defects
  - allergies.

It also warns that some substances can accumulate in the body (for example heavy metals such as lead and mercury or organic solvents), and/or have a cumulative effect. “Some substances can penetrate through the skin.”

On the website it is concluded that: “The precise impact of many substances on human health and the environment is not fully known, however: this is one of the main motivations behind the new REACH system.”

The Directive is an individual Directive within the meaning of the Framework Directive. The Directive should be seen in close relation with the other OSH and non-OSH legislation e.g. internal coherence between the CAD and the Carcinogens or Mutagens Directive (CMD) and external coherence with non-OSH legislation such as the REACH Regulation.

Coherence with other OSH and non-OSH legislation is analysed in Chapter 6.

### 2.3 Provisions

Table 2-1 lists the Key Requirements (KR) of the CAD which embody the principles of assessment, elimination and substitution in respect of hazardous chemicals:

- Assessment of the risks associated with the use of a given chemical;

- Elimination of the need to use the chemical;

- Substitution with a different (safer) chemical;

- Substitution with a different physical form of the same chemical.

Where the use of a hazardous chemical cannot be avoided, for example through eliminating the need for its use, or substituting it with a different (less hazardous) chemical; then employers are required (Article 5) to adopt protective and preventive measures to eliminate or reduce to a minimum any risks arising from its use. These measures include, in order of priority:

- Changing the design and organisation of systems of work at the workplace;

- Providing suitable equipment (and maintenance procedures) for work with chemical agents;

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• Reducing the number of workers exposed or likely to be exposed;
• Reducing the duration and intensity of exposure;
• Implementing appropriate hygiene measures;
• Reducing the quantity of chemical agents present at the workplace;
• Ensuring suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents.

As appropriate, priority has to be given to the design of appropriate work processes and engineering controls and the application of collective protection measures at the source of the risk, rather than the application of individual protection measures including personal protective equipment.

The original text of this Directive, (Article 2) provided definitions for chemical agents and hazardous chemical agents as indicated below. These definitions applied over the period of this review (2007-2012). However, Directive 2014/27/EU has amended that for hazardous chemical agents. For completeness both are given below:

‘Chemical agent’ means any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market.

Under the CAD, prior to recent amendment, ‘Hazardous chemical agent’ meant:

(i) any chemical agent which meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive 67/548/EEC, whether or not that substance is classified under that Directive, other than those substances which only meet the criteria for classification as dangerous for the environment;

(ii) any chemical agent which meets the criteria for classification as a dangerous preparation within the meaning of Directive 88/379/EEC, whether or not that preparation is classified under that Directive, other than those preparations which only meet the criteria for classification as dangerous for the environment;

(iii) any chemical agent which, whilst not meeting the criteria for classification as dangerous in accordance with (i) and (ii), may, because of its physico-chemical, chemical or toxicological properties and the way it is used or is present in the workplace, present a risk to the safety and health of workers, including any chemical agent assigned an occupational exposure limit value under Article 3.

However, the provisions of Directive 2014/27/EU amend this so that ‘Hazardous chemical agent’ now means:
(i) any chemical agent which meets the criteria for classification as hazardous within any physical and/or health hazard classes laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council, whether or not that chemical agent is classified under that Regulation;

(ii) deleted

(iii) any chemical agent which, whilst not meeting the criteria for classification as hazardous in accordance with point (i) of point (b) of this Article may, because of its physico-chemical, chemical or toxicological properties and the way it is used or is present in the workplace, present a risk to the safety and health of workers, including any chemical agent that is assigned an occupational exposure limit value under Article 3.

‘Activity involving chemical agents’ means any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work.

Table 2-1 then lists the provisions of the Directive that have been identified during the analysis as those which particularly need to be addressed when assessing the impacts of the Directive. Hence, the assessment focuses on the so-called CPMs and other KRs:

- CPMs are the KRs that derive from the Framework Directive and that are included in all or several of the individual Directives (i.e. specific Directives such as the CAD).

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, e.g. provisions on limit values.

While Table 2-1 shows that five CPMs are included in the specific articles in the CAD, the intervention logic figure (Figure 2-1) provides a little detail on how the CPMs are presented in the CAD. For example, with respect to risk assessments, the employer is required to revise risk assessments based on the results of health surveillance. It should be noted that, for the 6th CPM (Preventive and protective services) the provisions of the Framework Directive (FD) apply.

The Directive aims to remove and/or reduce risks through multiple channels.
## Key requirements: Scoping and definitions

### Scope of application

**Arts. 1 and 2**

The requirements of this Directive apply where hazardous chemical agents (as defined earlier) are present or may be present at the workplace, without prejudice to the provisions for chemical agents to which measures for radiation protection apply pursuant to Directives adopted under the Treaty establishing the European Atomic Energy Community. Chemical agent is defined as any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market.

## Key requirements: Common processes and mechanisms

<table>
<thead>
<tr>
<th>CPM</th>
<th>Conducting a risk assessment</th>
<th>Preventive and protective services</th>
<th>Information for workers</th>
<th>Training of workers</th>
<th>Health surveillance</th>
<th>Consultation of workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant Articles</td>
<td>4(1), (2)</td>
<td>See FD</td>
<td>8</td>
<td>8</td>
<td>10</td>
<td>11</td>
</tr>
</tbody>
</table>

## Key requirements: Directive-specific provisions

### General principles for prevention of risks associated with hazardous chemical agents and application of this Directive in relation to assessment of risks

**Article 5**

Article 5 of the Directive presents general principles for the prevention of risks including:

- the design and organisation of systems of work at the workplace;
- the provision of suitable equipment and maintenance procedures;
- the reduction of the number of workers exposed or likely to be;
- the reduction of the quantity of chemicals present at the workplace;
- storage, handling, and segregation of incompatible chemical agents.

### Specific protection and prevention measures

**Art. 6**

In turn, Article 6 provides for specific protection and prevention measures for the elimination by substitution or, where not possible, reduction of the risk to a minimum by, inter alia:

- design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work;
- application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organizational measures;
- where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

### OELs and biological limit values

**Arts. 3 and 6(4) and (5)**

MS shall establish, on the basis of the values established at EU level, national (binding) occupational exposure limit values and national binding biological limit values. The employer shall measure the exposure of workers to occupational exposure limit values on a regular basis and take steps to remedy the situation where any such value is exceeded.

### Procedures for accidents, incidents & emergencies

**Art. 7**

The employer shall establish procedures (action plans) in case of accident, incident or emergency. In case of occurrence, the employer shall take steps to mitigate the effects and inform the workers. The employer shall put in place communication systems in case of accidents, incidents and emergencies.

### Prohibitions

**Art. 9 + Annex III**

The production, manufacture, or use of chemical agents and activities set out in Annex III are prohibited.

Derogations are allowed under certain conditions (6(2)).

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**Table 2-1**  
**CPMs and other Key requirements for the Chemical Agents Directive**
The following Directive-specific provisions are not considered to constitute key requirements in the context of the evaluation:

- provisions that do not have a direct impact to limit the risk from exposure to chemicals, such as provisions of a technical nature (technical amendments, repeal, reporting to the Commission);

* Article 5 sets out the general requirement of elimination or reduction of the risks resulting from working with hazardous chemicals. The principles of Article 5 are applied in more specific terms in Article 6. The implementation of Article 6 would result in the implementation of Article 5. Elements of both will clearly be expected to have an impact on the health and safety of workplaces.

### 2.4 Intervention logic

The impact logic diagram (Figure 2-1) illustrates the logical steps of how the Chemical Agents Directive – represented by its KRs – leads to impacts, i.e.:

- **CPMs and other KRs** are, as discussed above, the provisions of the Directive that have been identified during the analysis as the ones that particularly need to be addressed when assessing impacts. The figure illustrates that, because of the multifaceted nature of the Directive, it is not possible to identify the impact of each individual KR. In other words, the KRs work in unison to produce impacts and so they are analysed together.

- **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, organisational 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 of 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 chemical agents. 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.

The intervention logic was used to generate an impact storyline which reflects the logic chain through which improvements in the health and safety of workers would be expected to be achieved and specifies 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 Chemical Agents Directive is expected to lead to a series of outputs from the requirements of the CPMs and KRs which will all be expected to have outputs, results and effects which will influence the anticipated final impact. In theory, each of these outputs could be recorded and quantified in some way (e.g. the extent and quality of compliance with the CPM to carry out a risk assessment).
The risks potentially arising from the use of hazardous chemicals are the result of a complex interplay of factors which have to be taken into consideration and any risk assessments should have taken these factors into account.

Similarly, a variety of methods and approaches are available relating to risk management. The appropriate implementation of each of these measures will help to reduce the overall risk to safety and/or health. As presented in more detail in Chapter 2.3, measures can include:

- Replacement of a hazardous chemical with an alternative (less hazardous) substance, such as using a less flammable or toxic solvent – possibly including prohibiting or strongly controlling the use of certain substances;

- Reducing the quantities of hazardous chemicals used;

- Providing suitable equipment which might reduce the need for direct handling of chemicals (e.g. tongs or dispensers); contain the spread of chemicals (e.g. glove boxes); remove airborne chemicals from the work area (e.g. extraction systems); etc.

- Where the risk of exposure cannot be avoided by other means (or there is a risk of sudden, uncontrolled exposure, then protection for individual workers (PPE) might be necessary although this option should always be regarded as the ‘last resort’.

Careful design and organisation of workplaces can help to avoid or minimise the risk of release of hazardous chemicals. Inspection reports or audits can identify where this has been done.

Where unintended release of chemicals can occur, having plans and procedures in place to deal with this where appropriate, in a timely manner, can help to reduce the risks to safety or health.

Where the risk to health warrants it, health surveillance can provide additional reassurance of the effectiveness of control measures, or serve to identify those individuals who display a particular susceptibility to the effects of exposure.

It is established good working practice not to assume that control measures are having the expected effect. Measurement or monitoring systems can provide additional reassurance, or can indicate where control measures need to be improved. In any case, risk assessments and preventive and protective measures should be periodically revised.

As noted above, exposure to chemicals can have a myriad of adverse effects on health and/or safety. Apart from obvious safety hazards such as fire or explosions, the health effects can be acute (e.g. skin burns from strong acids or alkalis) or chronic (e.g. occupational asthma from exposure to respiratory sensitisers). In some instances there can be synergistic effects with other agents (e.g. the ototoxic effects of some chemicals can enhance the impact of excessive noise, or combined exposures to multiple chemicals might have a greater effect than the
individual chemicals). Generally speaking, acute effects are more readily attributable to the offending exposure and therefore more likely to be correctly identified. In other cases, the multi-causal nature of a condition can make apportionment of the role of workplace chemical exposure more problematic. For example, as noted in Section 2.2, various respiratory diseases can be a consequence of occupational exposure to chemicals. One such disease is Chronic Obstructive Pulmonary Disease (COPD). While the most important cause of COPD is smoking, past exposures to fumes, chemicals and dusts at work may have also contributed to or caused individual cases. These include cadmium dust and welding fumes although there are many such substances which can present a risk. Some statistical estimates of the ‘attributable fraction’ of the overall incidence are available, although such evidence is of limited value in determining causation in individual cases.
Key Requirements

**CPMs**
- Conducting a risk assessment
  - Determine and assess risks (Art. 4)
  - Revise the risk assessment in the event of health surveillance and measurements of limit values (Art. 4)
- Ensuring internal and/or external preventive and protective measures (Art. 5)
- Information for workers
  - Provide information to workers (Art. 6)
- Training of workers
  - Provide training to workers (Art. 8)
- Health surveillance
  - Make health surveillance available to workers (Art. 10)
- Consultation of workers
  - Consult with workers (Art. 12)

**Other KRs**
- Specific protection and prevention measures
  - The Directive provides for specific protection and prevention measures for the elimination by substitution or where not possible reduction of the risk to a minimum (Art. 6)
- ELVs and biological limit values
  - MS shall establish national (binding) occupational exposure limit values and national (binding) biological limit values (Art. 3, 6)
- Procedures for accidents, incidents & emergencies
  - The employer shall establish procedures (action plans) in case of accidents, incidents or emergencies (Art. 7)
- Prohibitions
  - The production, manufacture, or use of chemical agents and activities set out in Annex VIII are prohibited (Art. 9; Annex VIII)

Workplace Impacts

**Indicators**
- Workplace impacts are measurable changes that occur at the workplace as 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 risk management actions
  - Evidence of arrangements to deal with accidents and emergencies
  - Evidence of reduction in use of hazardous chemicals by replacement with safer alternatives

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 hazardous chemical agents above ELVs & BVLs

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 wellbeing and job satisfaction
2.5 Measuring impacts

In continuation of the above impact storyline, 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 and ill-health arising from exposure to chemical agents, 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 is presented in the Main Report.

The assessment of impacts requires that the addressed impact indicators are quantifiable. A set of indicators has been developed by a number of OSH experts. 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 2-2). 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 (as defined earlier) within this evaluation also are based on the results of existing studies and on stakeholder views gathered through interviews.

Table 2-2 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 hazardous chemical agents</td>
</tr>
<tr>
<td>Evidence of provision of information</td>
<td>Reduction in the levels of exposure to hazardous chemical agents</td>
</tr>
<tr>
<td>Evidence of provision of training</td>
<td>Reduction in ill-health related to exposure to chemicals</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 risk management actions</td>
<td></td>
</tr>
<tr>
<td>Evidence of arrangements to deal with accidents and emergencies</td>
<td></td>
</tr>
<tr>
<td>Evidence of reduction in use of hazardous chemicals by replacement with safer alternatives</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 fully can inform the indicator. Hence, Table 2-2 should be seen as a list of indicators for which potential statistical sources could exist.
On the basis of Table 2-2, Table 2-3 provides an overview of identified data variables and statistical sources that are expected to provide useful information on the above indicators in the evaluation of the Directive. This table focusses on the sources of objective data from EU sources. However, as noted above, use has also been made of other sources where appropriate, including interview material obtained for the study, the NIRs and published existing studies such as the CADimple study (which analysed and evaluated the impact of the practical implementation in the workplace of national measures implementing the CAD).

Table 2-3

<table>
<thead>
<tr>
<th>Workplace impacts</th>
<th>Variable</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to chemicals in the workplace</td>
<td>&quot;Are you exposed at work to - Breathing in smoke, fumes, powder or dust etc.?&quot;</td>
<td>EWCS 2010 (Q23-E); EWCS 2005 (Q10-E); EWCS 2000 (Q23-E);</td>
</tr>
<tr>
<td></td>
<td>&quot;Are you exposed at work to - Breathing in vapours such as solvents and thinners?&quot;</td>
<td>EWCS 2010 (Q23-F); EWCS 2005 (Q10-F); EWCS 2000 (Q10-F);</td>
</tr>
<tr>
<td></td>
<td>&quot;Are you exposed at work to - Handling or being in skin contact with chemical products or substances?&quot;</td>
<td>EWCS 2010 (Q23-G); EWCS 2005 (Q10-G); EWCS 2000 (Q10-G);</td>
</tr>
<tr>
<td></td>
<td>For each of the following issues, please tell me whether it is of major concern, some concern or no concern at all in your establishment. Dangerous substances (Int.: explain if necessary: e.g. dusts, chemical, biological or radioactive)</td>
<td>ESENER 2009</td>
</tr>
<tr>
<td></td>
<td>Chemicals, dusts, fumes, smoke or gases</td>
<td>LFS 2007 Persons reporting the physical factor they were most exposed to by type - % [hsw_exp4]</td>
</tr>
</tbody>
</table>

<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 injuries or ill-health possibly relating to chemical exposures</td>
<td>&quot;Over the last 12 months, did you suffer from any of health problems - skin problems?&quot;</td>
<td>EWCS 2010 (Q69-B); EWCS 2005 (Q33A-C);</td>
</tr>
<tr>
<td></td>
<td>&quot;Over the last 12 months, did you suffer from any of health problems - respiratory difficulties?&quot;</td>
<td>EWCS 2010 (Q69-H); EWCS 2005 (Q33A-H);</td>
</tr>
<tr>
<td></td>
<td>Persons reporting their most serious work-related health problem work in the past 12 months, by type of problem - % [hsw_pb5] Pulmonary disorders.</td>
<td>LFS 2007</td>
</tr>
<tr>
<td></td>
<td>Standardised prevalence rate of work-related</td>
<td>LFS 1999</td>
</tr>
</tbody>
</table>

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Data challenges

One of the greatest challenges with the variables identified in the above table is the limitations in the data available. For example, information about exposure to chemicals, etc. from the EWCS provides no details about the nature of the chemicals involved (i.e. their toxicity), or the level of actual exposure (although some general indications of duration are available).

Similarly, statistics on health problems (e.g. pulmonary disorders) provide no insight into whether or not such disorders have developed as a result of exposures to chemicals.

An added complication, relating to health consequences, is the latency period which can occur between exposure to a particular chemical and the emergence of health problems. This can present challenges in exploring the effectiveness of control measures as it is widely recognised that there can be a considerable time lag between any reduction in exposure and any consequential improvement in health.

These problems were also identified in the detailed study, cited earlier, of the practical implementation of the CAD (known as CADimple).

“Therefore it is not possible to compare impact reliably, either in terms of outcomes in relation to overall exposures to hazardous substances or in terms of their health effects, because good data on these matters do not exist.”

“Moreover, because of the latency of occupational diseases, current publications on the incidence and prevalence of such conditions refer to past exposures that predate the implementation of the CAD and are therefore not helpful in evaluating its impact.”

In order to counter these challenges, the above variables are supplemented with national data and information (where it is available from national OSH research institutes, social security institutions, and competent authorities), to estimate the effectiveness and implementation of the Directive. In addition, qualitative information from national studies and interviews has informed the analysis. For a complete overview of published sources, see the references in Appendix A.

Additional data

In order to counter these challenges, the above variables are supplemented with national data and information (where it is available from national OSH research institutes, social security institutions, and competent authorities), to estimate the effectiveness and implementation of the Directive. In addition, qualitative information from national studies and interviews has informed the analysis. For a complete overview of published sources, see the references in Appendix A.

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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 has been mapped according to seven mapping questions. This chapter provides a summary of the findings of the mapping exercise for the Chemical Agents Directive.

The National Implementation Reports (NIR) 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 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

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?

Table 3-1 below shows an overview of data collected in the national studies regarding each of the CPMs and their transposition into national legislation. Although, as agreed with the project steering group, the main focus was on the CPMs, national experts were also asked to consider and report on any significant differences with other KRs.

9 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  

<table>
<thead>
<tr>
<th>Member State</th>
<th>One (O) or several laws</th>
<th>Infringement proceedings / delays (Y/N)</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</td>
<td>Y (Art. 3, 4, 8, 10, 11)</td>
</tr>
<tr>
<td>BG</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3, 4, 8, 10)</td>
</tr>
<tr>
<td>CZ</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3, 4)</td>
</tr>
<tr>
<td>DK</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 1, 2, 3, 8, 10)</td>
</tr>
<tr>
<td>DE</td>
<td>S</td>
<td>Y</td>
<td>Y</td>
<td>Y (Art. 3, 4, 8, 10)</td>
</tr>
<tr>
<td>EE</td>
<td>S</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 10)</td>
</tr>
<tr>
<td>IE</td>
<td>O</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3)</td>
</tr>
<tr>
<td>EL</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3, 4, 8, 10)</td>
</tr>
<tr>
<td>ES</td>
<td>S</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 4, 8, 10)</td>
</tr>
<tr>
<td>FR</td>
<td>O</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3, 4, 10)</td>
</tr>
<tr>
<td>IT</td>
<td>S</td>
<td>Y</td>
<td>Y</td>
<td>Y (Art. 3, 4, 8, 10)</td>
</tr>
<tr>
<td>CY</td>
<td>S</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 1, 2)</td>
</tr>
<tr>
<td>LV</td>
<td>O</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 4, 8, 10)</td>
</tr>
<tr>
<td>LT</td>
<td>S</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 3, 8, 10)</td>
</tr>
<tr>
<td>LU</td>
<td>O</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 1, 2, 3, 4, 8)</td>
</tr>
<tr>
<td>HU</td>
<td>S</td>
<td>N</td>
<td>Y</td>
<td>Y (Art. 4, 10, 11)</td>
</tr>
<tr>
<td>MT</td>
<td>O</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 4, 10)</td>
</tr>
<tr>
<td>NL</td>
<td>O</td>
<td>Y</td>
<td>Y</td>
<td>Y (Art. 3, 4, 8, 10, 11)</td>
</tr>
<tr>
<td>AT</td>
<td>O</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3, 4, 8, 10)</td>
</tr>
<tr>
<td>PL</td>
<td>S</td>
<td>N</td>
<td>Y</td>
<td>Y (Art. 10)</td>
</tr>
<tr>
<td>PT</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 1, 2, 3, 4, 8, 10)</td>
</tr>
<tr>
<td>RO</td>
<td>S</td>
<td>N</td>
<td>Y</td>
<td>Y (Art. 3, 4, 10)</td>
</tr>
<tr>
<td>SI</td>
<td>S</td>
<td>N</td>
<td>N</td>
<td>Y (Art. 1, 2, 3, 4, 8, 10)</td>
</tr>
<tr>
<td>SK</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 4, 8, 11)</td>
</tr>
<tr>
<td>FI</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3)</td>
</tr>
<tr>
<td>SE</td>
<td>S</td>
<td>Y</td>
<td>N</td>
<td>Y (Art. 3, 4, 8, 10, 11)</td>
</tr>
<tr>
<td>UK</td>
<td>S</td>
<td>Y</td>
<td>Y</td>
<td>Y (Art. 3, 10)</td>
</tr>
</tbody>
</table>

**Sums**  
S = 19  
O = 8  
Y = 16  
N = 11  
Y = 8  
N = 19  
Y = 27  
N = 0

Source: Country Summary Reports on each Member State

Table 3-1 shows that infringement proceedings have been initiated for a small majority of MSs, mainly for non-communication of transposing measures. In all these cases, the proceedings have been closed as the necessary steps have been taken.

