Study on the implementation of the autonomous agreement on workers' health protection through the good handling and use of crystalline silica and products containing it

Final report

June 2016

ICF INTERNATIONAL

EUROPEAN COMMISSION

Directorate-General for Employment, Social Affairs and Inclusion
Directorate A — Employment and Social governance
Unit A2 — Social dialogue

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Luxembourg: Publications Office of the European Union, 2017

ISBN: 978-92-79-65347-6
doi: 10.2767/233850

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List of Acronyms

ASA Register	Finnish Register of Workers Exposed to Carcinogens
BIBM	European Federation of the Precast Concrete Industry
CAD	Chemical Agents Directive (Directive 98/24/EC)
CAEF	European Foundry Association
CAREX	International Information System on Occupational Exposure to Carcinogens
CEEMET	Council of European Employers of the Metal, Engineering and Technology-Based Industries
CEMBUREAU	European Cement Association
CERAME-UNIE	European Ceramics Industries
COLCHIC	French Occupational Exposure to Chemical Agents Database
COPD	Chronic Obstructive Pulmonary Disease
COSHH	Control of substances hazardous to health
EEA	European Economic Area
EFBWW	European Federation of Building and Woodworkers
EMO	European Mortar Industry Organisation
EU	European Union
EU OSHA	European Agency for Safety and Health at Work
EU-LFS	Eurostat's Labour Force Survey
EURIMA	European Insulation Manufacturers Association
EUROMINES	European Association of Mining Industries
EUROROC	European and International Federation of Natural Stones Industries
EXCA	European Expanded Clay Association
ExpoSYN	Exposure Measurement Database On Five Lung Carcinogens
FEVE	European Container Glass Federation

FIEC	European Construction Industry Federation
FINJEM	Finnish Information System on Occupational Exposure
FMP	Fonds des Maladies Professionnelles
GISBAU	Hazardous Materials Information System of the Building Industry Professional Association
GISCOP	French Scientific Interest Group on Occupational Cancer
Glass for Europe	Europe's Manufacturers of Building, Automotive and Transport Glass
GlassFibreEurope	European Glass Fibre Producers Association
HSE	Health and Safety Executive
HSWA	Health and Safety at Work Act
ICT	Information and communications technology
IMA-Europe	European Industrial Minerals Association
IndustriALL	European Trade Union
INS	Institute National de Silicosis
MEGA	German Chemical Workplace Exposure Database
MS	Member State
NACE	Statistical classification of economic activities in the European Community
NEPSI	European Network for Silica
NEPSI GP	NEPSI Good Practices
NOCCA	Nordic occupational cancer study
OCCAM	Italian Occupational Cancer Monitoring
ODIN Register	German Service for the Organisation of Post-exposure Medical Examinations
OEL	Occupational Exposure Limit Value
OSH	Occupational Safety and Health
PPE	Personal Protective Equipment
RCS	Respirable crystalline silica
SCHOLA	French Occupational Exposure Database

SCOEL	European Commission's Scientific Committee for Occupational Exposure Limits
SIREP	Italian Information System for Recording Occupational Exposures to Carcinogens
SLIC	Senior Labour Inspectors Committee
SUMER Survey	French Medical Monitoring Survey of Professional Risks
TLV	Threshold Limit Value
TPM	Total Productive Management
UEPG	European Aggregates Association
WASP	Workplace Analysis Scheme for Proficiency
WEL	Workplace Exposure Limit
WHO	World Health Organization

Executive summary

Background

Crystalline silica is a material that is naturally abundant and raw materials and products containing crystalline silica are used in a wide variety of industries. Concerns have been raised about the health impact of exposure to respirable crystalline silica (RCS) which can be released during extraction or production processes. The European Commission's Scientific Committee for Occupational Exposure Limits (SCOEL[1]) has argued that 'the main effects in humans of the inhalation of RCS are silicosis. There is sufficient information to conclude that the relative lung cancer risk is increased in persons with silicosis […]. Therefore, preventing the onset of silicosis will also reduce the cancer risk. Since a clear threshold for silicosis development cannot be identified, any reduction of exposure will reduce the risk of silicosis'. There are currently no occupational exposure limits (OEL) for RCS at EU level. On 2 March 2004, the European Commission consulted the EU social partner (in line with Art.154 TFEU) regarding the opinion on a possible revision of Directive 90/394/EEC (the Carcinogens Directive) as regards, in particular, the OEL list. Following a six-month period of negotiation, on 25 April 2006, a multi-sectoral Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it was signed, the first of its kind, which brought together social partners from 14 different sectors. Importantly, this does not include the construction sector, where the risk of exposure to RCS is greatest.

The objectives of the Agreement are:

- Protection of the health of employees and other individuals occupationally exposed at the workplace to respirable crystalline silica from materials / products / raw materials containing crystalline silica;
- Minimising exposure to respirable crystalline silica at the workplace by applying the Good Practices stipulated herein in order to prevent, eliminate or reduce occupational health risks related to respirable crystalline silica and;
- Increasing the knowledge about potential health effects of respirable crystalline silica and about relevant Good Practices.

Study objectives

The objective of this study was to provide the Commission with an assessment of the implementation of the Agreement. As stated in the Terms of Reference and announced in the Commission Communication on social dialogue[2], the Commission intends to undertake an independent monitoring of the Agreement aimed at assessing the contribution of this instrument towards achieving the Union's objectives.

The main purpose of this assignment therefore was to:

- Assess the implementation of the Agreement
- Assess the role of the signatories and their affiliated members as well as the actions undertaken by them, in the framework of the procedures and practices specific to management and labour, and of the Member States in the field of OSH
- Assess the impact of the Agreement on national regulations/legislations (if applicable)
- Collect background information and data on exposure levels at company, industry, sector and country level at the time the Agreement was signed and today
- Analyse the reporting system put in place by the signatories and their national affiliated members and by national public authorities where possible

[1] SCOEL SUM Doc 94-final on respirable crystalline silica, June 2003

[2] COM (2004) 557 – "Partnership for change in an enlarged Europe – Enhancing the contribution of European Social Dialogue"

The study covered the EEA countries and aims to inform the assessment, follow-up and reporting of the implementation of the Agreement carried out by the Commission.

Methodology

The information presented in this report is based on a range of sources including transnational literature review, interviews with stakeholders at European and national level, 12 in-depth country studies (selected based on a methodological assessment of presence of NEPSI members in Member States and geographical spread of countries: Belgium, France, Germany, Italy, Lithuania, Netherlands, Poland, Romania, Slovakia, Spain, Sweden and the UK), an online survey and the analysis of the NEPSI reporting data.

An online survey of employers and employee representatives was launched to investigate whether the Agreement has had an impact at site level on the protection of workers exposed to RCS; minimisation of exposure to RCS at the workplace by applying the NEPSI Good Practices; knowledge about potential health effects of RCS; as well as the extent to which the Agreement has contributed to improve health and safety in the workplace. The survey targeted employers and employee health and safety representatives in the sectors covered by the Agreement. A total of 196 respondents completed the survey with a majority of responses coming from employer representatives, with only 1% of responses coming from employee representatives.

Although it was not possible to correct an imbalance in the number of participants from the employer and the trade union side in the interview and in the survey (in both cases, the employer side was over-represented), no significant differences were found in the assessment of the implementation and impact of the agreement between employer and employee side respondents.

Work-related illnesses resulting from exposure to RCS

Exposure to RCS can cause a number of permanent respiratory diseases including silicosis and lung cancer. The level of risk depends on the duration of exposure (how long), the intensity of exposure (how much) and the concentration of crystalline silica in the dust. There is usually a delay of more than 10 years between the exposure to dust and the first symptoms of pneumoconiosis (i.e. lung disease). However, in cases of high concentration and long exposure, symptoms may occur quickly such as in cases of acute silicosis.

Due to the long latency period, statistics on health outcomes mainly reflect past working conditions. In Europe there are no harmonised statistics on silicosis and work-related cancers because of differences in occupational diseases recognition criteria and compensation schemes.

At national level, the collection of such data also proved challenging as data gathering techniques and the presentation of such information is not comparable.

Bearing in mind these limitations, overall, declining trends in cases of silicosis and other pulmonary diseases recognised as being linked to the exposure of RCS have been found in all countries studied. However, it is interesting to note that new cases of silicosis have been diagnosed among active workers in relation to new sectors such as the manufacturing of kitchen countertops or new work processes (e.g. sanding of jeans). The overall reduction of silicosis cases could be seen to be at least partly linked to the decline in some industries where workers are likely to be at risk of exposure to RCS. Given the overall process of ongoing economic restructuring, it is difficult to disentangle the impact of such changes from that of various legislative, implementation or enforcement regimes when looking and trend data in occupational illnesses linked to exposure to RCS.