As shown in Table 3-1, the national summary reports indicate that, in eight MSs, there was an observed discrepancy between the Directive and national legislation. In most cases, this related to the setting of Limit Values. Some MSs have higher limit values although, in many instances, the difference is minimal. For example, several MSs including BE and UK have an eight-hour limit for Nitrogen Monoxide.
of 31 rather than 30 mg m\(^{-3}\). In other cases however, the differences are more substantial.

These differences have been indicated as discrepancies because they appear to imply a lower level of protection. However, in each case the differences relate to substances for which the OEL is indicative not binding. In such cases, the CAD requires MSs to:

“establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice.” (Article 3(3))

Unlike binding limit values therefore there is no constraint on MSs to apply specific indicative values and so, such discrepancies should not be regarded as deviating from the provisions of the CAD.

It is not intended to explore each of these differences and the reasons behind them in detail, although it is clear from comments that, in many cases, the MS considers their (different) value to be justified by the evidence available to them. For example, in Germany, higher limit values for some substances are justified in criteria documents prepared by the AGS (Committee on Hazardous Substances), and some by the DFG Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Kommission). However, it is noted that, under the provisions of the CAD (Article 3(8)), MSs who introduce or revise a national occupational exposure limit value or a national biological limit value for a chemical agent, are required to inform the Commission and other MSs of this, “together with the relevant scientific and technical data on which this is based”. It is understood that this can include, for example, socio-economic feasibility factors as well as any scientific rationale. Such material is presumably therefore made available by the Commission to the SCOEL for future consideration in setting or revising OELs.

In the Netherlands, they have evolved a different national system for setting limits. This has resulted in some discrepancies and possible missing values. Under this system, introduced in 2007, OEL’s are privately set, through cooperation between employers and workers. Employers may also choose to apply a ‘safe working method’ (which has proven to maintain exposure levels below the OEL) instead of working with (and measuring on the basis of) OEL’s.

In addition to these private OEL’s the Ministry sets public OEL’s in cases where:

- the EU requires a threshold value (OEL);
- substances are deemed to be ‘without an owner’ or have ‘high risks for health’;
- substances for which no threshold value can be set (most of the carcinogenic and allergenic substances).

The resulting OELs (public and private) are considered to be at a level at which the health of the worker cannot be harmed (‘gezondheidskundige waarde’). These are
therefore binding values. There are some substances (Acetic acid, Picric acid, Calcium dihydroxide, Cresols (all isomers), Tin (inorganic compounds as Sn)) for which the Directive sets an OEL where there is no public OEL, although employers might have established private OELs.

A number of MSs set more stringent limits for some substances, or have limits for substances for which there is no EU limit. However, as the Directive sets minimum standards this is permissible and does not constitute a negative discrepancy or failure. The CADimple study report comments that the number of substances with OELs in the different MSs surveyed as part of that study varied from 'little more than 50 to more than 1,100'.

In many MSs the limit values set are regarded as binding. In general therefore, it appears that the indicative limit values defined at EU level are often used to provide the basis for binding limit values at MS level.

Amongst the few discrepancies not relating to limits, some aspects of the scope and the requirements for health surveillance have not apparently been transposed into Hungarian national legislation. Similarly, the requirement for information for workers has not been explicitly transposed into Polish legislation, although it could be considered to be covered by the general duty under the Framework Directive legislation.

Legislation in the Netherlands has a different definition of dangerous (rather than hazardous) substances,

"Dangerous substances: substances, mixtures or solutions of substances to which workers are or can be exposed at work and which due to the characteristics of or circumstances under which these substances, mixtures or solutions occur, may jeopardise health or safety."

The requirements of the legislation thus apply 'in all the cases in which workers are or can be exposed to dangerous substances'.

Romanian legislation requires employers to identify risk control measures that 'must be taken' as opposed to those which 'have been taken' in the Directive. Although seemingly a small semantic difference this could be interpreted as not necessarily seeking affirmation that the measures identified as necessary are actually in place.

No discrepancies were identified in relation to other Articles of the CAD.

Table 3-1 also shows that all MSs have some more detailed requirements. Thus, as summarised below, 19 incorporate changes to Articles 3 and 4; 16 have changes to Article 8; and 19 have changes to Article 10. As shown in Table 3-1,

some other Articles are also the subject of more stringent requirements in a few MSs. Details of these are contained in the CSRs included as an Annex to the Main Report.

It will be noted that there are no more detailed requirements indicated in any of the CSRs relating to Articles 5 (General principles for prevention of risks), 6 (Specific protection and prevention measures), and 7 (Arrangements to deal with accidents, incidents and emergencies).

**Article 3** relates to Occupational Exposure Limit Values (OELs) and Biological Limit Values, with the limits for Binding OELs presented in the Annexes I and II of the CAD and subsequent Directives establishing lists of Indicative OELs\(^\text{11}\). Both eight-hour and short-term OELs were explored. This issue has been detailed above. From comments from stakeholders, the large number of changes appears, at least in part, to be a function of the evolving knowledge regarding the potential harmfulness of such substances and the relative ease with which individual MSs can introduce new limits compared to the protracted process of such change at the EU level. There would appear to be a need to explore ways of streamlining this process to speed the development of OELs by the Standing Committee and their subsequent transition into legislation.

**Article 4** relates to the determination and assessment of risk of hazardous chemical agents. A frequent feature of many of the additional requirements in MSs is for the national legislation to require employers to submit risk assessments to national authorities, usually on request\(^\text{12}\) although, in the case of Latvia, their national legislation specifically requires employers to submit written information to the closest State Fire and Rescue Service department on any possible chemical accident risks.

Some MSs also provide a more detailed specification for the risk assessment, embodying features which might be included within guidance material in other MSs. These include: specifying that all potential channels for exposure must be considered (e.g. inhalation, skin absorption, ingestion); indicating the nature of the person or persons who should carry out an assessment (including the involvement of a physician in certain circumstances); and references to the need, in particular, to consider mixtures of chemicals.

**Article 8** concerns information and training for workers. In most cases the additional requirements relate to detailing more specifically the content of any such training. Some MSs require the information to be provided in writing; and/or require workers to be informed of actual levels measured. In one interesting development, Austria includes requirements regarding the information in the workers' native language or another language the worker understands, possibly indicating a sizeable migrant worker population. Whilst employers in some other MSs are known to do such things this appears to be the only MS where it is enshrined within the legal framework.

\(^{12}\) CZ, DE, FR, IT, LU, MT, AT, PT, SI, SE
**Article 10** concerns the provision of health surveillance. Almost half of the MSs (13) have some additional specifications relating to the periodicity of surveillance / examinations. In some instances this specifies an actual period for example, France and Lithuania specify no more than two years (24 months). Others are more complex and define different frequencies for different classes of chemicals. For example, Belgium has a scale of periodicities ranging from six months to three years depending on the substance involved. In some cases however, the additional specification simply serves to indicate that the period for repeating any examination etc. shall be determined by the medical advisor involved. Thus Estonia specifies that the periodicity shall be determined by the advising physician (but shall be not more than three years). The UK combines these two, with annual surveillance for specified chemicals, or shorter at the discretion of the advising physician.

In a small minority of MSs the legislation specifies in more detail what should be recorded in any surveillance records maintained.

**MQ1: Answer**

Most MSs have implemented the CAD in one rather than several pieces of legislation. Although there are some minor variations in detail in implementing the separate CPMs (and KRs) they appear generally to function as a coherent legal entity.

Much of the attention in respect of discrepancies or more detailed provisions relates to the setting of Limit Values (Article 3). Some MSs have limit values which are less stringent than the OELVs although, in many instances, the difference is minimal. In other cases however, national limits are substantially higher. The number of national OELs varies considerably, with some MSs adopting OELs for many more substances than are included in the various Directives setting such limits.

In addition to Article 3, the provisions of Articles 4, 8 and 10 featured most often in more stringent requirements. There are no more detailed requirements indicated in any of the CSRs relating to Articles 5 (General principles for prevention of risks), 6 (Specific protection and prevention measures), and 7 (Arrangements to deal with accidents, incidents and emergencies).

**Article 4** relates to the determination and assessment of risk of hazardous chemical agents. A frequent feature of many of the additional requirements in MSs is for the national legislation to require employers to submit risk assessments to national authorities, usually on request or occasionally automatically.

**Article 8** concerns information and training for workers. In most cases the additional requirements relate to detailing more specifically the content of any such training.

**Article 10** concerns the provision of health surveillance. Almost half MSs (13) have some additional specifications relating to the periodicity of surveillance / examinations.
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 CAD does not contain any provisions for extended deadlines.

In terms of derogations, the CAD contains two possibilities for derogations, namely (1) derogation from the prohibition of the chemical agents set out in Annex III in any of the following circumstances; for the sole purpose of scientific research and testing, including analysis; for activities intended to eliminate chemical agents that are present in the form of by-products or waste products; for the production of the chemical agents referred to in paragraph 1 (Article 9.1) for use as intermediates, and for such use (Article 9.2) and (2). When derogations are permitted pursuant to paragraph 2 (Article 9.2), the competent authority shall request the employer to submit the detailed information on the use of the derogation (Article 9.3). Table 3-2 shows an overview of how these have been applied in the Member State legislation.

Table 3-2 Derogations and their application in Member States

<table>
<thead>
<tr>
<th>Member State</th>
<th>Derogation applied, 9.2 (Y/N)</th>
<th>Conditions reflected 9.2 (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>BG</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>CZ</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>DK</td>
<td>N</td>
<td>N</td>
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<tr>
<td>DE</td>
<td>Y</td>
<td>Y</td>
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<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>UK</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

Sums

Y= 20
N= 7

Y= 17
N= 10

Source: Country Summary Reports on each Member State
Table 3-2 shows that a majority of Member States have applied the derogation. For the 20 MSs that have done so, the conditions were not reflected in three of them (Poland, Finland and the UK). In each case, none of the conditions appear to be explicitly reflected, although they may be considered to be covered by others aspects of the national legislation. For example, the UK legislation does not explicitly refer to a closed system but it does qualify any exemption as being ‘to the extent permitted by article 9’.

No MSs have any statistics relating to other KRIs (non-CPM) and so this column is omitted.

The CAD does not contain any provisions for extended deadlines. However, it contains two possibilities for derogations both of which relate to the prohibition of certain specified chemical agents (Annex III). The first provides for exceptions to this derogation and the second places requirements on reporting where this derogation is used. Most MSs implement both of these.

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 3-3 summarises the information available, derived from the CSRs, in terms of the percentage of establishments which comply with the CPM requirements of the Directive.\(^\text{13}\) For brevity, only those MSs who were able to provide information available are shown. It should be noted that, in some instances, national experts provided an estimate of compliance based on their own knowledge and experience. In some such cases they felt unable to differentiate degrees of compliance with individual provisions, providing an overall estimate of compliance.

\(^\text{13}\) The table shows only Directive-specific data, e.g. risk assessment comprising the particular requirements to risk assessment in the CAD (for an overview of compliance with the general requirements (CPM) to perform risk assessment, please consult the Directive report on the Framework Directive (89/391/EEC)).
Table 3-3  Compliance with CPM key requirements 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>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>DE</td>
<td>10-60%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>EE</td>
<td>93%</td>
<td>82%</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>54%</td>
<td>40%</td>
<td>40%</td>
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<td>-</td>
</tr>
<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>45%</td>
<td>45%</td>
<td>45%</td>
<td>45%</td>
<td>45%</td>
</tr>
<tr>
<td>SK</td>
<td>45%</td>
<td>45%</td>
<td>45%</td>
<td>45%</td>
<td>45%</td>
</tr>
</tbody>
</table>

Source: Country Summary Reports on each Member State

Table 3-3 gives rise to two main findings. The first is that data on levels of compliance with the requirements of the Directive is quite scarce. The experience from conducting the studies at the national levels is that national authorities do not keep directive-specific accounts of levels of compliance and, further, national stakeholders are 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 estimates of the level of compliance with the CPMs is varied – ranging from 10% to 93%. In many instances it was only possible to provide a blanket assessment across all CPMs (hence the same percentage estimates). As these estimates are derived from less than half of the MSs, it is not clear to what extent they can be extended 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, for different industrial sectors or for public or private enterprises. The data indicates that the level of compliance increases with the size of establishment. This is also supported by NIRs, where a number of Member States highlight the difficulties faced by Small and Medium-sized Enterprises (SMEs) and microenterprises in complying with the requirements. Lack of knowledge, specialised personnel and financial resources, are common explanations to the challenges of implementation. Some examples are given in Box 3-1 below. In some instances the problems can be seen as relating to most or all Directives but it will be apparent from the comments that there are some difficulties specifically relating to the CAD. However, some Member States also indicate that SMEs have no difficulties in implementing the Directive (Austria, Bulgaria, Cyprus, Czech, Denmark, Estonia, Finland, Germany, Italy, Lithuania, Luxembourg, Slovenia, UK).

14 Is the risk assessment reviewed regularly and in any event when any changes occur in the conditions which may affect workers exposure?
No data could be obtained relating to different industrial sectors (e.g. chemical and other sectors) or to differentiate between public or private enterprises.

For the non-CPM KRs the position was that data was even more scarce and patchy. Some estimate of compliance could be provided for nine of the 27 MSs. Because of their patchy nature these data are not tabulated.

Belgium provide a blanket 20-39% estimate of compliance across all KRs.

In the Czech Republic, although information doesn’t directly map onto individual KRs, the reported experience from Labour Inspectors is that the principle of ensuring OSH when using chemical agents at work has a very high (>80%) estimated compliance.

Based on a national survey Lithuania indicated an overall compliance of just under 50%, although no further details are available regarding the nature of this compliance.

In the Netherlands, from a report from the Labour Inspectorate, it is estimated in respect of the requirement to take specific protection and prevention measures (Article 6) that 88% of relevant establishments have taken adequate protective and preventative measures. However, the same source estimates that, in respect of the OELs and biological limit values, (Articles 3, 6(4) and 6(5)) there is a very low degree of compliance and that 6% of relevant establishments make a full assessment whilst 99% make a partial assessment.

In Poland it is estimated that Polish enterprises formally display a high level of compliance (60-79%) although concerns were expressed in stakeholder interviews regarding the quality of the implementation.

In Romania, based on the annual reports from the Labour Inspection over the period 2007-2012, a blanket estimate of 40% compliance was derived, although no KR-specific estimate could be derived.

Similarly, in Slovakia, based on the annual reports from the Labour Inspection over the period 2007-2012, a blanket estimate of 45% compliance with KRs was derived, although again no KR-specific estimate could be derived.

In Spain, an estimate has been provided based on the number of businesses that have conducted a risk assessment regarding chemical agents at work and have adopted preventive measures. This suggests that there is a high (60-79%) level of compliance in general. Further data suggests that for 48.0% no additional measures have been needed; for 1.3% additional measures have been studied; and for 15.1%, additional measures have been carried out. However, no data are available as to whether the risk assessment is reviewed regularly or when changes occur in the work conditions which may affect workers exposure.

Finally, in Sweden an estimate was derived from interview material which suggested low to medium compliance (20-59%) with the need for specific protection and prevention measures (Article 6).
The CADimple report provides some further insight into the question of compliance in a section on implementation. In this it comments:

“It is evident from our findings, that there are still far too many enterprises in which there is low awareness, low knowledge and inadequate risk assessment and risk reduction.

A large proportion of the total of enterprises in most Member States have never performed a risk assessment in accordance with its meaning as understood in EU Directives, or if they have, they have never introduced any risk management measures as a result. Where risk assessment is done it is often merely a formal procedure to achieve paper compliance. Many interviewees stated that there was often a weak connection between risk assessment and risk management measures. From our CADimple research we conclude that not more than 50% of the enterprises have performed an overall OSH risk assessment. This must be seen as a very cautious assessment.”

“The larger the enterprise the greater the probability that a risk assessment will be performed, which means that less than 50% of the enterprises but more than 50% of the employees are covered by at least a general OSH risk assessment. However there are many doubts expressed concerning the quality of these risk assessments and whether they tackle the risks of hazardous substances adequately. On average across the 27 Member States it is likely that the proportion of enterprises that have performed a chemical risk assessment will be much lower than 50%.”

The NIRs also included direct questions regarding implementing particular aspects of different Directives. In the case of the CAD, specific questions were asked regarding:

- The practical difficulties Member States have experienced in implementing indicative occupational exposure limit values.
- The practical experience of substituting hazardous chemical agents for less hazardous ones in the workplace.

As a general comment, the quality of the responses to these questions is very varied, with a number of MSs responding by stating the legal duties in their national legislation rather than describing any difficulties (or otherwise) in implementing this legislation. The following section provides a synopsis of the entries from the NIRs. The NIRs themselves can be examined for further detail.

On OELs some MSs responded by describing the development of national OELs rather than any difficulties employers have experienced in complying with these

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OELs. Many MSs responded that they had no indications of any problems or no information regarding any problems, or that statistics on this issue were not collected.

Amongst those who gave a usable response, a commonly expressed difficulty was that of adequate measurement/monitoring. It was seen that the costs and/or technical challenges of monitoring (or the perceived need for large numbers of samples) were seen as barriers to adequate monitoring and that, without this, implementing control measures to reduce exposures below the OELs became problematic. Inevitably this was sometimes (but not always) seen as more of a problem for SMEs.

One MS (Romania) reported limited findings from a survey of employers which found that 24% of the representatives of micro-enterprises, 29% of the representatives of small businesses, 65% of medium-sized enterprises, and 80% of the representatives of large enterprises surveyed said that they had made determinations of pollutants in their companies.

On substitution, responses varied from substitution being difficult and constituting an extremely rare or one-off event; to it not being difficult – but with room for improvement. A number of MSs indicated that it seemed to be more common in certain sub-sectors or product groups. For example, the use of water-based rather than oil-based paints was referred to as a common action (although one MS raised a dissenting voice, pointing out that it was seen to result in a deterioration in product effectiveness). One action taken in some MSs (e.g. Netherlands) was to make substitution, at least of certain products, mandatory. This approach was suggested by another MS (Greece) where it was indicated that employers did not adopt substitution because the substances they were using were not banned and there was therefore no legal compunction to stop using them. Clearly, where the supply of a substance of ‘Very High Concern’ is authorised it can be appreciated that this could cause some confusion for the employer (user), who is nevertheless ‘expected’ not to use the substance under the CAD provisions on substitution.

Four MSs provided numerical estimates of the use of substitution. Bulgaria stated that “approximately 20% of the inspected undertakings using hazardous chemical substances are undertaking efficient measures to replace them with analogues”. In Estonia, a survey identified 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 and 23% could not answer the question. It was reported that technical challenges (mainly), but also costs were the main barriers. In Ireland, chemical substitution was recommended by inspectors in approximately 10% of inspections carried out (although it is not stated whether or not this substitution ever took place). Finally, in Romania, a survey identified that 26% of the representatives of micro-enterprises, 29% of the representatives of SMEs and 81% of the representatives of large companies surveyed said that they had made substitutions.

The report from Romania also included a list of some examples of substitutions. These are repeated here as they reflect similar references in other NIRs. Thus, materials substituted included:
organic solvent based paints have been substituted with water based paints where possible;
benzene has been substituted with toluene;
v vinyl chloride monomers and acrylonitrile have been substituted with other less hazardous monomers;
lead-containing alloys have been substituted with lead-free alloys, or with alloys of a low lead content;
adhesives containing toluene have been substituted with adhesives based on aliphatic hydrocarbon;
TDI has been substituted with MDI;
solvent-based stains have been substituted with water-based stains.

Data on levels of compliance with the requirements of the CAD is quite sparse with relatively few MSs having numerical data available. Such data as were sourced made no distinction between private undertakings and public-sector bodies, across different sectors of economic activity, or across different sizes of companies.

The level of reported compliance with the CPMs and other KRs is very varied, for example, estimates of compliance with risk assessments range from 10% up to 93%.

Although no numerical data are available, subjective opinion seemed to suggest that compliance was generally related to employer size (increasing with increasing size). This view was supported by the findings from an earlier (2010) impact evaluation of the CAD.

Opinions are divided as to the extent to which SMEs had problems with complying. However, it should be noted that no evidence of a problem (as reported in a number of NIRs) is different from evidence of no problem.

No information was available from the MSs regarding variations in compliance by companies in different industrial sectors or between the public and private sectors.
Box 3-1 Examples of difficulties related to compliance for SMEs and microenterprises (from NIRs)

SMEs often lack the expertise to take effective action against risks. The hierarchy of preventive measures is too abstract for them to be able actually to implement them in their own particular situation (Belgium).

Nevertheless, 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, a lack of resources and limited awareness of the benefits of launching a risk-prevention drive (France).

We are already considering the possibility of supporting SMEs with the provision of additional preventive and protective services by a body, e.g. the Chamber. This will help SMEs improve the preventive and protective services offered to their workers with no additional financial burden for enterprises (Greece).

The majority of SMEs using hazardous substances is in a worse situation in terms of the achievement and maintenance of health and safety requirements as they do not normally employ experts with special skills due to financial difficulties (Hungary).

Some SMEs have had difficulty understanding the elements of risk assessment and the prioritising of measures to eliminate or reduce risk (Ireland).

Only 6% of the respondents replied that their enterprises have certain difficulties but did not specify them (Lithuania).

Some factors include the lack of technical competence, problems of access to dedicated professionals in the sector, as well as the costs involved in engaging external experts (Malta).


The main problem with following the requirements of the Directive 98/24/EC... is the identification of chemical agents and dusts posing health risks to workers, and first of all occupational risk assessment (Poland).

The main difficulties relate to the identification of chemical agents to be assessed in the company and how to assess them, due to the fact of not having defined methodologies for the analysis of a greater number of compounds. In a similar manner to other Directives, SMEs have a greater difficulty in complying with that laid out in the Directive due to a lack of financial resources, and a greater difficulty for those human resources dedicated to HSW to find the time to monitor legislative and technical developments, namely with regard to harmonisation in the establishment of reference values relating to occupational exposure. (Portugal).

Employers have difficulties concerning what is meant by "low chemical risk" referred to in the directive (Romania).

Although small and medium-sized enterprises assessed risks in general, they often failed to incorporate all hazardous factors present at specific workplaces in those assessments (Slovakia).