Coverage of the NEPSI Agreement and exposure to RCS in Europe

Understanding the coverage of the member organisations/company of the European signatories to the NEPSI Agreement is key to understanding the scope of workers covered by the Agreement. Four key indicators have been identified to try to assess the coverage of the NEPSI Agreement: number of workers in Europe in relevant sectors covered by the Agreement, number of workers covered by the

NEPSI members, number of workers exposed to RCS in Europe, number of workers exposed to RCS and covered by the NEPSI Agreement.

However, it is important to highlight that the number of workers in Europe/Member States and/or in a given sector cannot be considered a proxy of number of workers exposed or potentially exposed to RCS. Similarly, the number of companies operating in a sector is not a proxy of companies with risk of exposure.

CAREX is the only available source of exposure data at European level, however this dataset is out of date and efforts should be made to update the estimates. The recent SHEcan study conducted by the IOM[3] has produced updated estimates across Europe based on CAREX data. It is estimated that across Europe a total of 5.3 million workers are potentially exposed[4] to RCS. The study estimated that in the sectors covered by the NEPSI agreement, 23% of these workers are covered by NEPSI. However, SHEcan estimates are likely to overestimate the number or workers potentially exposed to RCS in the sectors covered by the NEPSI. This is primarily because there is not a perfect match between NEPSI sectors and industrial sectors as defined by international codes and in each sector exposure to RCS concerns only certain industrial processes and only workers involved in those processes. Therefore, it is likely that the NEPSI network covers a greater proportion of workers exposed to RCS, although efforts need to be made to continue expanding the network and ensure wider coverage.

[3] The SHEcan project, financed by the European Commission in 2008 and published in May 2011, aimed to assess the socioeconomic, health and environmental impacts of possible amendments to the European Carcinogens and Mutagens Directive (2004/37/EC) for 25 occupational carcinogens including RCS. Available at: http://www.occupationalcancer.eu/

[4] "Workers exposed" to RCS are workers actually exposed to RCS due to the nature of their work, while "workers potentially exposed" are workers who do not work with silica but could potentially enter areas where exposure might take place.

Overview of workers' exposure to RCS and NEPSI coverage					
Data Sources	**Data**		**N**	**%**	**Methodological background to data sources**
SHECan Data (Estimated number of exposed workers using CARExand EUROSTAT data 2006)	Estimates of total workers potentially exposed	a	5,299,619		The SHECan data provides and overestimation of workers potentially exposed to RCS. As reported in the study: "Eurostat data for certain sub-sectors that have been identified to have workers exposed to RCS have been used, the estimation were based on the assumption that (based on the Eurostat sector descriptors) workers employed in these sectors are more likely to be exposed to RCS. The study recognises that the number of workers and enterprises affected by the proposed reduction in the OEL are likely to be overestimated since the NACE codes include activities in which workers may not necessarily be exposed to RCS." Additionally the mapping of the sectors covered by NEPSI does not necessarily delimit the NESPI sectors, as based on assumptions made by the study team.
	Estimates of total workers potentially exposed in construction	b	4,112,824	78% (of 5.3M) (b/a)	
	Estimates of total workers potentially exposed in sectors other than construction	c	1,186,795		
	Estimates of total workers potentially exposed in NESPI NACE sectors (10, 11, 12, 13, 14, 26)	d	718,145	14% (of 5.3M) (d/a)	
NEPSI Data	Employees potentially exposed in companies reporting to NEPSI (2004)	e	164,206	23% (of 718,145) (e/d)	NEPSI data are likely to underestimate the number of workers potentially exposed to RCS for the following reasons: ■ Only companies with individuals exposed to RCS make the report. ■ The number of exposed workers in NEPSI companies is assessed through a specific risk assessment and refers to exact figures, rather than estimations. ■ In the NEPSI data only employees are reported, it is not possible to assess how many self-employed are not reached by NEPSI whereas SHECan covers all workers i.e. also self-employed.
	Employees potentially exposed in companies reporting to NEPSI (2014)	f	176,306	3% (of 5.3M) (f/a) 25% (of 718,145) (f/d)	
	Number of employees reported to NEPSI (i.e. employees working in companies reporting to NEPSI) (2014)	g	439,268	61% (of 718,145) (g/d)	

Source: SHEcan Report, IOM Research project P937/8, May 2011; NEPSI reports

To improve the measurement of the number of workers covered by the NEPSI Agreement in Europe, further effort is needed in the following areas:

- To map the presence of NEPSI members across Member States; the NEPSI network should collect reliable information on the number of companies affiliated to national member organisations of NEPSI signatories (or directly company members among NEPSI signatories), thus making it possible to clearly establish the coverage of workers in the sector by NEPSI members;
- As current employment and exposure data cannot be mapped against the NEPSI sectors, the NEPSI network should agree on how the sectors they represent best align with existing international codes for the purposes of aligning with existing employment and exposure data; and,
- Update existing data on occupational exposure to RCS (e.g. CAREX) and ensure comparability across national data.