The financial cost of the specific assessment of chemical agents must be pointed out, especially where this requires measurements and there is insufficient guidance from the external prevention services with regard to chemical risk assessments and the implementation of preventive measures (Spain).

Supplier information about chemical products is difficult to understand for those who do not have specialist skills regarding how this information is written (Sweden).
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?

This section distinguishes 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 3-4 shows the type and number of actions undertaken in each MS. Emphasis is on key documents and actions. In many MSs additional items, such as leaflets etc., may have been produced. It must be emphasised that enquiries were primarily directed to material relating to the review period of 2007-2012 and that some earlier material may not therefore be included. From national interviews with stakeholders and others, no information needs were identified which were not met by the available material.
Table 3-4 indicates that guidance documents are by far the most common action undertaken by Member States in respect of supporting the implementation of the legislation transposing the CAD. Awareness campaigns and support tools are both actioned quite commonly. The remaining actions are adopted considerably less often.

Information on the nature of this material is presented in the Country Summary Reports. A limited number of campaigns are listed, including one in Lithuania on prevention. Support tools include the ‘Stoffenmanager’ tool prepared in the Netherlands, which was developed as a control banding tool for hazardous chemicals and the ‘Chemiguide’ online tool prepared in Sweden.

Also, the table shows that, generally, the Member States consider that available information and guidance is sufficient. Although, when asked directly about whether there are gaps no stakeholders answered yes; some national implementation reports which highlight challenges to SMEs also mention a lack of knowledge about measurement methods, etc. which could indicate a need for additional accompanying actions in this area.
3.4.2 Actions at EU level

Commission guidelines:

European Commission (2006). ‘Practical guidelines of a non-binding nature on the protection of the health and safety of workers from the risks related to chemical agents at work’.

“The purpose of these practical guidelines is to assist Member States in drawing up their national policies and to facilitate compliance with their regulations on the health and safety of workers”.


This guidance, endorsed by ACSH, “sets out, step by step, what employers need to do to meet the obligations of REACH, a relatively new Regulation, and CAD, an established legal framework for which guidance already exists. In particular, it demonstrates that one process of assessing risks can often meet the relevant requirements of both REACH and CAD.”

European Commission (2013). ‘Chemicals at work – a new labelling system’\(^\text{16}\).

This document provides guidance to help employers and workers to manage the transition to the new classification, labelling and packaging system. Although not specifically relating to the CAD it provides a source of additional assistance to employers and workers.


“This document is intended as guidance for National Labour Inspectorates (NLI’s) and their Inspectors. It is not intended as guidance for manufacturers and users of chemicals.” However, employers might find the information of value.


“The purpose of this Guidance is to assist employers, health and safety practitioners and workers in fulfilling their regulatory obligations, namely those

under the provisions of Framework Directive 89/391/EEC and the Chemical Agents Directive 98/24/EC (CAD), whenever exposure to MNMs or use of nanotechnology in a professional capacity is known or likely to take place, with the ultimate aim of ensuring adequate protection of workers’ health and safety.”


This guidance is specifically intended to provide employees working with Manufactured Nanomaterials (MNMs) and nano-enabled products, with an introduction to the issues surrounding – and approaches to working safely with MNMs.

EU-OSHA:

Resources on the EU-OSHA website include over 25 E-facts, over 20 Reports, over 15 factsheets and up to 20 reviews and summaries. This section lists some of those more directly aimed at employers. It therefore excludes the more research oriented material.

An OSH wiki section “Dangerous substances” can also be found on the EU-OSHA website web pages on ‘Dangerous substances’.

E-fact 26 - Dangerous substances in HORECA

In the hotel, restaurant and catering sector (HORECA) sector, many substances pose a risk to employees. Cleaning, disinfecting, handling food and biological waste can lead to allergic reactions and skin diseases such as dermatitis. Employees are also exposed to cooking fumes and second-hand smoke. This E-Fact describes the risks that employees face from dangerous substances in the sector and offers practical measures that can be introduces to lessen their impact.

E-facts 29, Occupational safety and health in Europe’s forestry industry

Includes material on pesticides and other dangerous substances.

E-fact 41 - Cleaners and dangerous substances

Skin problems are the most common problem for cleaners, who are also at increased risk of developing asthma, chronic bronchitis and other respiratory problems. This e-fact looks at how to recognise dangerous substances and

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17 http://oshwiki.eu/wiki/Dangerous_substances_%28chemical_and_biological%29
explains how they can enter the body and cause harm. It also offers ways to prevent or minimise risk.

E-fact 66\(^{21}\): Maintenance and hazardous substances

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

E-fact 67\(^{22}\): 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.

E-fact 72\(^{23}\): Tools for the management of nanomaterials in the workplace and prevention measures

After a short introduction to nanomaterials and the safety and health risks they present to workers, this e-fact describes and compares a number of tools that can be used by employers, together with workers, to manage these risks in the workplace, and details the prevention measures recommended.

E-fact 73\(^{24}\): Nanomaterials in the healthcare sector: occupational risks and prevention

This e-fact explains how healthcare workers may come across manufactured nanomaterials when undertaking everyday activities in their workplaces. It provides information concerning the specific occupational risks involved and what should be done to prevent exposure.

E-fact 74\(^{25}\): Nanomaterials in maintenance work: occupational risks and prevention


This e-fact provides a short introduction to nanomaterials and their risks to workers’ safety and health. It explains how workers may encounter nanomaterials when undertaking maintenance work and also presents information on what should be done to prevent exposures.

**E-fact 75**: Dangerous substances and successful workplace communication

Workplace safety depends on risk awareness. Employers and workers need to know what dangerous substances are in the workplace and how to deal with them. This e-fact offers hints for successful communication in the workplace about dangerous substances, including the use of safety data sheets, and provides a list of sources of further information.

**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 39** - Respiratory sensitisers

Respiratory sensitisers are biological and chemical agents that can induce allergic respiratory diseases in humans. This factsheet discusses important characteristics of the exposure to these agents and appropriate prevention measures.

**Factsheet 40** - Skin sensitisers

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This factsheet contains information on skin sensitisers as well as preventive measures for skin exposure. Occupational skin diseases were estimated to cost the EU EUR 600 million a year, resulting in around 3 million lost working days. They affect virtually all industry and business sectors and force many workers to change jobs.

**Factsheet 44**32 - 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 for laying down preventive and protective measures against these risks. This report describes 19 initiatives addressing the existing information gap.

**Report - How to convey OSH information effectively: the case of dangerous substances**33

Within the EU’s legislative framework, worker information and consultation about hazardous chemical agents occurring in the workplace, health and safety risks and protective and preventive measures is a legal obligation for the employer. This report presents some good practice examples describing how to transfer information effectively to different target groups and how to assess the relevance of the information for these groups.

**Report - The practical prevention of risks from dangerous substances at work**34

The 29 examples of good practice on the prevention of dangerous substances presented here are all award winners or commended entries in a European competition, run as part of the European Week for Safety and Health at Work 2003. The aim of this Agency initiative is to support the dissemination of good practice information about risks from dangerous substances and promote the application of ‘practical solutions’ in workplaces in Member States and across Europe.

**Online Interactive Risk Assessment - OiRA**

OiRA is a European online platform to create free and easy-to-use sectoral risk assessment tools for small and micro-companies. It is used by Sectoral Social Partners (employers’ and employees’ organisations) and National authorities (Ministries, Labour Inspectorates, OSH institutes, etc.) to produce sector-specific risk assessment tools targeting small businesses.

In relevant sectors, the assessment of risks related to the use of chemicals will obviously be included, but it is not a directive-specific tool.

Other sources: ECHA (European Chemicals Agency)

Guidance on Information Requirements and Chemical Safety Assessment\(^35\).

“This guidance describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment. It is part of a series of guidance documents that aim to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation.” Although this guidance is framed around REACH it nevertheless provides a source of potentially useful information. It is available as a web-based guide with individual elements separately downloadable as pdf documents.

Guidance documents are by far the most common action undertaken by Member States in respect to supporting the implementation of the legislation transposing the CAD. Generally, the Member States consider that available information and guidance is sufficient. However, some national implementation reports which highlight challenges to SMEs also mention a lack of knowledge about measurement, risk assessment and risk reduction methods, etc. which could indicate a need for additional accompanying actions in this area. However, the extensive amount of material already available, including that at EU level, suggests that the problem might be more one of adequate communication rather than a need for additional material.

In addition to national material, further guidance is available at EU level, from the Commission, EU-OSHA and the European Chemicals Agency. This includes material on labelling chemicals, risk assessments and on the specific topic of nanomaterials as well as guidance for specific sectors or occupations and for specific tasks, such as maintenance.

However, no evidence is available regarding uptake and usage of this material. This view was echoed in the earlier (2010) evaluation of the impact of the CAD which commented that there was little robust evaluation of the extent or the effectiveness of activities by MSs to provide help and guidance to employers in implementing the provisions of the CAD\(^36\).


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 shows that the Member States typically have a general enforcement authority responsible for OSH enforcement and inspections related to all OSH matters. The same can be said about enforcement strategies. But there are exemptions. Table 3-5 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);
- 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).

For brevity, only those MSs where there are Directive-specific enforcement activities are shown. In the case where the answer to the questions is no, reference is made to the report on the Framework Directive, which provides a summary of the general systems in force. For specific details, please see the individual CSRs.

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<tr>
<td><strong>Sums</strong></td>
<td><strong>Y=5</strong></td>
<td><strong>Y=8</strong></td>
<td><strong>Y=11</strong></td>
</tr>
<tr>
<td></td>
<td><strong>N=22</strong></td>
<td><strong>N=19</strong></td>
<td><strong>N=16</strong></td>
</tr>
</tbody>
</table>

*Source: Country Summary Reports on each Member State*

No specific information is available, from the NIRs or elsewhere, regarding the competency of the specific authorities to manage chemical risks. It might be
assumed that those MSs who indicate that they have specific departments within their enforcing authority (e.g. BE) or at least individual inspectors with specific training (e.g. PL) would have a greater degree of competence than others, but there is no evidence relating to this assumption.

National strategies

MSs usually have specific campaigns or strategies addressing health or safety concerns. They appear to have a variety of criteria for selecting these, including national injury or health statistics, feedback from Inspectors, and tying-in with EU campaigns. Such campaign topics are selected to reflect national needs and priorities.

Specific sanctions

As noted above, most MSs do not have sanctions specifically relating to their legislation implementing the CAD. Those which do, utilise a variety of sanctions, ranging from fines (a number have a scale of fines ranging from administrative breaches to causing actual bodily harm or even death); operating prohibition, professional exclusion or closure of the establishment; or periods of imprisonment.

The employer who has not fulfilled his obligations regarding health protection according to special legislative acts can be subject to an administrative fine of up to 2 000 000 CZK. Where that breach of duties has a consequence of damage to human health or epidemic, an administrative fine up to 3 000 000 CZK can be administered.

Table 3-5 shows that only five Member States have designated a specific authority responsible for the enforcement of the CAD. The enforcement of the Directive typically comes under the general authority responsible for OSH inspections/enforcement. Also, MSs seldom have criminal or administrative sanctions specific to offences which are committed under the legislation concerning chemical agents, as opposed to the standard sanctions applicable in the OSH area.

3.6 MQ6: Vulnerable groups

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\(^3\). Typically, there are no specific tools or approaches which focus in particular on vulnerable groups and the risks associated with the CAD. However, the following MS-specific provisions have been found:


3.7 MQ7: SMEs and microenterprises

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

Although some MSs offer support to SMEs in the general implementation and application of OSH legislative provisions no MS appears to provide any specific national support in respect of the CAD by way of lighter regimes, exemptions or financial incentives (although some, e.g. Estonia, do facilitate access to EU funding support for eligible SMEs). Most provide guidance material which, in some cases, is prepared in a simplified version to facilitate its use by SMEs and others who lack professional OSH support in-house.

The NIR template included the specific question and instruction “Have the Member State or the social partners taken any specific measures to support SMEs in implementing the Directive? Please describe these measures.”

Details of individual responses can be seen in the NIRs. In general however, in response to this question, almost all MSs (one, CY, did not give any specific response) have reported the provision of guidance and other support material although, in many cases, they indicate that this is general support material, available to enterprises of any size and is not necessarily prepared with SMEs in mind (e.g. HU, LV).

In contrast, as noted above, some MSs report having prepared material which is ‘simplified’ or ‘basic’ with SMEs in mind (e.g. “The emphasis in all these publications is on supporting the SMEs special needs” IE). In a number of cases, support material appears to be aimed at support in respect of REACH as well as the CAD (e.g. Italy). Guides to assessing the risk from chemicals appear to be a tool commonly prepared with SMEs in mind (e.g. LI, PT), although not restricted in its use to SMEs. Such guides include webpages (e.g. RO, SE) although leaflets

\(^3\) Vulnerable groups as defined within the report: Occupational health and safety risks for the most vulnerable workers

and information sheets (e.g. UK) also feature. See also Section 3.3 with regard to SMEs and compliance with the CAD.
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 4-1 Summary of the five relevance parameters

<table>
<thead>
<tr>
<th>Coverage of Workforce and Member States</th>
<th>Accidents 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>50%</td>
</tr>
</tbody>
</table>

* See section 4.1

The Directive has been transposed into national legislation in all MSs according to evidence from the NIRs\(^38\). The use of chemicals in some form (even if solely as cleaning agents) will arise in each of the 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 (and self-employed) within the appropriate sectors. The Directive is relevant to all such workers.

There are a variety of sectors and occupations where exposure to chemicals is possible. 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 chemicals, without estimating numbers in such subsectors, a procedure was adopted whereby the whole employment figure was adopted for

\(^{38}\) Individual NIRs
those sectors where the majority can be assumed to be at risk of exposure (not necessarily exposed) and to omit those in relatively small subsectors. This will clearly result in an overestimate of those potentially at risk in some sectors and an underestimate in others. 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 (Nomenclature of Economic Activities) coding of economic sectors suggests that the following main sectors are relevant to the Chemical Agents Directive: agriculture, forestry and fishing (NACE A); mining and quarrying (NACE B); manufacturing (NACE C); electricity, gas, steam and air conditioning supply (NACE E); construction (NACE F); transporting and storage (NACE H), human health and social work activities (NACE Q).

LFS data documents that, for 2012, a total of 215,678,600 people were employed within the EU-27 (15-74 years). Combining the total of workers from each relevant sector gives a total of 97,546,200 workers or 45.2% of the EU workforce to whom this Directive is relevant. As noted above, it is not assumed that all workers in these sectors are necessarily exposed to chemicals but it is assumed that this over-counting will be at least to some extent compensated for by the exclusion of workers from other sectors or sub-sectors.

In addition to this estimate, Eurostat statistics indicate that around 9-10% of persons are employed in 'size zero' businesses (self-employed). Including these would increase this proportion to around 50% of the ‘economically active’ population corresponding to 107,839,300 workers. Some sectors (e.g. construction) do have a larger proportion than others, but there is no rationale for suggesting applying different proportions to the different sectors identified above. Although this seems a large proportion it should be recognised that the CAD does not just apply to those actively 'working with' chemicals in the sense of being involved in their manufacture. Some corroboration of this figure can be derived from the EWCS data, reported in Chapter 5, which recorded that approximately 50% of respondents (the actual percentage varying over time) reported ‘never’ working with chemicals (meaning presumably that the other 50% do so at least from time to time).

### 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?

Fatal accidents at work

Exposure to chemical agents could result in a fatal injury. However, the European Statistics on Accidents at Work (ESAW) database records fatalities by economic sectors (NACE codes) for the EU-27. These statistics are not comprehensive and may not capture all fatal injuries involving hazardous chemicals. However, they provide an indication of the occupational risks associated with chemical agents.

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39 Employment by sex, age and economic activity (from 2008 onwards, NACE Rev. 2) - 1 000 [lfsa_eggan2]
40 Key figures on European business with a special feature on SMEs. Eurostat 2011
sector, not the cause of death. Although fatal accidents are recorded for the economic sector engaged in the manufacture of chemicals and chemical products (32 fatalities in 2012 representing an incidence rate of 2.54 per 100,000 employed) there is no indication what proportion (if any) of these could be attributed to chemical exposure. Equally, in the many other sectors where chemicals of various forms are used extensively, there are no indications whether any fatal injuries arose from exposure to chemicals.

The ESAW database\(^{41}\) records non-fatal injuries by ‘type of injury’. However, this does not specifically record such injuries arising from exposure to chemicals. Such exposure could, for example, lead to chemical burns which are not differentiated from other forms of burn (e.g. from heat or cold) or poisoning (combined with infections).

However, statistics are recorded for accidents arising from contact with “chemical, explosive, radioactive, biological substances - not specified”\(^{42}\). This database records that, in 2005 (the only year for which the statistics appear to be available) there were 40,411 such accidents\(^{43}\) (representing an incidence rate of 36.9 injuries resulting in more than three days lost per 100,000 employed), compared to a total of 1749.5 for all causes, (0.6% of the total).

LFS data can be used to examine the level of work-related health problems (self-reported) relevant to the Chemical Agents Directive. Although relying on the self-reporting of work-relatedness, recent evidence from the UK suggests that such reports are generally reliable.\(^{44}\) One limitation is that, where respondents reported two or more problems, the LFS data only records that which the respondent considered to be the most serious. In general, the complaint which had the biggest impact on the worker’s activities should be that which is recorded\(^{45}\). The values quoted below from this source should therefore be regarded as minimum values, as others may also experience such problems which were not recorded as being considered less serious.

Two types of health problem can be identified which, it might reasonably be supposed, possibly arose from exposures to chemicals or dusts. These are ‘pulmonary disorders’ and ‘skin problems’\(^ {46}\). According to the EU LFS (2007) data, 3.6% of respondents reported experiencing work-related pulmonary disorders in the last 12 months whilst 1.8% reported skin problems. Whilst chemical agents were not necessarily responsible for these problems they are common causes.

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\(^{41}\) Accidents at work by type of injury and severity (NACE Rev. 2, A, C-N) [hsw_mi07]

\(^{42}\) Incidence rate of accidents at work by material agent of contact - mode of injury, economic activity, sex, age and severity [hsw_aw_mac2]

\(^{43}\) Number of accidents at work by material agent of contact - mode of injury, economic activity, sex, age and severity [hsw_aw_mac1]


\(^{46}\) Persons reporting their most serious work-related health problem work in the past 12 months, by type of problem - % [hsw_pb5]
One difficulty in interpreting any data sources is that many of the health problems related to chemical exposures have a long latency and might not be apparent until some time has elapsed, possibly when exposure has ceased. This also means that problems can continue to emerge even though suitable control measures are in place.

From the EWCS 2010 data, three questions can be identified which probably relate to exposure to chemicals. Respondents were asked the extent to which their work involved:

- breathing in smoke, fumes, powder or dust;
- breathing in vapours such as solvents and thinners;
- handling or being in skin contact with chemical products or substances

For breathing in smoke, fumes, powder or dust, 16.5% of respondents reported doing so at least a quarter of the time. For breathing in vapours such as solvents and thinners, and handling or being in skin contact with chemical products or substances the equivalent values were 10.4% and 14.7% respectively.

From the same survey, respondents were also asked about a number of health issues, including breathing difficulties and skin problems, both of which are frequently associated with exposure to chemicals. Further analyses were used to explore this, comparing the percentages reporting particular health problems against the extent of reported exposures to chemicals etc. Figures 4-1 and 4-2 illustrate the outcomes from these analyses which clearly show an increasing proportion of respondents with these two health issues with increasing exposures to assumed chemical agents. There can be many explanations for these apparent dose-response relationships. However, they clearly indicate that, the more a worker reports being exposed to ‘chemicals’ the more likely they are to report relevant health problems. This would seem to illustrate the ongoing relevance of controlling chemical exposures in the workplace and therefore of the CAD.

*Figure 4-1: Percentage of EWCS respondents with breathing difficulties compared to the extent of exposure to dusts, solvents or skin contact with chemicals*
Another source of relevant data is the LFS. In this survey, respondents were asked whether or not they had suffered any illness in the last 12 months. Where the person suffered from more than one work-related health problem during the reference period, only the most serious of these is considered. Thus these statistics are described as ‘the most serious health problem’ and, as other health problems are discounted, should be regarded as a minimum figure.

Respondents who indicated a health problem were then asked whether or not they considered this problem to be work related.

Figure 4-3, shows the percentage who reported work-related pulmonary disorders for each MS, together with the overall EU-27 average of 3.6%. Such disorders are a significant problem in Romania, where 19.9% of respondents emphasised this illness in particular. Similarly, Lithuania and Czech Republic are also burdened by relatively high proportions of their respondents reporting work-related pulmonary disorders, with 16.4% and 12.2%, respectively. The least burdened MSs are Sweden, Denmark and France with shares of 1.2%, 1.5% and 1.8%, respectively. These are self-report data and therefore unlikely to be susceptible to national differences in defining a work-related problem. One shortcoming of the data from this source is that no incidence statistics are available. It is therefore possible that these differences reflect variations in the relative scale of relevant economic activities between these MSs, and they should not be regarded as indicating any ‘better’ or ‘worse’ management of chemical hazards. Alternatively, the focus of the LFS on the most serious problems could be taken to indicate that, in those MSs, other health problems were seen as more serious than skin problems or breathing difficulties.

Figure 4-3: Proportion of respondents whose most serious work-related health problem was pulmonary disorders, by Member State

Note: Persons reporting that their most serious work-related health problem in the past 12 months was pulmonary disorders, in %.

Figure 4-4 shows the proportion of respondents in EU-27 in the same survey, who reported that the most serious work-related problem they experienced within the last 12 months was skin problems. As for Figure 4-3, it shows replies by Member State as a percentage for all economic activities, as data is not available at sector level.

As illustrated by Figure 4-4, work-related skin problems are generally identified as the most serious work-related health problem less often than other health problems, as the EU-27 average is 1.8% of respondents. The MSs with the highest proportion of respondents emphasising skin problems are Finland and France, both reporting 2.6% (compared with 19.9% for the most burdened MS for pulmonary disorders - Romania).

The least burdened MSs are Poland and Luxembourg both with a share of 0.7% of respondents.

These data may give some insight into those MSs where safety and health concerns caused by chemical agents may be more severe and most relevant or may, as indicated above, indicate a higher level of relevant economic activity in those MSs (or a stronger concern about other problems).
Figure 4-4: Share of respondents whose most serious work-related health problem was skin problems, by Member State

Note: Persons reporting that their most serious work-related health problem in the past 12 months was skin problems, in %.

Turning to the published literature, Sigsgaard and co-workers (2010) cite a 2000 study as reporting 52,700 deaths attributable to non-cancer respiratory disease (asthma: 6,200; COPD: 39,300; pneumoconioses: 7,200) with 868,000 Disability-Adjusted Life Years (DALYs) attributable to these conditions (asthma: 139,000; COPD: 468,000; pneumoconioses: 261,000)\(^{48}\). They report respiratory diseases as ranking as the third most prevalent occupational disease category (after ergonomic and stress-related diseases) in the European Union (EU). Many of these diseases will be attributable, at least in part, to exposure to chemicals. The authors focus these conditions on what they regard as traditional high-risk occupations (such as mining, farming, manufacturing and service work (e.g. hairdressers)) although the authors note high rates of occupational lung disease in newer professions, such as public administration, education, and occupational cleaning.

The same report cites a study by Ameille and co-workers in one MS (France) where the six highest risk occupations for occupational asthma were identified as car painters (33 per 100,000 per year), hairdressers (31 per 100,000 per year), woodworkers (22 per 100,000 per year), cleaners (6 per 100,000 per year) and healthcare workers (4 per 100,000 per year) (1996–1999). The most often implicated agents were isocyanates, latex, alkaline persulphates and aldehydes.\(^{49}\)

In the UK, the HSE state that COPD is common in later life and estimate that it is likely that over a million individuals currently have the disease in Britain, with over


25,000 deaths each year. Although the most important cause of COPD is smoking, past exposures to fumes, chemicals and dusts at work will have also contributed to causing many currently occurring cases. The HSE cite research as estimating that about 15% of COPD is likely to be work-related with around 4,000 occupational COPD deaths per year in Great Britain as a result.

Workplace exposures likely to contribute to this COPD burden include various dusts (including, coal, grain, and silica) as well as certain fumes and chemicals (including welding fume, isocyanates, and polycyclic aromatic hydrocarbons).

Thus it is clear that exposure to chemicals makes a significant contribution to respiratory health, reinforcing the view that the Chemical Agents Directive is and is likely to remain of considerable relevance.

In 2008, EU-OSHA stated that skin diseases were one of the most important emerging risks related to the exposure to (and extensive use of) chemicals. However, the report states that the recording of occupational diseases (including skin diseases) is very much influenced by national recognition and compensation systems and, as a result, their occurrence is very difficult to analyse. A lack of a standard definition for skin diseases makes it difficult to obtain accurate epidemiological data.

Similar concerns were expressed by Diepgen (2003) who, writing of skin diseases in Europe, commented that different occupational health systems and legislation in the countries across Europe makes it difficult to sketch a detailed picture for the whole continent. He added that reporting bias and selection bias have a considerable impact on the perceived prevalence and incidence, while reliable data are hard to extract from official registries.

The author states that the most important risk factor for Occupational Contact Dermatitis (OCD) is exposure to irritants. He identifies well-known irritants as water (wet work), detergents and cleansing agents, hand cleaners, chemicals, cutting fluids, and abrasives. Actual agents are often sector-specific so that, according to Diepgen, glycercylymonothioglycolate (GMTG), p-phenylene diamine, ammonium persulphate and toluene diamine sulphate are the most frequent sensitisers and the most frequent occupationally relevant allergens in hairdressers whilst, in metalworkers, OCD is mostly caused by irritants.

As a corollary to this, the author refers to what he describes as “an impressive downward trend of stated cases of occupational skin diseases in hairdressers in Northern Bavaria over the past decade [1990s]”. According to Diepger, this appears primarily to reflect improvements in working conditions “due to the

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51 Occupational skin diseases and dermal exposure in the European Union (EU-25): policy and practice overview
Concerns about exposure to chemicals

initiation of legislative and intensified preventive measures” giving an indication of the potential impact of legislative change such as that brought about by the Chemical Agents Directive.

Having thus examined the exposure levels and health effects, we wish to investigate the extent to which chemical agents are a concern in the workplace. Figures 4-5 and 4-6 show how employee representatives (ERs) and managements (MMs), respectively, estimate the degree of concern caused by dangerous substances in their workplaces. In this 2009 ESENER survey, dangerous substances include dusts, chemical, biological or radioactive agents. In other words, the concerns do not distinguish between chemical agents covered by the present Directive; biological agents governed by Directive 2000/54/EC; or chemicals with carcinogenic or mutagenic properties, covered by Directive 2004/37/EC.

Examining the degree of concern for dangerous substances across sectors, we find that as many as 69% of ERs and 68% of MMs find that dangerous substances constitute some or a major concern in the workplace. For ERs the overall concern is divided into 38% who consider dangerous substances a major concern while 31% consider it to be of some concern. Managers are somewhat more worried as 42% consider dangerous substances a major concern while 26% consider them to be of some concern.

These figures also illustrate the degree of concern for dangerous substances by NACE Rev 1 sector (no data is available for Agriculture), for ERs and MMs, respectively. This segregation shows a variation between sectors with major concerns predominating in the Manufacturing and Electricity, gas and water supply sectors, amongst both ERs (41% and 45%) and MMs (45% and 52%).

In contrast, the lowest level of concern appears to be within the Transport sector, where 42% of managers find that dangerous substances are of no concern.
Figure 4-5: Degree of concern for dangerous substances according to Employee Representatives

Source: EU-OSHA: ESENER (2009), ER250.1, NACE Rev 1 codes: C, D, E, F, I, N (data is not available for Agriculture).

Note: Question asked: "Please tell me whether [Dangerous substances (e.g. dusts, chemical, biological or radioactive)] is of major concern, some concern or no concern at all in your establishment?"

Figure 4-6: Degree of concern for dangerous substances according to Management

Source: EU-OSHA: ESENER (2009), MM200.1, NACE Rev 1 codes: C, D, E, F, I, N (data is not available for Agriculture).

Note: Question asked: "Please tell me whether [Dangerous substances (e.g. dusts, chemical, biological or radioactive)] is of major concern, some concern or no concern at all in your establishment?"
The extent of concern for dangerous substances remains high, giving a further clear indication of the continued relevance of the CAD.

Estimates based on employment within appropriate industrial sectors suggest that the CAD is potentially relevant to 45.2% of the EU workforce, with the addition of an estimated 10% self-employed workers making a total of 50%.

ESAW statistics on fatal accidents at work do not give any indications as to whether any of the fatal injuries recorded arose from exposure to chemicals. Similarly, the collated statistics on non-fatal accidents do not generally permit those arising from chemical exposures to be identified. However, statistics are recorded for accidents arising from contact with “chemical, explosive, radioactive, biological substances - not specified”. Although not exclusively concerning chemicals this database records that, in 2005 there were 40,411 such accidents (representing an incidence rate of 36.9 injuries resulting in more than three days lost per 100,000 employed), or 0.6% of the total.

According to EU LFS (2007) data, 3.6% of respondents reported experiencing work-related pulmonary disorders in the last 12 months whilst 1.8% reported skin problems. Whilst chemical agents were not necessarily responsible for these problems they are common causes of such problems and give some insight into health problems possibly related to exposure to chemicals.

EWCS 2010 data shows that 16.5% of respondents reported breathing in smoke, fumes, powder or dust, doing so at least a quarter of the time. For breathing in vapours such as solvents and thinners, and handling or being in skin contact with chemical products or substances the equivalent values were 10.4% and 14.7% respectively. Plotting the reported duration of such factors against those reporting breathing difficulties and skin problems shows a trend for increasing likelihood of reporting such problems with increasing daily duration of reported exposure.

These sets of data appear to indicate the ongoing need for risk management and the relevance of the CAD.

Support for this can be derived from the research literature which shows continuing respiratory health problems such as occupational asthma and COPD. From such material it is clear that exposure to chemicals makes a significant contribution to respiratory health, reinforcing the view that the Chemical Agents Directive is and is likely to remain of considerable relevance.

There is evidence of other health problems as well. For example, research studies suggest that the most important risk factor for Occupational Contact Dermatitis (OCD) is exposure to ‘irritants’ a term which encompasses many chemicals as well as other agents.

As further evidence of the need for managing occupational risks associated with chemicals, the 2009 ESENER survey asked managers and employees about their concerns regarding dangerous substances (including dusts, chemical, biological or radioactive agents). Almost 70% of both groups indicated some or major concerns.
Clearly therefore, there is an ongoing need for control of risks to health and safety arising from exposure to chemicals in the workplace.

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?

Six EU stakeholder groups expressed views and opinions regarding the Chemical Agents Directive. All regarded the Directive as being of continuing relevance. One endorsed the view that this Directive and that for Carcinogens or Mutagens should be merged into a single Directive. Several others commented that the distinction between the two was not always clear and could lead to some confusion – which could be interpreted as tacitly endorsing a single directive. It was suggested that the ‘legacy’ of ill-health associated with past exposures served to raise current awareness and recognition of the importance of reducing risks.

Another stakeholder expressed concerns about the complexities and difficulties in understanding limit values. References were made by single stakeholders to the value of various CPM requirements including health surveillance, and informing and consulting workers.

One group expressed the view that problems with exposure to chemicals were increasing and that the relevance of this Directive was also therefore increasing. Other groups looking to the future specifically mentioned nanoparticles or nanomaterials. Another group expressed the view that nanomaterials should be considered under a revision of the Chemical Agents Directive, as they are like any other chemical agents and could therefore be included in this Directive. However, nanoparticles were also referred to as carrying a degree of unknown risk. This was mentioned in the context of concerns regarding reliance on setting evidence-based limits, advocating precautionary limits where there were concerns regarding potential or unknown risks.

The interviews with national stakeholders identified largely the same issues as those identified during EU-level interviews. Thus it was suggested by some that dividing chemicals into Chemical Agents and Carcinogens was unhelpful and possibly confusing, whilst others advocated their retention as separate Directives.

Issues were raised about limit values, for example in the UK, an employer’s representative expressed great concern over the constant classification and reclassification of limit values. A further factor mentioned was the issue of the complexities of determining the extent of risk from mixtures of chemicals and that the rate of introduction of new chemicals into the workplace tended to move faster than the level of knowledge and awareness of those in authority (such as Inspectors) could keep pace with.
In Finland, there were concerns that setting limits at an unrealistic level would lead to work being directed towards other countries where higher or no limits existed. This was easier to counter where limit values were evidence-based as the decision to allow their workers to be put at risk was one for the other countries to determine. It perhaps becomes harder where the limit is based on the precautionary principle where evidence of actual harm is not available.

Referred to (but not defined) in respect of the risk of environmental damage in the TFEU (Article 191), the precautionary principle can be interpreted as the concept that when an activity raises threats of harm precautionary measures should be taken even if some cause and effect relationships are not established scientifically. Such an approach (referred to as a concern-based approach) ‘based on suspicion and precaution’ was advocated by a subject expert from the Netherlands.

The expert from the Netherlands used nanoparticles as an example of an area of chemicals where such an approach could (and should) be applied. Opinions seemed divided over whether or not the risks associated with nanoparticles warranted a new Directive or whether the provisions of the current Directive were sufficient.

Subsidiary issues raised included a need for guidelines for the development of Personal Protective Equipment (PPE) and inadequate labelling (covered by separate provisions). On the issue of PPE, comments elsewhere (not specific to this Directive) have indicated the feeling that Directives are not an appropriate vehicle for guidance. However, there were suggestions that EU-level guidance on the selection of PPE could be helpful as part of risk management.

No interviewee specifically raised the alternative approach known as ‘control banding’ in which chemicals are grouped according to similar physical or chemical characteristics, how the chemical will be handled or processed, and what the anticipated exposure is expected to be. Initially developed within the pharmaceutical industry, the UK HSE has developed this approach as part of their guidance to employers. They did so in response to ‘extensive market research’ which showed that SMEs in particular found the requirements for controlling exposure to chemical substances too difficult. Control Banding can be seen as using a simple model to identify the most appropriate control strategy to be adopted. It is a fairly crude tool (it can provide an unreliable assessment of how much exposure might occur) but, when coupled with more detailed advice for employers, can be more helpful. The concept is also included in measures such as the ILO Chemical Control Toolkit.

A study of the predictive model included in the UK approach, based on field studies in Germany, found agreement between measured and predicted exposures for solids to be ‘reasonably good’ whilst less so for liquids, particularly for small-scale applications. A comparison of the UK and ILO approaches concluded that the ILO

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53 The technical basis for COSHH essentials: Easy steps to control chemicals. London: HSE
54 Tischer et al, (2003) Evaluation of the HSE COSHH Essentials Exposure Predictive Model on the basis of BAuA field studies and existing substances exposure data
version was more protective of worker health but expressed a note of caution prompted by concerns that some safety margins were rather narrow. A further study, this time utilising the predictions incorporated in the Stoffenmanager tool developed in the Netherlands, also found that the model worked less well for liquids than solids. The authors also expressed a note of caution in that, even where good correlations were obtained, ‘data show substantial variability in exposure measurements given a certain Stoffenmanager score’. The authors perhaps provided the most useful overview in concluding that such approaches were ‘an ongoing process’.

MSs were specifically asked whether the CAD adequately addresses the risks from nanomaterials. Most did not provide an unequivocal answer although the majority appear to indicate that the provisions of the CAD should be adequate. Nevertheless, some other MSs gave a clear response that they considered a new Directive to be required. The general view appeared to be that the framework for assessing and managing risks from chemicals outlined in the Directive should be sufficient but that, in reality, the lack of clear knowledge and understanding of what those risks were made this problematic. There was a need for further research to identify the risks, and for a mechanism to ensure that knowledge about those risks was disseminated to those who needed that knowledge in order to control risks.

As noted in Section 3, many MSs have implemented additional Limit Values for chemicals not covered by the CAD and those supplementary lists issued since. Some have also implemented lower limits than those established under the Directive. Although in some cases this reflects a divergence of opinion between national experts and those advising the EU as to what the limit should be it more usually reflects the relatively slow rate with which limits for new substances can be incorporated into legislation at an EU-level.

Several explicit recommendations for simplifications were offered by the UK:

› ‘Modify Article 5 (General principles for prevention of risks associated with hazardous chemicals) to provide a more logical approach to the ordering of the risk prevention principles. For example, ‘reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned’ is next to the last entry on the list whereas we would expect this to be after the first entry concerning elimination of the risks.’

› ‘Modify Article 7 (Arrangements to deal with accidents, incidents and emergencies) to provide member states with the flexibility to determine in what circumstances duty-holders should provide information on their emergency arrangements for hazardous chemicals to external accident and emergency services, given that this obligation already exists in relation to major hazard

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55 Jones and Nicas (2005) Margins of safety provided by COSHH Essentials and the ILO Chemical Control Toolkit.

sites under Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances.'

› 'Modify Article 8 (Information and training of workers) to include security considerations as a factor in plant labelling requirements and the option that contents could be identified using a site only applicable bar code.'

Also, one explicit recommendation for amendment was offered by the UK:

› 'Review the limits for exposure to lead set out in Annex I and II, in the light of current scientific evidence.'

One explicit recommendation for amendment was offered by Denmark:

› 'When the chemical Directives are updated, it should be clarified that some nanomaterials are hazardous chemical substances, so that the risks of these nanomaterials is taken into account and health and safety measures are established. The EU legislation should also include a common definition of nanomaterials, and work on common limit values should also be stepped up.'

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. With regard to the use of nanomaterials, further research is required in order to determine the need to extend the legal framework and the scope of Directive 98/24/EC.'

One explicit recommendation for amendment was offered by Slovakia:

› 'We believe it would be advisable to specify in more detail the requirements of Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work concerning nanoparticles and ultrafine particles, fibres, aerosols, etc.'

All EU stakeholder groups interviewed regarded the CAD as being of continuing relevance. One (of six) speaking for an employer group endorsed the view that this Directive and that for Carcinogens or Mutagens should be merged into a single Directive.

One group expressed the view that problems with exposure to chemicals were increasing and that the relevance of this Directive was also therefore increasing. Other groups looking to the future specifically mentioned nanoparticles or nanomaterials. Another group expressed the view that nanomaterials should be considered under a revision of the CAD, as they are like any other chemical agents and could therefore be included in this Directive.

The interviews with national stakeholders identified largely the same issues as those identified during EU-level interviews. Thus it was suggested that dividing
chemicals into Chemical Agents and Carcinogens was unhelpful and possibly confusing; issues were raised about limit values; and concerns were expressed about the possible risks associated with nanoparticles. Opinions seemed divided over whether or not the risks associated with nanoparticles warranted a new Directive or whether the provisions of the current Directive were sufficient.

When this issue of combining the CAD and CMD was discussed amongst stakeholders attending the seminar held to consult them on issues arising from the review (“validation seminar”), views were quite polarised. Although there were some subtleties of opinion, most delegates representing employers were in favour of combining the Directives while those representing workers were against the proposition. Some delegates argued that, because of the similarity in approaches, merging the directives would be beneficial, reducing duplication and removing confusion amongst employers. Others argued however that there was no need to merge the directives and that any such changes would be burdensome for MSs in having to alter legislation. They indicated that, in any case, to ensure adequate worker protection any combined legislation would need to contain the same provisions as currently found in the CAD/CMD. A further argument was that the greater hazard associated with carcinogens justified a separate Directive. Thus whilst there might be a clear legal rationale for such a merger it is clear that there are what might be regarded as ideological differences against such a move. A subject expert commented that, as any carcinogenicity risk is taken into account in establishing OELS under the CAD this would further diminish any benefit from merging the two Directives as the risk is already accommodated under the present system.

A further factor mentioned was the issue of the complexities of determining the extent of risk from mixtures of chemicals and that the rate of introduction of new chemicals into the workplace tended to move faster than the level of knowledge and awareness of those in authority (such as Inspectors) could keep pace with. However, it is not immediately apparent whether this reflects any need to amend the Directive to maintain its future relevance, or a challenge relating to its implementation and enforcement.

On limit values, a view was expressed that setting limits at an unrealistic level would lead to work being directed towards other countries where higher or no limits existed. This was easier to counter where limits values were evidence-based as the decision to allow their workers to be put at risk was one for the other countries to determine. It perhaps becomes harder where the limit is based on the precautionary principle where evidence of actual harm is not available.

Member States were specifically asked whether the CAD adequately addresses the risks from nanomaterials. Most did not provide an unequivocal answer although the majority appear to indicate that the provisions of the CAD should be adequate. Nevertheless, some other MSs gave a clear response that they considered a new Directive to be required (although they did not generally indicate reasons for this view).

This was a further issue addressed at the seminar held to consult stakeholders on issues arising from the review (“validation seminar”), again opinions were divided
between those (mainly employers) who considered that existing provisions were sufficient and those (mainly workers) who felt that special precautions were required for nanoparticles and that a specific directive was therefore needed.

Many MSs have implemented additional Limit Values for chemicals not covered by the CAD and those supplementary lists issued since. Some have also implemented lower limits than those established under the Directive. Although in some cases this reflects a divergence of opinion between national experts and those advising the EU as to what the limit should be, it more usually reflects the relatively slow rate with which limits for new substances can be incorporated into legislation at an EU-level.

Several explicit recommendations for amendments to the Directive are made in NIRs. These mainly originate from the UK, although Denmark, Greece and Slovakia also made recommendations. Several of these relate to nanoparticles and/or nanomaterials.
5 Assessment of effectiveness

The assessment of the effectiveness of the CAD takes its point of departure in the impact storyline presented in Chapter 2 of this report. On the basis of the data gathered from statistics, studies and interviews, we examined whether the initial hypotheses can be confirmed regarding the impacts of the CAD.

This was done by looking into the values of impact indicators developed as part of the elaboration of the intervention logics for the CAD and by analysing stakeholder assessments of the effectiveness of the CAD.

In practice, we present the assessment by answering evaluation questions 1-4 on effectiveness (EQE1-4).

Data was assessed from the following NACE sectors. These were chosen on the basis of expert assessments, and their identification of those sectors and sub-sectors which are likely to be affected by the implementation of the Directive.

Table 5-1: Chosen sectors of relevance for the assessment of effectiveness of the CAD

<table>
<thead>
<tr>
<th>Nace Rev 2 sector codes</th>
<th>Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Agriculture, forestry and fishing</td>
</tr>
<tr>
<td>B</td>
<td>Mining and quarrying</td>
</tr>
<tr>
<td>C</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>D</td>
<td>Electricity, gas, steam and air conditioning supply</td>
</tr>
<tr>
<td>E</td>
<td>Water supply; sewerage; waste management and remediation activities</td>
</tr>
<tr>
<td>F</td>
<td>Construction</td>
</tr>
<tr>
<td>H</td>
<td>Transporting and storage</td>
</tr>
<tr>
<td>Q</td>
<td>Human health and social work activities</td>
</tr>
</tbody>
</table>

57 Sectors are translated into the corresponding NACE Rev 1 sectors, where relevant.
5.1 EQE1: Effect on occupational safety and health

In line with the intervention logic shown in Chapter 2, the impacts are first assessed by looking into workplace impacts – i.e. the direct changes/improvements that occur at the workplace as a result of implementing the KRs. Secondly the actual improvement in the safety and health situation arising from the workplace impacts is examined.

EU stakeholders were asked to assess the extent to which national legislation transposing the CAD had been successful. Nine stakeholder organisations provided a score from 1 – 5 (indicating ratings from ‘very low’ to ‘very high’). The total average score of 3.4 indicates that, according to EU stakeholder organisations, national legislation derived from the CAD has had an overall positive influence, but that some significant shortcomings are still observed (a rating of 3 indicates medium success, 4 = high). Interestingly, the worker organisations had a significantly less positive assessment of this legislation (2.7) than the employer organisations (3.8) or other stakeholders (3.8) (other stakeholders in this case encompass SLIC and OSHA). It is not clear from the available evidence whether this reflects differing degrees of knowledge on the implementation of the Directive or a different perception of what the level of protection afforded to workers should be.