EU and national legislation

At EU level, the European Framework Directive 89/391/EEC, sets out the general framework for health and safety at work. It is supplemented by other individual Directives such as Directive 98/24/EC on the risks related to chemical agents at work[5] or Directive 2004/37EC on exposure to carcinogens or mutagens at work[6]. While all Member States have implemented the EU acquis, there are some differences, particularly in relation to the setting of OELs and concerning whether RCS is officially classified as a carcinogen and thus whether illnesses linked to exposure to RCS are recognised as occupational illnesses.

Out of the 12[7] Member States assessed in more detail only Slovakia, the Netherlands and Belgium recognise RCS as a carcinogenic agent and Belgium, does so for sandblasting activities only.

In the absence of an occupational limit value (OEL) at EU level, there is likewise no harmonisation on the national OEL in the countries studied and variations can be observed. Fourteen (14) countries out of 24 (BE, DK, EE, EL, ES, FI, FR, IT, LT, NL, NO, PT, RO SE) for which information was available had a limit of 0.05 mg/m3 for Cristobalite and Tridymite. The majority of Member States are above the SCOEL recommendation for Quartz and only Finland, the Netherlands and Portugal set the value below or equal to 0.05 mg/m3.

Few estimates are available on compliance with relevant health and safety regulations[8] and none are specific to RCS. It is generally estimated that compliance rates are in the region between 30-40%.

In terms of the effectiveness of existing legislation, it can therefore be considered that compliance remains an issue and can be affected by a number of factors such as:

- Awareness raising
- Clarity of guidance on the existence and implementation of legislation
- Frequency of inspections and level of sanctions

The dearth of robust comparable data on exposure to RCS and occupational illnesses linked to RCS and the lack of impact studies showing impact over time of any legislative changes linked to the control of exposure of workers to RCS make it challenging to conduct a meaningful assessment of the impact of different national regulations on health outcomes (and therefore their effectiveness).

The only judgement that can be made based on existing research is that improvement in awareness raising and the delivery of clear guidance and practice tools can have an impact on company practice.

[5] Directive 98/24/EC of 7 April 1998 on the risks related to chemical agents at work

[6] Directive 2004/37EC (repealing Directive 90/394/EEC) on exposure to carcinogens or mutagens at work

[7] 12 countries were selected for in-depth research plus, further research was carried out in Austria, Finland, Cyprus and Ireland

[8] For instance a study in the UK on compliance with health and safety regulations among SMEs found compliance rates between 19 – 61%; http://www.hse.gov.uk/research/rrpdf/rr366.pdf

The implementation of better control mechanisms and work organisation/production design is key to improving health outcomes.

Implementation of the NESPI Agreement and data from the NESPI network

The implementation of the NEPSI Agreement required a number of actions to be taken at European and national level by European and national organisations, as well as companies. At European level this included setting up the NEPSI Council, translation and dissemination of the agreement, regular review of good practice guidance and the steering and analysis of the regular reporting cycle.

At national level, national organisations implemented four measures:

- Dissemination activities - Dissemination of the NEPSI Agreement through newsletters, emails and organisations' websites, etc.;
- Training activities - Face-to-face and online training sessions with companies; and,
- Awareness-raising initiatives - Workshops and conferences to raise awareness on exposure to RCS and associated health risks.

Other activities at national level include measurement campaigns in the Netherlands, implementing a 'Silica Round table' in Germany.

At company level, implementation of the Agreement required changes to workplace procedures and management. For instance, this generally involved the introduction of new training modules in the company to raise awareness among managers and employees or adding symbols on Personal Protective Equipment (PPE). For some companies, particularly large multinationals, no specific action was undertaken to implement the NEPSI Agreement as they already had internal procedures in place considered compliant with the NEPSI Agreement.

Reporting

The reporting of data collected at site level to the NEPSI Council is a key feature of the NEPSI Agreement and is unique of its kind within autonomous social dialogue agreements. NEPSI national members are required to report every two years via the NEPSI online reporting system. Key indicators they must report on include: the exposure risk, the risk assessment and dust monitoring, training and the implementation of NEPSI Good Practices.