Comparing these figures to the assessments provided by national stakeholders, shown in Figure 5-1, it will be noted that the score from stakeholder organisations representing employers and other stakeholders, remain relatively stable compared to the EU-level assessments, both giving relatively high average scores of 3.9.

Although national interviews in all MSs addressed this issue, 16 stakeholders in five MS provided a quantitative assessment. Clearly, these would appear to be unlikely to be considered representative of the whole EU-27, especially given the absence of such comment from any of the longer-established MSs. Care must therefore be taken in interpreting this finding. Given this however, it is interesting to note that worker organisations in this sample were markedly more positive than the corresponding stakeholder groups at EU level and provided an average score as high as 4.3 (compared to 2.7 at EU level). Again the reasons for this are unclear, although it might be suggested that those operating at a national level are ‘closer’ to the national workforce and workplaces and therefore have a more informed view. It might also be suggested that this difference reflected the greater scope for employers in these particular MSs to have an impact. This latter point has been identified previously in respect of the whole EU safety and health strategy, to suggest a great impact of the strategy in the newer MSs. However, as noted above, care should be taken in extrapolating these views to the wider national stakeholder population as relatively few national stakeholders gave a numerical score.
5.1.1 Workplace impacts

The purpose of the CAD is to lay down "the minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents." (CAD, Article 1). One means of accomplishing this overall objective, exploited in the Directive, is the establishment of occupational exposure limit values and biological limit values. The effectiveness of the Directive is therefore *inter alia* reflected in the degree of exposure by workers to chemical agents in the workplace. Simultaneously however, exposure levels should be assessed against the extent of any risk to health represented by that exposure.

As reported in chapter 4, the European Working Conditions Survey (EWCS) provides some insight into exposure to chemicals amongst the EU workforce; and the results from the 2010 survey were used to illustrate the ongoing relevance of the CAD, including an apparent association between the extent of exposure and the occurrence of symptoms. Some insight into changes in the extent of exposure and, through this, possibly some suggestions of the possible impact of the Directive, can be obtained through a comparison of these findings with the results from a similar survey conducted five years previously (2005). During these surveys, workers were asked to report on their potential exposure to a number of risk factors, including smoke, fumes, etc.
Figure 5-2 shows the extent to which workers reported being exposed to breathing in smoke, fumes, powder or dust. It shows that the proportion of workers who reported exposure around ¾ of the time, half the time and around ¼ of the time has remained relatively unchanged from 2005 to 2010 at 4%, 6% and 10%, respectively. A minor decrease may be seen however, in the proportion of workers who are exposed all of the time or almost all of the time (from 16% in 2005 to 12% in 2010) while a similar increase may be seen in the workers who reported never being exposed (from 49% to 53%). The proportion of workers reporting being exposed half the time or more decreased slightly from 26% in 2005 to 21% in 2010, while workers reporting exposure never or almost never increased from 64% to 69%. Although the results are far from unequivocal, they appear to suggest a positive trend towards a reduction in reported exposure to breathing in smoke, fumes, powder or dust between the two surveys.

Figure 5-2: Exposure to breathing in smoke, fumes, powder or dust, 2005 and 2010

Source: Eurofound: EWCS – Q23_e, NACE Rev 1 codes: A, C, D, E, F, I (data is not included for Health and Social Work, as it could not be independently extracted)

Note: Question asked: “Are you exposed at work to - Breathing in smoke, fumes, powder or dust etc.?"

Figure 5-3 shows the proportion of workers from the same survey who reported being exposed to breathing in vapours, such as solvents and thinners. Interestingly, figures have remained steady for all categories from 2005 to 2010. The proportion of workers who reported being exposed all the time or almost all of the time decreased slightly from 2005 to 2010, from 6% to 4.6%, while those workers who reported never or almost never being exposed to breathing in vapours remained stable at 83.4% in 2005 and 83.7% in 2010. Again there are (small) reductions in those reporting exposure for all or most of the time.
Finally in relation to exposure, Figure 5-4 shows the proportion of workers who reported exposure to handling or being in skin contact with chemical products or substances. As is the case for exposure to breathing in vapours, values have remained stable for all categories from 2005 to 2010. The proportion of workers who reported being exposed to handling or being in skin contact with chemical products all the time or almost all of the time decreased slightly from 2005 to 2010, from 6.7% to 5.2%, while the proportion who reported never or almost never being exposed remained stable at 80.9% in 2005 and 81.3% in 2010.
Figure 5-4: Exposure to handling or being in skin contact with chemical products or substances, 2005 and 2010

Source: Eurofound: EWCS – Q23_g, NACE Rev 1 codes: A, C, D, E, F, I (data is not included for Health and Social Work, as it could not be independently extracted)

Note: Question asked: "Are you exposed at work to - Handling or being in skin contact with chemical products or substances?"

It must be emphasised that these figures, derived from the EWCS survey, do not give any indication of the extent of any risk, as they take no account of the degree of exposure, or of the potential toxicity of the chemicals in question. For example, if all chemicals used had been substituted with safer substances, or the exposure levels reduced to 50% of previous levels, respondents would still report that they were ‘exposed to chemicals’. Such information was not collected as part of this survey.

Additionally, care should be taken in necessarily attributing any change (or lack of change) to the CAD (or any other single factor). As noted above, changes in types of chemicals or the degree of exposure would not be reflected in the figures. Additionally, such statistics take no account of any changes in the industry in terms of shifts in production etc.

As a further indicator of exposures relating to the CAD, Figure 5-5 shows the proportion of respondents who, during the 2007 Labour Force Survey, responded that the physical factors they were most exposed to at the workplace were chemicals, dusts, fumes, smoke or gases (as compared to noise or vibration, difficult work postures, work movements or the handling of heavy loads and the risk of accidents). The figure shows replies in percentages by Member State for all economic activities, as data are not available at sector level and thus cannot be extracted for those sectors most relevant to the CAD. This makes it more difficult to isolate problem areas, which fall under the domain of the CAD. Nevertheless, the Figure may give some insight into where safety and health concerns caused by chemical agents may be more commonly encountered within the EU-27.
As illustrated in Figure 5-5, the overall EU-27 average was 8.4%. Within this average, markedly more Slovenian workers report themselves as being exposed to chemicals, dusts, fumes, smoke or gases than in some other MSs, as 28.3% replied that this was the factor they were most exposed to. A relatively high proportion of Austrian, French and Croatian workers also reported exposure to chemicals, dusts, fumes, smoke or gases, with shares of 15.3%, 15.2% and 14.9%, respectively. In contrast, fewest workers in Luxembourg, Germany and Denmark reported exposure to chemicals, dusts, fumes, smoke or gases with shares of 2.5%, 2.7% and 3.3%, respectively. As before, the absence of any information regarding the nature of the chemicals to which workers are exposed, or the levels of exposure, makes these differences difficult to interpret. Additionally, as the information is not divisible by sector, it is not possible to make comparisons on a sectorial basis to provide any understanding of how well risks are managed in any one sector in different MSs. Part of the differences between MSs may reflect structural differences in their economies.

Figure 5-5: Share of respondents most exposed to chemicals, dusts, fumes, smoke or gases, by Member State

Source: Eurostat (LFS 2007), [hsw_exp4]

Note: Persons reporting that the physical factor that they were most exposed to were Chemicals, dusts, fumes, smoke or gases (compared to noise or vibration, difficult work postures, work movements or the handling of heavy loads and the risk of accidents) in %.

To provide a possible alternative view on the use of chemicals at work, statistics were examined of changes in the extent of production of chemicals with the EU. Although clearly production does not necessarily equate to exposure, such statistics could be regarded as representing the opportunity for exposure. As the Eurostat website indicates: “..production and consumption are not synonymous
with exposure, as some chemicals are handled in closed systems, or as intermediate goods in controlled supply chains.\(^{58}\)

Figure 5-6 shows Eurostat data for the overall production of chemicals.\(^{59}\) This shows a steady decline in the production in chemicals (both overall, and those regarded as ‘toxic’) in the period from a peak in 2007 to 2013.

*Figure 5-6: Annual production of all and toxic chemicals across the EU (Eurostat graph)*

Figure 5-7 shows a more detailed breakdown of toxic chemicals across the same period, with chemicals classified as ‘harmful’, ‘toxic’, ‘very toxic’, ‘chronic toxic’, and ‘carcinogenic, mutagenic and reprotoxic’ (CMR). The exact source of the classification used is not given “these classes of … toxicity to human health follow official classifications in EU legislation based on scientific expert judgement”.\(^{60}\) The graph appears to suggest a marginal decline in production of the two most toxic classes since the peak in 2007. Production of CMR chemicals fell in absolute terms from around 36 million tonnes in 2007 to 30.7 million tonnes by 2013 whilst, in relative terms, it fell slightly from 9.7% in 2007 to 9.5% in 2013. Examination of the source data table shows that production of all toxic chemical classes fell from 2007-2013. However, the change seems relatively small when viewed against changes in overall chemical production. In 2013, total chemical production fell to 86.9% of the 2007 value. In contrast, production of all toxic chemicals combined fell to 85.8% of the 2007 figure. It seems possible therefore that the reduction in toxic chemical production mainly reflects the reduction in overall production (and year on year fluctuations within that) rather than being due to any concerns regarding their toxicity.


Kromhout and co-workers (2013) reported on trends in exposure to respirable dust and quartz over a 12-year period (2000-2013) in the industrial minerals industry. This was based on measurements at work sites in 18 countries across Europe, of which 14 were from the EU. The authors reported that there was a clear downward trend in the proportion of location cells which exceeded >5% for respirable dust and for quartz. However, they note that the four most recent series of measurements have identified a reversal of this trend. They hypothesise that this might be attributable to economic circumstances, as employers reduce the number of workers resulting in them having less time for ‘housekeeping’\(^{61}\).

The latest report from NEPSI (The European Network on Silica) on the application of the European autonomous Social Dialogue “Agreement on workers’ health protection through the good handling and use of crystalline silica and products containing it” states: “Compared to 2012, and on a longer timeframe to 2008, all Key Performance Indicators (KPIs) prove to be steady or having improved”\(^ {62}\). These KPIs include:

- The provisions of the percentage of potentially exposed workers of around 41% in 2014 is remaining steady since 2008 and over the following years;
- the percentage of potentially exposed workers covered by risk assessment is 93% in 2014, representing an increase by 1.5 % since 2012 and by 5 % since 2008;
- the percentage of potentially exposed workers covered by exposure monitoring is 71.5% in 2014, representing an increase by 1.5 % since 2012 and by 10 % since 2008;


\(^{62}\) NEPSI Executive Summary. September 2014
in 2014, 95% of potentially exposed workers whose risk assessment indicate that they require Health Surveillance Protocol for Silicosis are actually covered by this Protocol: this percentage remains steady compared to 2012 and has improved by 6% since 2008;

the percentage of potentially exposed workers covered by information, instruction and training on General Principle is 88.4% in 2014, representing an increase by around 4% since 2012 and by 14% since 2008;

the percentage of potentially exposed workers covered by information, instruction and training on specific task sheets is 66% in 2014, representing an increase by around 5% since 2012 and by 22% since 2008.

In a paper based on some of the data collected by NEPSI, Tuomi et al (2014) report that application of good practices as described by the NEPSI agreement has coincided with a strong decline in the exposure to respirable crystalline silica in Finnish workplaces. The authors report a >10-fold decrease in the average and median exposures to respirable silica. As a result, only approximately 10% of the workplace measurements obtained in 2013 were above or identical to the OEL_{8h} (0.05 mg m^{-3}).

These reports therefore indicate considerable progress across one industry at least which can be related to concerted efforts at the EU level to improve workers health.

5.1.2 Safety and health impacts

This section attempts to assess how changes to the workplace which can potentially be related to the CAD have impacted safety and health in sectors assumed to be most influenced by its implementation. More specifically, it assesses whether Directive provisions such as exposure limit values and requirements for protective installations and equipment, may arguably be said to have influenced the degree of work-related pulmonary disorders, respiratory problems and skin problems, which are all illnesses potentially arising inter alia as a result of exposure to chemical agents.

Returning to data from the EWCS, Figures 5-8 and 5-9 show the proportions of workers in the period from 1995 to 2005 who reported that their work had a negative influence on their health. Figure 5-8 presents responses relating to perceived work-induced respiratory difficulties while Figure 5-9 relates to perceived work-induced skin problems. Both illustrate a similar rising trend for the proportion of workers who experience problems believed to have been caused by their work.

The proportion of workers mentioning respiratory difficulties rose across the three surveys, from 10% in 1995 and 11% in 2000/2001 to 21% in 2005. For skin

problems these figures are slightly higher, with 13% in 1995, 14% in 2000/2001 and 23% in 2005.

Figure 5-8: Work-induced respiratory difficulties, 1995-2005


Note: The data for 1995 only cover EU12. Question asked: "Does your work affect your health [respiratory difficulties]? Data for 2010 exist but has been excluded due to a difference in question wording that obstructs comparisons with the other datasets.

Figure 5-9: Work-induced skin problems, 1995-2005


Note: The data for 1995 only cover EU12. Question asked: "Does your work affect your health [skin problems]? Data for 2010 exist but has been excluded due to a difference in question wording that obstructs comparisons with the other datasets.
It should be noted that the data cannot be compared between the EWCS and LFS due to significant differences in question wording between the two surveys. The LFS data thus only contain workers who reported the respective health problem as the most serious (possibly of several) and thus exclude workers who may find that their work does cause pulmonary disorders or skin problems, but that it causes e.g. backache more. Also the formulation 'in the past 12 months' gives rise to significant differences in numbers. However, the relative comparison of MSs provides useful insight into where safety and health concerns caused by chemical agents may be more severe and more prevalent.

As part of the assessment of Directive effectiveness, all EU stakeholders interviewed were asked to give an overall score of how they perceived the Directive to have impacted the safety and health of workers. Eleven stakeholder groups were interviewed at EU level on the CAD, and eight of those provided a score on a scale from 1-5.

The employer organisations generally assessed the CAD to have had a higher impact on the overall safety and health of workers (3.75), compared to worker organisations; who considered the effectiveness of the CAD to be markedly lower (2.75). Both interviewed stakeholders in the ‘others’ category (SLIC and OSHA) responded that the CAD has had a high impact (4) on the safety and health of workers. The overall average of these three EU stakeholder groups is thus 3.5 (midway between medium and high). It is not known why the worker interviewees tended to assign a lower score than the employer groups.

EU stakeholders have assessed the national legislation transposing the CAD to have been reasonably successful, with nine stakeholder organisations providing an average score of 3.4 (on a scale from 1–5, indicating ratings from ‘very low’ to ‘very high’).

National stakeholders provided a higher rating. Stakeholder organisations representing employers and other stakeholders both gave relatively high average scores of 3.9. Contrarily, in the five Member States that provided a quantitative assessment, worker organisations provided an average score as high as 4.3 (compared to 2.7 at EU level).

In contrast, when directly asked about the impact on the overall safety and health of workers, EU employer organisations gave an average rating of 3.75, compared to 2.75 from EU worker organisations. OSHA and SLIC representatives were even more positive than the employers, giving a rating of 4.0.

Subjectively at least therefore the CAD is considered to have been at least reasonably successful, although the discrepancy between views of worker organisations relating to the two different questions demonstrates the care necessary in interpreting the significance of these ratings.

Turning to more objective evidence, data from the EWCS shows that the proportion of workers who reported exposure to breathing in smoke, fumes, powder or dust around ¾ of the time, half the time and around ¼ of the time has remained relatively unchanged from 2005 to 2010 at 4%, 6% and 10%, respectively.
However, there is a small decrease apparent amongst those most exposed (all of the time or almost all of the time) from 16% in 2005 to 12% in 2010, while a similar increase may be seen in the share of workers who reported never being exposed (from 49% to 53%).

Similarly, the proportion of workers who reported being exposed to breathing in vapours (such as solvents and thinners) all the time or almost all of the time decreased slightly from 2005 to 2010, from 6% to 4.6% although, in this instance, the proportion of those workers who reported never or almost never being exposed to breathing in vapours remained stable at 83.4% in 2005 and 83.7% in 2010.

In relation to exposure to handling or being in skin contact with chemical products or substances, the proportion of workers who reported being exposed to handling or being in skin contact with chemical products all the time or almost all of the time decreased slightly from 2005 to 2010 (from 6.7% to 5.2%), while the proportion of workers who reported never or almost never being exposed remained stable at 80.9% in 2005 and 81.3% in 2010.

These data appear to suggest only a minor change in chemical exposures over the years and therefore only a modest impact of the CAD. However, as noted above, the data provide no insight into the nature of the chemicals exposed to. Some insight into the production (but not exposure) of chemicals can be obtained from Eurostat data which shows a decline in the production of toxic chemicals (five classes of toxicity) from 2007 to 2012, although this largely appears to follow the decline in overall chemical production. Production of course only provides limited insight into exposure, although it could be regarded as reflecting the possibility of exposure.

Data from the EWCS show that the proportion of workers who reported that their work had a negative influence on their health (work-induced respiratory difficulties and work-induced skin problems) has increased from 1995 to 2005. The proportion of workers mentioning respiratory difficulties rose across the three surveys from 10% in 1995 and 11% in 2000/2001 to 21% in 2005. For skin problems, these figures are slightly higher, with 13% in 1995, 14% in 2000/2001 and 23% in 2005.

More positive data can be found in relation to various initiatives specifically targeting exposure to respirable silica, where a number of studies and reports suggest a clear downward trend in the proportion of locations, among those considered, where silica exposures were excessive.

It would seem therefore that, although there have been some positive changes recorded, there is little substantive evidence overall to indicate that the CAD has had a marked impact on the health and safety of workers.
5.2 EQE2: Effect of derogations and transitional periods

**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?

**EQE2: Answer**

The CAD does not contain any provisions for transitional periods, and no data are available which permit the assessment of the effect of any of the derogations applied within any MS.

5.3 EQE3: Effect of Common Processes and Mechanisms

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

**EQE3: Answer**

No objective data are available which enable the effectiveness of individual CPMs to be explored.

However, 11 EU stakeholders were interviewed on the CAD and eight of those gave their perceptions of the influence of individual CPMs on the effectiveness of the CAD. Risk assessment stood out as the most important key requirement followed by the provision of information, the hierarchy of control and exposure limits.

During interviews with national stakeholders, the key requirement relating to exposure limit values was often highlighted as being of high importance. One reason often cited for this was the element of knowledge embedded in establishing limits. Employers often lack specific knowledge on when exposure to Chemical Agents might have a negative impact on the safety and health of workers and targets and OELs constitute an important guideline for them to abide by.

5.4 EQE4: Effect of enforcement

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

**EQE4: Answer**

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

However, EU stakeholders were asked to assess the importance of enforcement measures for securing compliance with the CAD and to identify the enforcement measures they considered to have had the highest impact on its effectiveness, giving each a rating from 1-5. Eight EU stakeholders (four employer organisations, three worker organisations and OSHA) rated the overall importance of enforcement
measures in achieving compliance with the CAD. Employer organisations were generally the most sceptical with an average score of 3.6, although they did acknowledge that enforcement had a considerable role in securing compliance (note that this average is between medium (3) and high (4)). Worker organisations generally found enforcement measures to be of high importance (4.3) and OSHA assessed the importance of enforcement measures as very high (5).

When asked to consider effectiveness rather than compliance, ten of the eleven EU stakeholders expressed a view. They highlighted ‘Enforcement combined with guidance’ as the single most important enforcement measure, followed by the ‘Frequency of inspections’ and finally by ‘Monitoring’ as the three most effective measures.

Among national stakeholders the enforcement measures of inspections and other controls as well as obligation for corrective actions were emphasised as important enforcement measures, although no numerical ratings were provided.

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 Directives?

Answer to EQE5

This question is addressed in the Main Report in a cross-Directive perspective.

5.6 EQE6: Broader impacts

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

Answer to EQE6

This question is addressed in the Main Report in a cross-Directive perspective.

5.7 EQE7: Objective achievement

EQE7: To what extent are the Directives 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?

Answer to EQE7

This question is addressed in the Main Report in a cross-Directive perspective.
6 Assesment of coherence

6.1 EQC1: Coherence and complementarity between the Chemical Agents Directive (CAD) 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 requirements of the CAD apply where hazardous chemical agents are present or may be present at the workplace. Under this directive, ‘chemical agent’ means any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market. The hazardous nature of the chemical agents is defined by reference to the criteria for classification as hazardous set by Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the Classification, Labelling and Packaging (CLP) Regulation) Chemical agents that are not classified as dangerous under CLP are still covered by the CAD, if their physicochemical, chemical or toxicological properties and the way they are used or are present in the workplace, represent a risk to the safety and health of workers.

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Interaction with other OSH chemical directives

The provisions of the CAD apply without prejudice to more stringent and/or specific provisions contained in the CMD.\(^{65}\)

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 to asbestos as asbestos falls under the definition of chemical agents.

Risk assessment

Since the provisions of the CAD must apply without prejudice to the more stringent and/or specific provisions contained in the CMD, the following risk assessment measures under the CAD will also apply to carcinogens and mutagens:

- Information on safety and health to be provided by the supplier;
- The circumstances of work involving such agents;
- The effect of preventive measures taken or to be taken;
- The conclusions to be drawn from any health surveillance already undertaken;
- Additional information needed for the risk assessment that the employer must obtain from the supplier or from other readily available sources;
- Assessment in case of activities involving exposure to several hazardous chemical agents, based on the risk presented by all such chemical agents in combination.

However, some provisions from the risk assessment procedure of the CMD could also apply 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 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 nature of the risk.
- The CMD requires that the risk assessment must take into account all routes of exposure, such as absorption into and/or through the skin. In contrast, the CAD makes no reference to routes of exposure. Such criteria to define the risk of exposure are not only valid and pertinent for carcinogens and mutagens but also for many other hazardous chemical agents. 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). However, it is appropriate, in addition, that for all hazardous substances employers should consider all relevant routes of exposure in their risk assessment.

\(^{65}\) 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).
Preliminary conclusions:

› Consider the inclusion of elements of the CMD that could apply to all chemical agents i.e. the obligations to renew the risk assessment regularly, to supply the authorities responsible at their request with the information used for making the assessment and the explicit requirement to take into account all relevant routes of exposure, such as absorption through the skin or inadvertent ingestion of chemicals from hand-to-mouth contacts, in the risk assessment procedure of the CAD.

› An alternative option would be to consider the merging of the CAD and CMD.

The three chemical Directives follow different approaches with regard to the derived risk management measures. This is mainly due to the specificity of the risks covered and the different hazardous properties of these agents (e.g. carcinogens or mutagens/ asbestos/ hazardous chemical agents). All Directives set less stringent risk management measures if the risk of exposure is according to the risk assessment, apart from the CMD. The lack of exemption here is justified by the specific hazard posed by carcinogens and mutagens. No change to the CAD is considered to be warranted.

Requirements on demarcation of risk areas

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

› Only the CAD does not set 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 a 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 derived from the risk assessment under the CAD to include a measure related to the demarcation of risk areas and use of adequate warning and safety signs 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.

› An alternative option would be to consider the merging of the CAD and CMD.

Substitution requirements

The CAD provides that, in order to eliminate, or reduce to a minimum, exposure to hazardous chemical agents, substitution shall be the preferred solution, 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 is less hazardous to workers' safety and health, as the case may be.

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.
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 apply to all hazardous substances independently of the level or type of risk, as is the case in certain MSs (e.g. Germany). 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 carcinogens and mutagens. In addition, any more stringent requirement on substitution may involve a significant compliance cost for employers.

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.
› An alternative option would be to consider the merging of the CAD and CMD.
› 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 CAD does not include any requirement relevant to the appointment of preventive and protective services. This is the case for all three Directives relating to chemicals and does not create any issue of coherence, as the requirement to appoint such services/persons is linked to every specific establishment / undertaking and is 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 CAD includes a ‘without prejudice’ clause referring to the relevant article of the Framework Directive, while containing additional risk specific requirements (e.g. information on the hazardous chemical agents occurring in the workplace, access to any safety data sheet provided by the supplier) as well as some that are more general and could bring an added value to the general principle set in the Framework Directive (see Framework Directive report).

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

› The CMD is the only of the three chemical directives to establish access of workers and/or any workers’ representatives to anonymous collective information.

66 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
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).

Details concerning information relevant to PPE are not provided under the CAD, whereas the CMD and Asbestos Directive include information on wearing and use of protective equipment and clothing.

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 keep 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. Such measures are not considered to increase significantly the employer cost of compliance and can easily be implemented.

Training of workers

Using the same provision that sets the requirement on information to workers, in respect of the requirement on training of workers, the CAD contains a ‘without prejudice’ clause referring specifically to Article 12 of the Framework Directive and provides some additional, more specific requirements.

However some provisions on information from the CMD and Asbestos Directive could also apply 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 and asbestos:

- The CMD and Asbestos Directive include training requirements relevant to the potential risks/effects to health. Such a requirement is not set under the CAD.

- Hygiene requirements are a part of training only under the CMD. The CAD does not include a similar training requirement.

- Details concerning training relevant to PPE are not provided under the CAD (although, as noted earlier, one MS has suggested that guidance on PPE would be beneficial), whereas the CMD refers to training concerning the wearing and use of protective equipment and clothing and the Asbestos Directive includes training on the appropriate role, choice, selection, limitations and proper use of PPE (specifically respiratory protective equipment).

- Finally, only the Asbestos Directive includes the requirement to provide training on medical surveillance requirements, which is more of a multidisciplinary nature. However, health surveillance is of equal importance in relation to all chemical agents.
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, training on medical surveillance requirements.

› An alternative option would be to consider the merging of the CAD and CMD.

Health surveillance

The CAD provides a specific definition for health surveillance, as the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific chemical agents at work. This Directive is one of the fourteen Directives that include a health surveillance requirement. Moreover, the relevant provision contains a ‘without prejudice’ clause referring specifically to Article 14 of the Framework Directive while at the same time it establishes more detailed requirements regarding health surveillance.

The health surveillance provisions under the other two chemicals directives follow a similar approach, while containing some additional requirements specific to the risks they cover (e.g. specific chest examinations for asbestos). However two provisions on health surveillance from the CMD and Asbestos Directives could also apply to all chemical agents under the CAD:

› Out of the three chemicals directives, only the CMD and Asbestos Directives stipulate that the doctor or the authority responsible for the health surveillance must be familiar with the exposure conditions or circumstances of each worker. 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).

› The possibility for workers concerned or the employer to request a review of the results of health surveillance is foreseen in the CMD and Asbestos Directives, but not in the CAD.

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.

› An alternative option would be to consider the merging of the CAD and CMD.

Health records

The Framework Directive does not regulate health records, whereas almost all daughter Directives contain a provision on health records, including the CAD. The health record requirements in the CAD are more detailed than in the other two chemicals Directives, but as previously mentioned, this does not create any coherence issues due to the use of ‘without prejudice’ clauses.

Consultation of workers

The CAD, like 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
occupational exposure limit values (OELs) set limits for exposure via the airborne route such that exposure, even when repeated on a regular basis throughout a work life, will not lead to adverse effects on the health of exposed persons and/or their progeny at any time (as far as can be predicted from the contemporary state of knowledge). OELs can be established through either a ‘health based’ approach or a ‘risk based’ approach. The methodology to define OELs under the CAD follows a ‘health based’ approach.

The objective of establishing occupational exposure limit values (indicative and binding) was first introduced by Council Directive 80/1107/EEC as amended by Directive 88/642/EEC. A first set of indicative occupational values (IOELS) for 27 chemicals or group of chemicals was adopted in 1991.

The entry into force of the CAD in 1998 resulted in the adoption of several OELs, within a wider framework of risk management in relation to occupational exposure to chemicals. OELs under CAD can either be indicative OELs or binding OELs. The CAD also sets binding biological limit values (i.e. lead and its ionic compounds). These three terms are defined in Table 6-1 below.

67 SCOEL, Methodology for the Derivation of Occupational Exposure Limits, 2013 Available at: ec.europa.eu/social/BlobServlet?docId=4526&langId=en
68 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.
69 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 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).
Table 6-1: Definitions of Indicative OELs, Binding OELs and Binding Biological Limit Values according to CAD

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
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| Indicative OELs | IOELs are health-based non-binding values, they set threshold levels of exposure below which, in general, no detrimental effects are expected for any given substance after short term or daily exposure over a working life time. They are European objectives to assist the employers in determining and assessing risks. “For any chemical agent for which an indicative OEL value is established at EU level, Member States must establish a national exposure limit value, taking into account the Community indicative limit value, determining its nature in accordance with national legislation and practice.”

| Binding OELs | According to Article 3(4) of the CAD, binding occupational exposure limit values may be drawn up at EU level and, in addition to the factors considered when establishing indicative occupational exposure limit values, shall reflect feasibility factors (e.g. socio-economic and technical feasibility) while maintaining the aim of ensuring the health of workers at work. “Such limit values must be established by the Council and the European Parliament in accordance with Article 153(2) of TFEU and laid down in Annex I to this Directive.”

| Binding Biological Limit Values (BLVs) | Under certain circumstances biological monitoring offers advantages over air monitoring in assessing risk to health, e.g. for substances with a significant skin uptake. For such compounds, biological monitoring may be preferable, if suitable methods are available. In this context biological limit values (BLVs) are reference values for evaluating potential health risks in the practice of occupational health. A BLV is a guideline for the control of such risks and should not be used for other purposes. “Binding biological limit values should reflect feasibility factors while maintaining the aim of ensuring the health of workers at work.”

Within the framework of the CAD, three lists of IOELs were adopted through Directive 2000/39/EC, Directive 2006/15/EC, and Directive 2009/161/EU. Work is on-going for the adoption of a fourth list. Note that the definition of an IOEL given above provides flexibility to MSs in determining their national limit (including the adoption of a higher limit if they choose to do so). In contrast, although MSs have some flexibility in establishing national Binding OELs and Binding BLVs, these are constrained by the Directive to be possibly lower but no higher than the values set at EU level. Where MSs exercise the option of selecting lower limits this results in a certain lack of harmonisation between MSs.

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71 CAD Article 3(3)
72 Treaty on the Functioning of the European Union.
73 CAD Article 3(4)
74 Definition extracted from a 2014 SCOEL document on the list of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs) available at: ec.europa.eu/social/BlobServlet?docId=12629&langId=en
75 CAD Article 3(6)
The procedure of adoption of occupational limit values is initiated by the Commission which, according to Article 3 of the CAD, must evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure, by means of an independent scientific assessment of the latest available scientific data. This independent scientific assessment is carried out by the Scientific Committee on Occupational Exposure Limits for Chemical Agents (SCOEL) which is set up by Commission Decision 2014/113/EU. Members of the SCOELs must be highly qualified, specialised independent experts selected on the basis of objective criteria. They must provide the Commission with Recommendations or Opinions at the latter’s request on any matter relating to the toxicological evaluation of chemicals and more particularly on occupational exposure limits as defined in CAD and CMD. This Commission decision also requires that the SCOEL must adopt a methodology for the derivation of OELs.

On the basis of SCOEL scientific evaluation, the Commission must develop legal proposals for OELs. Legal proposals must be submitted for consultation to the tripartite Advisory Committee on Safety, Hygiene and Health protection at Work (ACSH)\(^76\) which has the task of assisting the Commission on the preparation, implementation and evaluation of all initiatives related to health and safety at work. The Commission proposal must then be adopted through the ordinary legislative procedure involving the Council and Parliament. Table 6-2 below presents the 16 detailed steps that must be completed in practice for the adoption of an occupational limit value at the EU level.

Table 6-2: Procedural steps for the adoption of limit values

<table>
<thead>
<tr>
<th>Detailed Commission procedural steps for the adoption of limit values(^77):</th>
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<tbody>
<tr>
<td>1. Substance priority identification</td>
</tr>
<tr>
<td>2. SCOEL evaluation and adoption of a Recommendation</td>
</tr>
<tr>
<td>3. Inclusion in Commission legislative work plan</td>
</tr>
<tr>
<td>4. Development and launch of a Social Partner consultation (stage one)</td>
</tr>
<tr>
<td>5. Set up and management of Inter-Service Group (ISG) throughout the future steps in the procedure</td>
</tr>
<tr>
<td>6. Research of funds for a study to help with the preparation of an Analytical Document (AD)</td>
</tr>
<tr>
<td>7. Launch specifications, appoint contractor and manage study</td>
</tr>
<tr>
<td>8. Preparation of AD and submission to the Regulatory Scrutiny Board (RSB)</td>
</tr>
<tr>
<td>9. Preparation and launch of a Social Partner consultation (stage two)</td>
</tr>
<tr>
<td>10. Discussion in the WPC (Working Party on Chemicals) followed by preparation of a draft Opinion</td>
</tr>
<tr>
<td>11. Consideration and adoption of Opinion by ACSH</td>
</tr>
<tr>
<td>12. Research of funds for possible additional study to support impact assessment (IA)</td>
</tr>
</tbody>
</table>

\(^76\) Composed of three full members per Member State, representing national governments, trade unions and employers’ organisations

\(^77\) Information retrieved from Commission services involved in the preparation of Commission proposals on a limit value.
Since 1991, around 200 IOELs have been adopted. In comparison around 12 500 DNELs have been set through the REACH registration procedure\(^7\) (for further details please see the section on external coherence under REACH). The long and complex procedure of adoption of OELs has detailed above and the relatively low number of OELs compared to DNELs would suggest the necessity to review and revise the procedure of adoption of limit values.

Concerning the coherence with CMD, there are no indicative limit values under the CMD. Similarly to the CAD, binding limit values on carcinogens or 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.

Although long and complex, the procedures for the adoption of limit values under the CMD and CAD are similar so no legal coherence issues arise. Similarly, although the flexibility given to MSs to vary Indicative OELs may result in different standards between MSs this does not lead to any legal coherence issues at MS level.

The CAD does not include any references to workers at particular risk. The CMD 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. This requirement is already covered under the Framework Directive. There are therefore no coherence issues here.

**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 or mutagens. The CAD, which also contains substitution requirements, does not contain such a provision.

**Preliminary conclusions:**

› Consider applying reporting provisions to all chemical agents in order to enhance substitution to less dangerous chemicals.

Inspection and enforcement measures. The CAD and CMD do not include any provisions relating to inspections or penalties. 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 alone and such requirements could cover the OSH acquis as a whole (see the 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 this was leading to difficulties in clarifying the boundaries (areas of application) of each Directive. The stakeholder suggested that, in consideration of the similarity of objectives, and the uncertainty deriving from the numerous overlaps, these two Directives could work better if they were consolidated into a single text.

One stakeholder referred to potential synergies between the CAD and Directive 92/85/EC (pregnant workers) without further explanation.

Information from the NIRs

One Member State underlined that the Asbestos Directive and CMD supplemented the CAD. The Member State stressed that it was inappropriate to bring the Directives together under one common regulation and emphasised that the combined application of the three Directives was easy to understand and to deal with, allowing simple chemical working-environment management at undertakings.

Another Member State stressed that provisions of the CAD overlapped with those of other directives on risk assessment, consultation and participation of workers, information and training for workers, health surveillance, maintenance of respiratory equipment, arrangements for dealing with accidents, incidents and emergencies involving chemicals, mining safety, control of exposure to chemical agents, prevention of explosive atmospheres, use of safety signs.

With regard to internal coherence, this section focuses primarily on coherence between the CAD (98/24/EC) and the two other OSH Directives addressing risks from chemical exposure in the workplace - the Carcinogens or Mutagens Directive (CMD - 2004/37/EC) and the Asbestos Directive (2009/148/EC). No major internal coherence issues were identified, apart from the identification of provisions under the CMD and Asbestos Directive that could potentially apply to all hazardous chemical agents and could therefore be included in the CAD. This examination of legal coherence raises the issue of the possible merger of the CAD with the CMD. Some discussion of this has been given above and the issue is discussed further in Chapter 7.

Findings related to coherence between the CAD and the Framework Directive are described and addressed in the report on the Framework Directive itself. 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 CAD.
6.2 EQC2: Coherence between the CAD 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\(^{79}\), Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?

Other EU non-OSH legal acts

The requirements of the CAD apply without prejudice to the provisions for chemical agents to which measures for radiation protection apply (CAD Article 1(2)), pursuant to Directives adopted under the Treaty establishing the European Atomic Energy Community and to more stringent and/or specific provisions related to the transport of hazardous chemical agents (CAD Article 1(5)).

Legal links with other EU legislation

REACH Regulation

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 EU workplace legislation, including the CAD, and Article 14(1) of REACH states that a chemical safety assessment (CSA) shall be performed and a chemical safety report (CSR) completed without prejudice to Article 4 of the CAD on risk assessment. At the same time, Article 1(3) of the Framework Directive provides that it “shall be without prejudice to existing or future national and Union provisions which are more favourable to protection of the safety and health of workers at work”.

This shows that the legislator’s intention was to ensure that OSH legislation (including the CAD) and REACH acts could co-exist, without one prevailing over the other, because of their difference of scope, actors involved and obligations as underlined in the paragraphs below. In this context, it is noted that the ‘Regulations’ page of the ECHA website (“the driving force among regulatory authorities in implementing the EU’s groundbreaking chemicals legislation for the benefit of human health and the environment”) does not include any specific reference to the CAD\(^{80}\). 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. In contrast, the EU-OSHA legislation pages on exposure to chemical agents and chemical safety include non-OSH legislation such as CLP and REACH as well as the OSH Directives\(^{81}\). It is clearly important that all involved in the chemicals industry and chemical safety are

\(^{79}\) Now the Cosmetics Regulation


as fully informed as possible and such cross-fertilisation of information provides a small but useful example.

The aim of REACH as described in Article 1(1) is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. It covers workers, consumers and the environment whereas the CAD only focuses on the protection of workers.

Whereas REACH places obligations on the manufacturers, importers, and downstream users, in the supply chain, the CAD imposes requirements on the employers; who could be manufacturers, importers, downstream users, distributors or suppliers under REACH.

REACH applies to the manufacture, placing on the market or use of substances (chemical elements and their compounds as defined in REACH Article 3(1)) on their own, in mixtures or in articles and to the placing on the market of mixtures. In contrast, OSH chemical legislation applies to worker exposure to chemical agents released by any work activity, whether or not produced intentionally and whether or not placed on the market.

A risk assessment under REACH is carried out by registrants of chemical substances. This must consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses whereas, under the CAD, employers must carry out a risk assessment at a specific workplace.

Under REACH, exposure scenarios are developed and ‘Risk Management Measures’ (RMMs) identified for named tasks and procedures. Under the CAD, the employer is required to control exposure in all uses by site and process-specific measures. The employer should therefore be able to make use of any assessment (and RMMs) provided on a REACH safety data sheet (SDS) and, at the same time, will have to demonstrate the applicability of the scenario and procedures described. By return, employers are expected to provide feedback on the relevance to them of the proposed risk management measures. Thus, although the requirements under REACH should assist the employer in complying with the CAD, providing a degree of synergy (e.g. the descriptions of appropriate engineering controls and individual protection measures required for the SDS under Annex II to REACH) these do not absolve the employer of his duties to adapt the information received to their appropriate workplace conditions and to implement additional risk management measures if necessary.

Worker exposure to chemical substances is initially controlled with reference to REACH through risk management measures identified by registrants and circulated in the supply chain by SDSs. These should reflect all the identified uses of the chemical substances in the supply chain and related control measures. Under the CAD, worker exposure to chemical agents is mainly controlled by measures identified through the employer's risk assessment. This assessment

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82 See REACH Annex I
must take into account the information provided in the SDS for the chemicals present and used in the workplace.

The REACH registration procedure sets differentiated requirements and exemptions based on the tonnage of chemical substances manufacture or placed on the market\textsuperscript{83} although, other obligations under REACH, namely authorisation and restrictions, apply regardless of the tonnage of the chemical substance. The CAD applies to all chemical agents at the workplace independently of the quantity used at that workplace.

\textbf{Reference to the CAD 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 sets the requirements for the compilation of SDS, refers a few times to the CAD. These references relate to the use of data from the SDS generated through REACH in the implementation of OSH requirements. REACH requires information to be provided in the SDS relating to the protection of human health and safety and the environment, in order to help employers implement suitable working procedures and organisational measures in accordance with OSH legislation such as the CAD. It also specifies that the information on the SDS must enable the employer to determine whether any hazardous chemical agents are present in the workplace, to assess any risk to the health and safety of workers arising from their use (i.e. information on occupational exposure controls) and to set control measures according to Article 5 of the CAD (i.e. handling and storage of chemicals).

\textbf{Exposure limits: potential overlaps}

As mentioned above under the section on internal coherence, an OEL is the level that describes ‘adequate control of occupational exposure by inhalation’.\textsuperscript{84}

As already mentioned above, for any chemical agent for which an indicative OEL value is established at EU level, Member States must establish a national exposure limit value, taking into account the Union indicative limit value, determining its nature in accordance with national legislation and practice\textsuperscript{85}. As provided for in the CAD, OELs can differ from one country to another. In other words Member States can set national OELs higher, lower or with the same value as the value of the EU IOEL for the same substance. The rationale for allowing this variation is not provided in the CAD and any comments regarding this in the absence of such knowledge would be pure conjecture. According to Article 3(9) of CAD, the Commission shall carry out an assessment of how MSs have taken

\textsuperscript{83} The authorisation and restriction obligations are not based on tonnage.
\textsuperscript{84} European Commission, guidance for employers on controlling risks from chemicals Interface between Chemicals Agents Directive and REACH at the workplace (October 2010)
\textsuperscript{85} Information retrieved from explanatory text on OELs and their procedure of adoption available at: http://ec.europa.eu/social/BlobServlet?docId=3879&langId=en
account of IOELs in establishing national OELs although no such analysis has been seen.

Binding OELs (BOELs) are adopted taking into account socio-economic factors, and feasibility factors as well as the factors considered when establishing IOELs. For any chemical agent for which a BOELV value is established at EU level, Member States must establish a corresponding national binding OEL value which can be stricter, but cannot exceed the Union limit value\(^\text{86}\). As already mentioned above these OELs are adopted based on the independent opinion of the SCOEL and in cooperation between Member States and the Commission.

REACH introduced a new approach to setting exposure reference levels of chemicals, based on human health and environmental effects covering all the exposure routes and the environmental compartments. 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). All relevant exposure routes must be taken into account when defining DNELs (i.e. oral, dermal and inhalation). REACH also requires that Derived Minimum Effect Levels (DMELs) must also be set by registrants for substances where no safe threshold can be set (e.g. carcinogenicity).

DNELs/DMELs are also part of the risk characterisation used to determine an unacceptable risk that would justify a restriction. MSs Competent Authorities or ECHA and ECHA’s Risk Assessment Committee (RAC) set up the DNELs/DMELs on the basis of the registration dossier. DNELs/DMELs established by registrants are also part of the risk characterisation in the Authorisation procedure, in assessing if the applicant’s proposed risk management measures are appropriate and effective. The RAC may re-define DNELs/DMELs during evaluation of applications for authorisation and establish a ‘reference DNEL’ and dose response curves for non-threshold substances. Unlike OELs the DNELs cannot differ from one MS to another.

The main differences between DNELs and OELs are their objectives and the methodologies used for their derivation. OELs are explicitly developed for occupational safety purposes whereas DNELs have been set-up to support industry in doing risk assessments and fulfilling obligations under REACH; as well as to establish a high level of protection during the use of chemicals. The REACH guidance for DNELs\(^\text{87}\) suggests using default factors if substance specific data is missing whereas for OELs, most countries (as well as SCOEL) argue that expert judgment is needed to fill this data gap and that no default factors should be provided\(^\text{88}\). Furthermore the point of departure of the analysis might not be

\(^{86}\) ibid


\(^{88}\) Information retrieved from conference document on harmonising OELs and DNELs at European Level - a position paper reflecting the results at the OEL-conference in Dortmund
similar\textsuperscript{89}. Table 6-3 below contains the DNELs and IOELs for the same substances.

\textit{Table 6-3: DNELs and IOELs for two substances}

<table>
<thead>
<tr>
<th>Substance</th>
<th>DNELs</th>
<th>IOELs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,4 dichlorobenzene</td>
<td>0.6 ppm</td>
<td>20 ppm</td>
</tr>
<tr>
<td>N-methyl-2-pyrrolidone</td>
<td>10 mg/m3 ≈ 2.5 ppm</td>
<td>10 ppm</td>
</tr>
</tbody>
</table>

Source: ECHA and SCOEL websites

Annex II Section 8 of REACH requires that the SDS must specify currently applicable specific control parameters including the national occupational exposure limit values and biological limit values that correspond to EU occupational exposure limit values and biological values in accordance with CAD.

It also mentions that, where a Chemical Safety Report is required, DNELs must be given for the relevant exposure scenarios. This scenario creates the potential for confusion in particular for the downstream users who may receive two different values on the same substance reported in the SDS. The process of adoption of OELs under the CAD, which unlike DNELs are only applicable to workers exposed to chemical agents; the methods to derive them\textsuperscript{90}; and their application at Member State level, are different to those for DNELs under REACH.

However, neither the REACH Regulation nor the CAD set a mechanism to articulate the application of OELs under the national legislation\textsuperscript{91} and DNELs for the same chemical substances. This can lead to potential overlaps and confusion among employers regarding which limit values they must take into account in their risk assessment. In particular, as indicated above, the SDSs under REACH mention both the OELs and the DNELs applicable to the chemical, which might differ. This raises confusion as to which value must be used for the risk assessment, with some consequences in choosing the appropriate risk.

\textsuperscript{89} Bowmer T (2014) DNEL setting using ECHA Guidance: NMP and DCB as examples. Available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7782&lang=en&title=Commission%2DWorkshop%2DOn%2DM%2D%2Drelated%2Drisks%2Drelated%2Dto%2Dchemicals%3A%2DREACH%2Dand%2DOccupational%2DSafety%2Dand%2DHealth%2D%28OSH%29%2DLegislation

\textsuperscript{90} Mainly through an independent body SCOEL whereas most DNELs are set by registrants. However as already mentioned DNELs can be revised by Member State Authorities and RAC during the restriction and authorisation procedures.

\textsuperscript{91} The values introduced at national level can be different from the ones adopted at Union level and can differ from Member State to another.
management measures. Schenk and Johanson (2011) draw attention to this potential for confusion. Based on a study of 88 chemicals, the authors concluded “Overall, the REACH safety margins were approximately six times higher than those derived from the SCOEL”, although the authors noted that the differences were not consistent and the two sets of values poorly correlated.92

The differences between the methodologies for the derivation of OELs and DNELs are briefly discussed in Chapter 7.

Preliminary conclusions:

› To coordinate how OELs and DNELs are derived in order to define the most accurate way of using them in the risk assessment. Other options would be:

› To enhance the cooperation between SCOEL and ECHA (RAC) when establishing limit values as required under Article 95(1) REACH and Article 5(5) COM Decision 2014/113/EU in order to clarify scientific divergences.

› To re-evaluate the methodologies used to define OELs and derive DNELs.

› To ensure that REACH registrants take into account OELs recommended by SCOEL when deriving DNELs without being challenged in other regulatory processes.

› To reconsider Member States competence to set higher or stricter OELs in order to allow the applications of harmonised OELs across the EU.

› Information generated under REACH fed into employer risk assessment and risk management measures under CAD

Employers carrying out risk assessment procedures and setting management measures under the CAD must rely on information transmitted down the supply chain through the SDSs 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).

Annex II section 7 of REACH provides that information on the SDSs on handling and storage must assist the employer in devising suitable working procedures and organisational measures according to Article 5 of the CAD.

Annex II section 8.2.1 of REACH provides that information on SDSs regarding appropriate control measures (e.g. personal protective equipment) 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 4 to 6 of the CAD.

Moreover, information on chemical substances generated under REACH and communicated through SDSs can be useful for drawing up safety and health guidance documents. Information on workers’ exposure to chemicals, generated under REACH, could also be useful for the health surveillance of workers. In other words the safety data sheets provide important information to employers to perform

92 Schenk & Johanson, 2011
their risk assessment at the workplace and to adopt the adequate risk management measures.

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 accessible and quickly understandable information. Lengthy legalistic documents tend to create a barrier to their use.

In situations where the exposure scenarios annexed to the 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. This may lead to revision of the SDS by the supplier to include the specific conditions of the downstream user; to the downstream user changing their conditions of use; to the downstream user conducting their own CSR; or to the downstream user changing supplier to one that has included their conditions of use in its SDS.

Preliminary conclusions:

› To prepare awareness raising campaigns (e.g. through the REACH helpdesks, labour inspections and/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 fulfil their obligations under the CAD.

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

› Substitution requirements under REACH and the CAD

As mentioned above, Article 6 of the CAD provides that, in order to eliminate or reduce to a minimum the risk from a hazardous chemical agent to the safety and health of workers at work, "substitution shall by preference be undertaken".

Under REACH the substitution principle applies, under the provisions of both 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 authorisation puts strong pressure on companies to move to safer alternatives within a defined timeframe. In both cases, the REACH purpose of ensuring the protection of human health (including workers) is enhanced.

93 31 entries under the authorisation list (Annex XIV) and 64 entries under the restriction list (Annex XVII). These entries in some cases cover more than one substance.
Furthermore, REACH will generate more data which will support employers to identify alternatives which are less hazardous than the chemical substances previously used.

› Article 58(2) exemption from authorisation under REACH

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirements uses or categories of use "provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled". The Decision to grant an exemption from the authorisation requirement under Article 58(2) of REACH is taken by the Commission, based on ECHA’s recommendations. The applicability of Article 58(2) of REACH on the basis of OSH legislation has been interpreted by the EU Court of Justice on 25 September 2015 (Case T-360/13). The Court mentioned that in absence of a specific limit value [for chromium trioxide] under Directive 98/24/EC and Directive 2004/37/EC the reference to the application of these Directives does not constitute ‘existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance’ within the meaning of Article 58(2) of REACH94.

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 CAD was recently amended by Directive 2014/27/EU95 in order to align the previous classification and labelling system with the new system laid down in the CLP Regulation. This concerns only the definition of ‘hazardous’ chemical agent.

Definition of hazardous chemical agents under the CAD:

- any chemical agent which meets the criteria for classification as hazardous within any physical

94 Case T-360/2013
and/or health hazard classes laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ( 19 ), whether or not that chemical agent is classified under that Regulation;

- any chemical agent which, whilst not meeting the criteria for classification as hazardous in accordance with point (i) of point (b) of this Article may, because of its physico-chemical, chemical or toxicological properties and the way it is used or is present in the workplace, present a risk to the safety and health of workers, including any chemical agent that is assigned an occupational exposure limit value under Article 3.

The definition of hazardous chemical agents does not entirely rely on the CLP classification, but also covers chemical agents not classified by CLP that can still pose risks to the workers at the workplace. Note that the scope of CAD is broader than the scope of the CLP since it applies to any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market.

The fact that CAD does not entirely rely on the CLP classification to define hazardous chemical agents is justified because the CAD is a risk-based Directive. Some chemical agents (e.g. by-product in a process such as exhaust fumes) can pose risks to the workers even though they are not classified as hazardous under CLP because, for example, they are not placed on the market. This is why OELs can be set for chemical agents not classified under CLP.

As underlined by the Commission guidance 96 on the new labelling systems, the new CLP Regulation will oblige employers to revise certain measures under the CAD (e.g. identification of hazardous chemicals, the risk assessment and derived measures, the safe use handling and storage of chemicals substances). However the impact assessment of the CLP Regulation 97 stressed that the CAD is a risk-driven Directive and the classification of a substance is not the decisive factor for the application of risk management measures.

Seveso Directive

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (the Seveso Directive) 98 lays down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment.

96 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)


The Seveso Directive takes a tiered approach to requiring safety measures at facilities, based on the volumes of dangerous substances present. As such, dangerous substances are defined in Annex I, together with the thresholds for each substance that trigger requirements. SEVESO sites are categorised as lower-tier SEVESO establishments or upper-tier SEVESO establishments. Operators of lower-tier SEVESO establishments have to notify the competent authority, design a major-accident prevention policy (MAPP), draw up accident reports and take into account land-use planning. In addition to these requirements, operators of upper-tier SEVESO establishment must establish a safety report, implement a safety management system, define an internal emergency plan and provide the competent authorities with all necessary information.

No coherence issues are identified between Seveso Directive and the CAD. The control measures and information generated under the CAD (e.g. on hazardous concentrations of inflammable substances) can be used by employers to prepare the safety reports and emergency plans under the Seveso Directive.


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’). 99

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 EU 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;

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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 these goals, it requires:

- 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 at 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 the application and implementation of the CAD.

Relevant European Social Partners Agreements

The aim of the Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it (2006)\(^{100}\) is threefold:

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\(^{100}\) Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it (2006)
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.

To minimise exposure to respirable crystalline silica at the workplace by applying good practices stipulated herein 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.

Good practices are defined in this Agreement as the general principles of the Framework Directive and of Section II of the CAD are further developed and illustrated by Annex 1 to this Agreement. This Agreement mentions that the Parties acknowledge that the general principles of the Framework Directive, and of the CAD remain at all times applicable (including, in particular, risk assessment; risk prevention; specific protection and prevention measures; arrangements to deal with accidents, incidents and emergencies; information and training for workers). No coherence issues are identified here since this agreement complements the CAD and specifies certain measures for workers exposed to crystalline silica.

The European Framework Agreement on the Protection of Occupational health and Safety in the Hairdressing Sector has been signed by BusinessEurope, UEAPME, CEEP and ETUC (and the liaison committee Eurocadres/CEC) in 2012. To date, the Commission is still assessing the request of the social partners to propose the adoption of a Council decision for the legislative implementation of the agreement.

The agreement aims at building an integrated approach for the prevention and reduction of occupational safety and health risks for workers in the hairdressing sector, especially skin problems and musculoskeletal disorders, through the application of the principles of risk assessment, risk management and prevention. The framework agreement, among others, contains several measures to limit hairdresser workers exposure to chemical agents. It provides that the mixing or transferring of chemical substances that can generate hazardous gases, fumes or particulates shall take place at special workstations that have an appropriate complementary ventilation system. It also mentions that the principle of substitution must apply to the following materials (permanent wave compositions containing thioglycolic acid ester, hair cosmetics releasing dust, powered natural rubber latex gloves, tool which can transfer nickel to the skin). Finally it requires that workers must wear suitable protective gloves when applying dyes, tints and blonding agents and also when preparing mixing or transferring chemical substances.

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101 European framework agreement on the protection of occupational health and safety in the hairdressing sector signed by Coiffure EU and UNI Europa Hair and Beauty 26 April 2012. Available at: file:///C:/Users/fp/Downloads/Agreement_hairdressing_EN%20(1).pdf
The 1990 International Labour Organisation ILO Chemicals Convention (No. 170) has been ratified by 6 EU MS\(^{102}\).

The ILO Chemicals Convention aims to protect workers against the harmful effects of using chemicals in the workplace. In this respect, it covers several issues that, within the EU framework, are not only relevant to OSH. The rules under Part III of this Convention require ratifying States to regulate the labelling of chemicals and hazardous substances. Given that these parts of the Convention coincide with an exclusive competence of the Union (internal market) and MSs cannot undertake international obligations outside the framework of the Union's institutions in relation to these parts, there is a need for Council authorisation prior to MS ratification\(^{103}\). The relevant Council decision was adopted recently\(^{104}\).

As regards OSH, the Convention applies to all branches of economic activity in which chemicals are used, in the same way that the CAD applies within the entire scope of the Framework Directive. However, as in most ILO Conventions, States which have ratified the Convention may exclude particular branches of economic activity, undertakings or products from the application of the Convention, or certain provisions thereof, after having consulted the most representative social partners.

Part IV of the Convention sets the relevant employers' responsibilities with regard to the identification of chemical products (labelling, marking and use of chemical safety data sheets for these products); their transfer into other containers or equipment; and the exposure of workers to hazardous chemicals. In a similar way to that under the CAD, employers are required under the Convention to adopt appropriate protective measures, to inform their workers and to instruct and train them in the use of chemicals at work, to conduct a risk assessment, provide for first aid and emergency measures, etc.

Overall, there is a consistent approach between the abovementioned ILO instrument and the CAD. However, unlike the Convention, the CAD does not mention that workers shall have the right to remove themselves from danger resulting from the use of chemicals when they have reasonable justification to believe there is an imminent and serious risk to their safety or health, and shall inform their supervisor immediately. The Convention also provides for an overall protection against any consequences to workers in the exercise of their rights as set by the Convention, including the right to remove themselves from danger.

Several stakeholders interviewed identified interfaces between REACH/CLP and the CAD. Amongst them, a majority flagged that there were coherence issues due to the application of both limit values: OELs under the CAD and DNELs under REACH.

\(^{102}\) Finland, Germany, Italy, Luxembourg, Poland, Sweden,
One stakeholder suggested that the DNELs proposed by industry are tested sampled and proofed by, for instance, national health councils or the SCOEL.

Another stakeholder considered that a lot of streamlining will have to take place. This will also require a more European-oriented stance from the national Health Councils. The need for coordination mechanisms was identified to ensure that legal requirements and policies for these issues did not contradict each other and that interfaces were well monitored.

Several stakeholders also mentioned that information generated under REACH and communicated through SDSs was supporting employers in performing risks assessments, procuring personal protective equipment, and training their workers.

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

Concerning external coherence, the main issues identified concern the interface between REACH Regulation and the CAD and, more specifically, the relationship between the limit values set under the two pieces of legislation. In particular, the SDSs under REACH require the simultaneous application of both OELs and DNELs while these values may differ. This is believed to result in some confusion amongst some employers as to which value must be used. The differences between DNELs and OELs, arising at least in part from differences in their derivation, are discussed in Chapter 7.

Potential synergies were identified in that information on chemical substances generated under REACH and communicated through SDSs can be useful for employers in fulfilling their obligations under the CAD to control risks to workers.

Thus, worker exposure to chemical substances is initially controlled with reference to REACH through risk management measures identified by registrants and circulated in the supply chain by SDSs. These should reflect all the identified uses of the chemical substances in the supply chain and related control measures. Under the CAD, worker exposure to chemical agents is mainly controlled by measures identified through the employer’s risk assessment. This risk assessment should take into account the information provided in the SDS for the chemicals present in the workplace.

On other EU non-OSH legal acts, coherence was also explored between the CAD and the CLP, and the CAD and the Seveso Directive. No coherence issues were identified between the CAD and the CLP Regulation or between the Seveso Directive and the CAD. In fact there was a possible synergy in that the control measures and information generated under the CAD (e.g. on hazardous concentrations of inflammable substances) can be used by employers to prepare the safety reports and emergency plans under the Seveso Directive.
7 Conclusions and recommendations

7.1 Implementation

Most MSs have implemented the CAD in one rather than several pieces of legislation. Although there are some minor variations in detail in implementing the separate CPMs (and KRs) they appear generally to function as a coherent legal entity.

Much of the attention in respect of discrepancies or more detailed provisions relates to the setting of Limit Values (Article 3). Some MSs have limit values less stringent than the indicative OELVs although, in many instances, the difference is minimal. In other cases however, national limits are substantially higher. In the Netherlands, for example, they have evolved different national system for setting Limit Values. Whilst most substances are covered (many with more stringent OELs which are also binding) there are five (Acetic acid, Picric acid, Calcium dihydroxide, Cresols (all isomers), Tin (inorganic compounds as Sn)) for which there is no public OEL, although employers might have established private OELs.

The number of national OELs varies considerably, with some MSs adopting OELs for many more substances than are included in the various Directives setting such limits.

In many MSs the limit values set are regarded as binding. In general therefore, it appears that the indicative limit values defined at EU level are often used to provide the basis for binding limit values at MS level.

In addition to Article 3, the provisions of Articles 4, 8 and 10 featured most often in more stringent requirements. There are no more detailed requirements indicated in any of the CSRs relating to Articles 5 (General principles for prevention of risks), 6 (Specific protection and prevention measures), and 7 (Arrangements to deal with accidents, incidents and emergencies).

Article 4 relates to the determination and assessment of risk of hazardous chemical agents. A frequent feature of many of the additional requirements in MSs is for the
national legislation to require employers to submit risk assessments to national authorities, usually on request or, in the case of one MS, automatically.

All MSs have some more stringent requirements, again mainly relating to Limit Values. Apart from national differences in the weight that is placed on sources of evidence to derive such values, this large number of changes appears to be a function at least in part of the evolving knowledge regarding the potential harmfulness of such substances. It also reflects the relative ease with which individual MSs can introduce new limits compared to the protracted process of such change at the EU level.

Article 8 concerns information and training for workers. In most cases the additional requirements relate to detailing more specifically the content of any such training.

Article 10 concerns the provision of health surveillance. Almost half of the MSs (13) have some additional specifications relating to the periodicity of surveillance / examinations. As detailed in section 3.1 the arrangements for such periodicity vary between MSs, with some specifying a ‘blanket’ frequency (or just ‘regularly’) and others with more complex requirements based on the chemical in question.

The CAD does not contain any provisions for extended deadlines. However, it contains two possibilities for derogations both of which relate to the prohibition of certain specified chemical agents (Annex III). The first provides for exceptions to this derogation and the second places requirements on reporting where this derogation is used. Most MSs implement both of these.

Data on levels of compliance with the requirements of the CAD is quite sparse with relatively few MSs having numerical data available. In some instances, national experts provided an estimate of compliance based on their own knowledge and experience. In some such cases they felt unable to differentiate degrees of compliance with individual provisions, providing an overall estimate of compliance. Such data as were sourced made no distinction between private undertakings and public-sector bodies, across different sectors of economic activity, or across different sizes of companies.

The level of reported compliance with the CPMs is very varied, for example, estimates of compliance with the requirements for risk assessments range from 10% up to 93%.

Although no numerical data are available, subjective opinion seemed to suggest that compliance was generally related to employer size (increasing with increasing size). However, it is not clear to what extent this opinion is based on a directive-specific appraisal or a general view of OSH compliance. Opinions are divided as to the extent to which SMEs had problems with complying. However, it should be noted that no evidence of a problem (as reported in a number of NIRs) is different from evidence of no problem.
These findings largely echo those from a previous Directive-specific report (published in 2010) which concluded that, according to survey evidence they obtained, there was generally low awareness and low knowledge and inadequate action taken in respect of risk assessment and reduction activities. On risk assessment alone they concluded that overall compliance was probably less than 50% with poorer compliance amongst SMEs.

No data could be obtained relating to different industrial sectors (e.g. chemical and other sectors) or to differentiate between public or private enterprises.

On substitution, responses to a specific question in the NIRs varied from substitution being difficult and constituting an extremely rare or one-off event to it not being difficult – but with room for improvement. A number of MSs indicated that it seemed to be more common in certain sub-sectors or product groups.

Guidance documents are by far the most common action undertaken by MSs in respect to supporting the implementation of the legislation transposing the CAD. Generally, they consider that available information and guidance is sufficient. However, some NIRs which highlight challenges to SMEs also mention lack of knowledge about measurements, risk assessment and risk reduction methods, etc. which could indicate a need for additional accompanying actions in this area. However, the extensive amount of material already available suggests that the problem might be more one of adequate communication rather than a need for additional material.

In addition to national material, further guidance is available at EU level, from the Commission, EU-OSHA and the European Chemicals Agency. This includes material on labelling chemicals, risk assessments and on the specific topic of nanomaterials. However, no evidence is available regarding uptake and usage of this material. This view echoes the earlier (2010) evaluation of the impact of the CAD which commented that there was little robust evaluation of the extent or the effectiveness of activities by MSs to provide help and guidance to employers in implementing the provisions of the CAD.

Five MSs have designated a specific authority responsible for the enforcement of the CAD. The enforcement of the Directive typically comes under the general authority responsible for OSH inspections/enforcement. Also, MSs seldom have criminal or administrative sanctions, which are specific to offences which are committed under the legislation concerning chemical agents, rather the standard sanctions applicable in the OSH area.

The findings from the national studies show that most Member States have general approaches to vulnerable groups, which are not targeted at specific Directives (except the following Directives, which are specifically designed to address vulnerable groups: Temporary Workers Directive; Pregnant 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. However, some MS-specific provisions have been found.

Although some MSs offer support to SMEs in the general implementation and application of OSH legislative provisions, no MSs appear to provide any specific national support in respect of the CAD by way of lighter regimes, exemptions or financial incentives. No MSs have developed specific guidance for SMEs, or virtually no other measures targeted at SMEs, which are particular to the requirements under the Chemical Agents Directive. Most provide guidance material which, in some cases, is prepared in a simplified version to facilitate its use by SMEs and others without professional OSH support in-house. However, it needs to be understood that many MSs have developed various accompanying actions targeted at SMEs, which are typically of a more general nature.

7.2 Relevance

There are a variety of sectors and occupations where exposure to chemicals is possible. 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. However, estimates based on employment within the main appropriate industrial sectors suggest that the CAD is potentially relevant to 45.2% of the EU workforce. The addition of an estimated 10% self-employed workers makes a total of 50%.

ESAW statistics on fatal accidents at work do not give any indications as to whether any of the fatal injuries recorded arose from exposure to chemicals. Similarly, the collated statistics on non-fatal accidents do not generally permit those arising from chemical exposures to be identified.

According to EU LFS (2007) data, 3.6% of respondents reported experiencing work-related pulmonary disorders in the last 12 months whilst 1.8% reported work-related skin problems. Whilst chemical agents were not necessarily responsible for these problems they are common causes of such problems and give some insight into health problems possibly related to exposure to chemicals. One limitation is that, where respondents reported two or more problems, the LFS data only records that which the respondent considered to be the most serious. The values quoted from this source should therefore be regarded as minimum values as others may also experience such problems which were not recorded, being considered less serious.

EWCS 2010 data shows that 16.5% of respondents reported breathing in smoke, fumes, powder or dust, doing so at least a quarter of the time at work. For breathing in vapours such as solvents and thinners; and handling or being in skin contact with chemical products or substances; the equivalent values were 10.4%.

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

and 14.7% respectively. Plotting the reported exposure durations of such factors against the percentage reporting breathing difficulties and skin problems shows a trend for increasing likelihood of reporting such problems with increasing daily duration of exposure. Although there can be many reasons for this apparent association (for example working with chemicals making you more aware of existing problems) the results clearly indicate that, the more a worker is exposed to ‘chemicals’ the more likely they are to report relevant health problems. These sets of data appear to indicate the ongoing need for risk management and the relevance of the CAD.

Support for this can be derived from the research literature which shows continuing respiratory health problems such as occupational asthma and COPD. From such material it is clear that exposure to chemicals makes a significant negative contribution to respiratory health, reinforcing the view that the Chemical Agents Directive is and is likely to remain of considerable relevance.

There is evidence of other health problems as well. For example, research studies suggest that the most important risk factor for Occupational Contact Dermatitis (OCD) is exposure to ‘irritants’ a term which encompasses many chemicals as well as other agents.

As further evidence of the need for managing occupational risks associated with chemicals, the 2009 ESENER survey asked managers and employees about their concerns regarding dangerous substances (including dusts, chemical, biological or radioactive agents). Almost 70% of both groups indicated some or major concerns.

Clearly therefore, there is an ongoing need for control of risks to health and safety arising from exposure to chemicals in the workplace.

Future relevance

In terms of future relevance, a number of issues are raised in respect of the future relevance of the CAD. The first of these were those of the possible merging of the CAD and CMD and the question of how best to deal with nanoparticles and other nanomaterials. The issue of the CAD and CMD (and other coherence issues) is discussed below (Section 7.4). A third issue relates to setting of limit values and, related to this, the issue of dealing with the risks associated with chemical mixtures. The related topic of the distinction between OELs and DNELs is addressed in Section 7.4.

Nanoparticles

There was a divergence of opinion apparent from interviews with various stakeholder groups at EU and national level over the issue of nanoparticles etc. Thus, some stakeholders considered that such material were adequately addressed under the provisions of the CAD (and possibly also the CMD given that some were at least suspected of having carcinogenic properties) whilst others took the opposing view that what they saw as the novel risks associated with nanoparticles warranted a new Directive. Discussions specifically with subject matter experts tended to the view that nanomaterials should be considered under the CAD, as they are like any other chemical agents and could therefore be included in this Directive. Certainly, although additional information regarding the nature of the risks arising from nanomaterials might be required for employers, this is arguably no different from the need to inform employers of the risks relating to
any novel chemical. The provisions of the Directive, most notably Articles 4 (Determination and assessment of risk of hazardous chemical agents) and 5 (General principles for prevention of risks associated with hazardous chemical agents and application of this Directive in relation to assessment of risks) are not specific and can be applied to any chemical hazard.

As noted earlier, Member States were specifically asked in the NIR template whether the CAD adequately addresses the risks from nanomaterials. Most did not provide an unequivocal answer although the majority appear to indicate that the provisions of the Directive should be adequate. Nevertheless, some other MSs gave a clear response that they considered a new Directive to be required (although they did not generally indicate reasons for this view).

In addition to the question responses, some MSs saw fit to include specific formal recommendations on this issue. Denmark recommended that “it should be clarified that some nanomaterials are hazardous chemical substances”. Slovakia recommended specifying in more detail the requirements on “the protection of the health and safety of workers from the risks related to chemical agents at work concerning nanoparticles and ultrafine particles, fibres, aerosols, etc.” Greece however was a little more circumspect recommending that “With regard to the use of nanomaterials, further research is required in order to determine the need to extend the legal framework and the scope of Directive 98/24/EC.”

This issue was also addressed at the seminar held to consult stakeholders on issues arising from the review (“validation seminar”), where again opinions were divided between those (mainly employers) who considered that existing provisions were sufficient and those (mainly workers) who felt that special precautions were required for nanoparticles and that a specific directive was therefore needed.

The view that the CAD is applicable seems to be reflected in the Commission guidance on nanomaterials.

On balance, it would seem that nanoparticles/materials are adequately addressed by the existing legislation at EU level, although more guidance might be required other at EU and national level to educate stakeholders and others of this fact and to provide guidance on the selection and implementation of control measures appropriate for the risks presented by nanomaterial use. It of course remains open to MSs, if they take a contrary view, or if the nature of their national legislation entails a more prescriptive approach, to adopt amendments to their own legislation to accommodate any specific measures considered necessary.

New Limit Values

A further factor mentioned in a number of interviews with stakeholders was the issue of the complexities of determining the extent of risk from mixtures of chemicals and that the rate of introduction of new chemicals into the workplace tended to move faster than the level of knowledge and awareness of those in authority (such as Inspectors) could keep pace with. However, it is not immediately apparent whether this reflects any need to amend the Directive to maintain its future relevance, or a challenge relating to its implementation and enforcement. On limit values a view was expressed that setting limits at an unrealistic level would lead to work being directed towards other countries where higher or no limits
existed. This was easier to counter where limits values were evidence-based as the decision to allow their workers to be put at risk was one for the other countries to determine. It perhaps becomes harder where the limit is based on the precautionary principle where evidence of actual harm is not available.

The Commission procedural steps required for the adoption of limit values is laid down in section 6.1. This complex (and time-consuming) process is seen by some as part of the problem in that, compared to national systems, it takes too long for new OELs to be adopted.

Many MSs have implemented additional Limit Values for chemicals not covered by the Chemical Agents Directive and those supplementary lists issued since; although none of these differences related to Binding OELs. Some have also implemented lower limits than those established under the Directive. Although in some cases this reflects a divergence of opinion between national experts and those advising the EU as to what the limit should be, it more usually reflects the relatively slow rate with which limits for new substances can be incorporated into legislation at an EU-level.

The complexities and lack of consistency in respect of national limit values was explored in some detail in the CADimple report\textsuperscript{106}. This commented on the marked differences between MSs in the numbers of national OELs, as well as other issues such as the challenges of addressing mixtures of chemicals and, moving into the workplace, the contrasting levels of knowledge about OELs amongst employers and the tendency, in some quarters at least, to regard the whole exercise of compliance as one of getting exposures below the OEL rather than managing risk.

In their conclusions, the authors question the focus on OELs, drawing attention to other means of communicating risk and risk management to employers. In this context, they refer (amongst other approaches) to the control banding approach (discussed in Section 4.2). Whilst scientific studies would suggest that this approach is not perfect, it does appear to offer some merit for consideration as a more accessible approach to risk management and, as such, one which is likely to achieve better levels of compliance and therefore better effective, practical control of workplace risks.

The modelling of risks usually implicit in the development of such approaches would also offer a possible solution to the growing number and complexity of chemicals and chemical mixtures otherwise requiring OELs to be established.

7.3 Effectiveness

EU stakeholders have assessed the national legislation transposing the CAD to have been reasonably successful, with nine stakeholder organisations providing an

average score of 3.4 (on a scale from 1–5, indicating ratings from ‘very low’ to ‘very high’).

National stakeholders provided a higher rating. Stakeholder organisations representing employers and other stakeholders both gave relatively high average scores of 3.9. Contrarily, in the five Member States that provided a quantitative assessment, worker organisations provided an average score of 4.3 (compared to 2.7 at EU level where employers again gave a rating of 3.9).

In contrast, when directly asked about the impact on the overall safety and health of workers, employer organisations gave an average rating of 3.75, compared to 2.75 from worker organisations. The rating given by OSHA and SLIC representatives was slightly higher than that for employers (4)

The CAD is considered to have been at least reasonably successful in the opinion of stakeholders, although the discrepancy between the views of worker organisations relating to the two different questions demonstrates the care necessary in interpreting the significance of these ratings.

Turing to more objective evidence, data from the EWCS shows that the proportion of workers who reported exposure to breathing in smoke, fumes, powder or dust has remained relatively unchanged from 2005 to 2010 with only minor changes in some categories of respondents. Similarly, the proportion of workers who reported being exposed to breathing in vapours, such as solvents and thinners, all the time or almost all of the time decreased only slightly from 2005 to 2010. Finally, the proportion of workers who reported handling or being in skin contact with chemical products all the time or almost all of the time decreased slightly from 2005 to 2010.

These data appear to suggest only a minor change in chemical exposures over the years and therefore only a modest impact of the CAD. However, as noted above, the data provide no insight into the nature of the chemicals exposures or whether or not they presented any risk to health or safety.

Some insight into the production of (but not exposure to) chemicals can be obtained from Eurostat data which shows a decline in the production of toxic chemicals (five classes of toxicity) from 2007 to 2012, although this largely appears to follow the decline in overall chemical production. Production of course only provides limited insight into exposure, although it could be regarded as reflecting the possibility of exposure.

Data from the EWCS show that the proportion of workers who reported that their work had a negative influence on their health (work-induced respiratory difficulties and work-induced skin problems) has increased from 1995 to 2005. In particular, there was an apparent virtual doubling from 2000/2001 to 2005 of the proportion of workers mentioning either respiratory difficulties or skin problems.

More positive data can be found in relation to various initiatives specifically targeting exposure to respirable silica where a number of studies and reports suggest a clear downward trend in the proportion of locations, among those
considered, where silica exposures were excessive. These data shows how more specifically targeted actions can bring clear benefits.

It would seem therefore that, although there have been some positive changes recorded in relation to particular hazards, there is little substantive evidence overall to indicate that the CAD has had a marked impact on the health and safety of workers, either in terms of exposure to chemical substances in various forms or in the incidence of health problems which might be related to chemical exposures (although the specific data does not make that link).

This absence of data makes any analysis of the effectiveness of the Directive problematic.

The CAD does not contain any provisions for transitional periods, and no data are available which permit the assessment of the effect of any of the derogations applied within any MS.

No objective data are available which enable the effectiveness of individual CPMs to be explored.

However, subjective views by EU-level stakeholders identified risk assessment as the most important key requirement followed by the provision of information, the hierarchy of control (i.e. inspections) and exposure limits. At national level however, limit values were regarded most highly by most stakeholders.

7.4 Coherence

No major internal coherence issues were identified, apart from the identification of provisions under the CMD and Asbestos Directives that could potentially apply to all hazardous chemical agents. Chapter 6 (Coherence) identified a number of different individual areas of legal inconsistency or a lack of coherence between the two Directives. One solution suggested was that of merging the CAD and CMD. Although it is widely recognised that the Asbestos Directive reflects a very different scenario (and there appears to be little support from any source for its merger with the CAD) there have been numerous comments and suggestions made from a variety of different sources both for and against any suggestion of merging the CAD and CMD.

Thus both EU and national stakeholders offered a mixture of opinions. As there were differences in the numbers of stakeholders from different groups interviewed care must be taken in assigning any numerical ‘score’ to those expressing either view.

EU stakeholder groups expressed views and opinions regarding the CAD. All regarded the Directive as being of continuing relevance. One (of six) endorsed the view that this Directive and that for Carcinogens or Mutagens should be merged into a single Directive. However, several others commented that the distinction between the two was not always clear and could lead to some confusion – which could be interpreted as tacitly endorsing a single directive.
When this issue of combining the CAD and CMD was discussed amongst stakeholders attending the seminar held to consult them on issues arising from the review (“validation seminar”), views were quite polarised. Although there were some subtleties of opinion, most delegates representing employers were in favour of combining the Directives while those representing workers were against the proposition. Some delegates argued that, because of the similarity in approaches, merging the directives would be beneficial, reducing duplication and removing confusion amongst employers. Others argued however that there was no need to merge the directives and that any such changes would be burdensome for MSs in having to alter legislation. They indicated that, in any case, combined legislation would need to contain the same provisions as currently found in the CAD/CMD to ensure adequate worker protection. A further argument was that the greater hazard associated with carcinogens justified a separate Directive. Thus whilst there might be a clear legal rationale for such a merger it is clear that there are what might be regarded as ideological differences against such a move.

Other than the legal rationalisation, there is no evidence-base on which to argue for or against such a move. The UK is often pointed out as an example of how merged legislation can be adopted – although there is no evidence that it works any better than the separate approach adopted by a number (probably the majority) of other MSs. Although some stakeholder opinion suggests that it would make it easier or less complicated for employers (and therefore presumably improve compliance) there is no evidence to suggest that compliance is any better (or worse) amongst employers using chemicals covered by one or both Directives. In fact no data has been seen even to establish the magnitude of the problem - i.e. how many employers use chemicals covered by both Directives and are therefore required to comply with two sets of provisions?

Given the absence of any coherent evidence-base therefore it is clear that, other than acknowledging the issue, no clear conclusions or recommendations can be drawn from this work.

Concerning external coherence, the main issues identified concern the interface between REACH Regulation and the CAD and, more specifically, the potential overlaps between limit values set under the two pieces of legislation. In particular, the SDS should list, if available, the OELs and DNELs values of the chemical, which may be different. This raises confusion as to which value must be used by employers when performing the risk assessment.

The origins and methodologies for the derivation of OELs and DNELs are different and comparing the detailed processes involved in their development is beyond the scope of this study on the implementation of the CAD. However, as noted above, differences between the two limits in terms of the numeric values eventually derived are seen as a source of confusion and complication for employers in endeavouring to comply with the CAD.

Comparisons between the two systems have provided the basis for a number of published scientific papers.

Two papers give a brief summary of the two processes:
For OELs:

“The setting of a health-based OEL starts with a review of toxicological data to identify health effects of concern and a point of departure (POD). The POD is the starting point for the extrapolation from toxicological data to an exposure limit. The POD can take several forms but is a quantification of some sort of exposure in relation to an adverse effect, based on empirical data. The POD might be derived from epidemiological studies, from controlled exposures of human volunteers or, often, from experimental animal data. In cases where the exposure is well controlled or well known, such as human and animal experiments, the lowest observed adverse effect level (LOAEL) or, preferably, the no observable adverse effect level (NOAEL) is commonly used as the POD. Another approach to determine a POD is the Benchmark Dose (BMD) approach, first suggested by Crump (1984). This method uses the complete data set for each end-point, unlike the NOAEL approach, to derive a model with which an acceptably low effect level can be calculated. The POD might need correction for differences in duration and route of exposure, for example when based on oral toxicity data.”

“The values are recommended by the Scientific Committee on Occupational Exposure Limits (SCOEL), agreed by Member States and adopted by the EC. They are health based and describe the air concentration of a chemical to which repeated and regular exposure throughout a worker’s working life does not cause harmful health effects. Values …are only given for substances whose threshold level of effects can be identified.”

For DNELs:

“A preferred approach is to base the calculations on the identification of no observed adverse effect levels (NOAELs), which are then converted to DNELs by applying different assessment factors, depending on the type and quality of the study reports. Also other starting points such as lowest-observed-adverse-effect level or benchmark doses can be utilized (ECHA, 2012). DNELs are given for workers and the general population, for acute and/or long-term exposure via inhalation, oral and/or dermal routes (EC, 2006b). DNEL values describe the exposure concentrations below which there should be no health risks.”

Although, in some cases at least, the starting material is the same in each case (NOAELs), the two approaches appear to provide different outcomes. Thus, according to one paper:

“Overall, the REACH safety margins were approximately six times higher than those derived from the SCOEL documentation but varied widely with REACH/SCOEL safety margin ratios ranging by two orders of magnitude, from 0.3 to 58 (n=88)\textsuperscript{110}.

The authors noted “The discrepancies may create confusion in terms of legal compliance, risk management and risk communication”.

In a second paper, this time comparing OELs in one MS, rather than the EU IOELs, found:

“The long-term DNEL value for workers (inhalation) was identical to the corresponding IOELV for the majority of the substances (64/87 cases). Comparison of DNELs with HTP values revealed that the values were identical or close to each other in 159 cases (49%), whereas the DNEL was considerably higher in 69 cases, and considerably lower in 87 cases\textsuperscript{111}.

In this instance, as well as commenting on the potential for confusion, the authors commented that the lack of a systematic difference suggested that the default assessment factors suggested by REACH technical guidance\textsuperscript{112} had obviously not been used in many of the REACH registrations, i.e. that the DNELs had not been correctly calculated.

Some authors have advocated a possible coming together “of the REACH and OSH worlds”\textsuperscript{113}. However, although if achieved this would resolve the issue of disparity it would not reduce the burden on manufacturers, or address the bigger issue of whether the OEL/DNEL approaches are the best way of communicating risk to employers and therefore enhancing compliance and improving the health of workers as a result.

Clearly, there is a need to review the process of establishing risks to health, ideally to formulate a common approach between the CAD and REACH, but also to bring into the discussion the whole approach behind the use of data in this manner. To put this into perspective, in addition to the considerable differences between MSs in the number of existing OELs referred to earlier, there are also many thousands of chemicals for which no OEL exists. One paper, written in 2009, summarized the

\textsuperscript{110} Schenk & Johanson (2011) A quantitative comparison of the safety margins in the European Indicative Occupational Exposure Limits and the Derived No-Effect Levels for workers under REACH.  
\textsuperscript{111} Tynkkynen et al (2015) A comparison of REACH-Derived No-Effect Levels for workers with EU Indicative Occupational Exposure Limit Values and National Limit Values in Finland  
\textsuperscript{112} https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf  
\textsuperscript{113} Wriedt (2012) New insights on exposure limits – DNELs / DMELs and OELs / BOELVs
position stating: “Under REACH the toxicological properties of approximately 30,000 substances need to be assessed in the next 11 years”\textsuperscript{114}.

The authors advocate exploring different approaches to communicating risk, such as the Control Banding approach referred to earlier (Section 4.2). Such an approach was also advocated by other authors who published a description of the process of determining a DNEL for one paint system which they calculated would require the calculation of 35 exposure scenarios\textsuperscript{115}.

As noted above, a detailed critique of the various approaches is clearly beyond the scope of the present study. However, the study has identified the considerable potential for confusion and possible inconsistencies in what employers see themselves as having to comply with, a confusion which, it can be suggested, is likely to lead to further poor quality compliance as suggested by the CADimple study\textsuperscript{116}.

### 7.5 Overall conclusions and recommendations

Although it appears that the provisions of the CAD have been implemented within all MSs and that it remains relevant to a large proportion of the EU workforce there is little or no substantive evidence overall to indicate that the CAD has had a marked impact on the health and safety of workers. Some isolated instances have been identified from specific scientific studies in respect of particular substances (e.g. silica) but these provide a very limited picture of the situation. Despite this, subjective opinions from stakeholders appear to suggest that it has been effective.

It would seem in large part that this absence of evidence can be related to a dearth of good-quality information and data, either of exposures to chemicals or on subsequent ill-health where health consequences can be unequivocally attributed to workplace chemical exposures.

One possible option is provided by the proposed development of European Occupational Diseases Statistics collation system. Whilst a pilot study for such a system identified many problems of comparability it concluded that these could be avoided with improvements in data collection. It specifically concluded that such data can be used both in directing prevention and in the evaluation of the impact of the problem (and measures taken to alleviate the prevention)\textsuperscript{117}.

\textsuperscript{114} Schaafsma et al (2009) REACH, non-testing approaches and the urgent need for a change in mind set.


It is suggested that there is a clear need to explore ways of collecting better data nationally on both exposure and health consequences and collating this at EU-level.

On the issue of nanomaterials, it would seem on balance that the risks to health associated with these are adequately addressed by the existing legislation at EU level, although more guidance might be required at EU and national level (or the better awareness of existing guidance – it is not possible to tell) to educate stakeholders and others of this fact and to provide guidance on the selection and implementation of control measures appropriate for the risks presented by nanomaterial use.

Other than the legal rationalisation, there is no evidence-base on which to argue for or against merging the CAD and CMD. Given the absence of any coherent evidence-base, it is clear that other than acknowledging the issue, no clear conclusions or recommendations can be drawn from this work.

At present it is open to individual MSs how they implement the CAD and CMD and, if they feel that a unitary approach provides the most effective solution, then it is open to them to do so.

One further suggestion, which does not require amendment of any Directive but which arose from this appraisal is to prepare awareness-raising campaigns (e.g. through the REACH helpdesks and/or EU-OSHA) to inform employers on how to use the SDSs for their risk assessment in order to ensure that they are able to extract relevant information from the SDSs. As discussed in Section 6.1 some employers find the size and complexity of some such SDSs daunting. This would also be of particular potential value given the considerable potential for confusion which can arise given differences in the CAD OELs and REACH DNELs.

Finally, there are considerable practical challenges in keeping on top of the considerable numbers of chemical substances and mixtures requiring the determination of exposure limits of some form under both CAD and REACH. This places a considerable burden on policy makers, including supporting bodies such as SCOEL and the ACSH, for the evaluation of the health effects arising from workers’ exposure to chemicals and the subsequent development and adoption of OELs under the CAD. In addition manufacturers are also under a considerable burden (as shown by one paper cited) and the challenges have the potential to cause immense confusion amongst employers. There is some evidence from other reports and published material to suggest that this confusion is unhelpful and presents a barrier to compliance.

As discussed in Section 7.4, some of this confusion arises from differences between OELs and DNELs for the same substance, which arise from the different approaches adopted in deriving these values. There is a need to explore the scientific bases for these approaches and to determine which appears to provide the best solution in providing a suitable level of protection for workers, without creating unnecessary burdens on employers. It is understood that such action is already being explored and more activity in this area is to be encouraged.
However, whilst in the longer-term scientific clarity on the derivation and comparability of OELs and DNELs would be welcomed (as suggested in Section 6), there is growing evidence that employers, especially SMEs, find alternative approaches easier to understand and it is recommended that, at present, rather than seeking to create better scientific alignment of the OEL and DNEL approaches, investigating other approaches to communicating information to employers regarding level of risk (such as the control banding approach) might be beneficial and should be investigated further.
Appendix A  References

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