Interviews with national associations revealed that, overall, a high proportion of members with an exposure risk actually report to the NEPSI system. Similarly, companies interviewed stated that all sites with a risk of exposure to RCS report. In addition, the NEPSI data shows that the percentage of sites reporting is relatively high across all Member States and sectors. Sectors with lowest percentages are usually those characterised by small companies. However, the coverage of the NEPSI reporting (i.e. how many members of national associations report to the NEPSI system) could not be assessed precisely for the methodological reasons highlighted above. Furthermore, there is no evidence of processes being put in place to spot check the information provided by sites (which is not required in the agreement, but leads to strong reliance on the data generated by self-reporting).

Most of the national members interviewed considered the online reporting system user-friendly, clear and efficient, even though some SMEs can find the system complex.

Impact of the Agreement

The impact of the Agreement needs to be assessed against the background of the original intention and its intended goals, which are:

- Protection of health of employees from exposure to RCS
- Minimisation of occupational exposure to RCS by applying the Good Practices
- Increasing the knowledge about potential health effects of RCS and about Good Practices

The NEPSI Agreement is an instrument designed and implemented by employer' organisations, trade unions and companies with the primary intention of improving health and safety in workplaces in accordance with existing national legislative frameworks.

The theory behind changes to the NEPSI Agreement is based upon three main steps: awareness raising of the risk of RCS, encouraging tailored risk assessments and the introduction (where relevant) of new risk management protocols and processes, including the implementation of good practices and training. This should ultimately lead to improved protection of health of workers (i.e. minimisation of exposure to RCS, overall improvement of risk management strategies, improved workplace health and safety conditions).

Changes to workplace health and safety management

The NEPSI Good Practice Guidance provides detailed guidance on risk assessment regarding exposure to RCS and relevant risk management. NEPSI members **interviewed reported that the NEPSI Agreement helped employers to implement a more coherent risk management strategy to control the risk of exposure to RCS**, by either introducing new procedures or improving already existing health and safety procedures.

Companies implementing the NEPSI risk assessment procedure reported **improvements in employers' ability to assess the risk of exposure and monitor the number of employees exposed to RCS**. The added value of the Agreement in this context relates to the fact that national legislations include provisions on generic risk assessment, whereas the NEPSI Agreement provides a very specific practical guidance on steps to follow to assess the risk of exposure to RCS.

NEPSI data shows that (amongst their members) an increasing number of workers has been covered by risk assessment. Overall, the proportion of employees covered by risk assessment increased from 88% in 2008 to 93% in 2014. In 2014, more than 129,000 were covered by dust exposure monitoring procedure, which represented 73% of employees potentially exposed to RCS. Over the years, an increasing proportion of employees potentially exposed to RCS have been covered by exposure monitoring, from 65% in 2008 to 73% in 2014; increasing trends have occurred across all sectors.

Stakeholders interviewed, including NEPSI members, experts and Labour Inspectorate, agreed that exposure monitoring is an area where the NEPSI Agreement has prompted employers to do it more consistently and has provided harmonised guidance on sampling methods, valuable in national situations where no clear indication was provided.

The online survey of employers shows that, since 2007, 87% of companies introduced changes to the measures taken to control exposure to RCS. Changes to the workplace can be made in response to national legal provisions and/or to implement the NEPSI Agreement, 74% of employers made changes in response to the implementation of the NEPSI Good Practice Guidance and 68% in response to national guidelines. Notably, 19% of employers made changes exclusively in response to the implementation of the NEPSI Agreement, while 15% exclusively in response to national guidelines.

Ultimately, the implementation of better management strategies should lead to a reduction of exposure to RCS. **There is evidence of decreased workplace exposure following the implementation of the Agreement**. An independent Finnish study investigating exposure of workers in Finnish workplaces concluded that the concomitant implementation of the NEPSI Agreement and the lowering of the national OEL resulted in lower levels of exposure to RCS. Almost three-quarters (73%) of employers participating to the online survey reported that the level of exposure in their workplaces has decreased since 2007, and 51% believed that there has also been a reduction in the numbers of employees exposed. Stakeholders interviewed (NEPSI members and experts) agreed that **the level of exposure has decreased thanks to a number of concurrent factors which include the implementation of the NEPSI Good Practices but also developments in technologies and work processes**.

The NEPSI Agreement requires employers to report information on the implementation of the Agreement every two years including a review of the exposure values. **The regular review of the dust monitoring data and the two years reporting cycle is deemed by NEPSI members as fundamental to the Agreement, which allows employers to check their progress, find gaps and**

regularly address the topic of exposure to RCS with managers and employees. Also Labour Inspectorates and experts agree that the regular cycle of reporting is key to maintaining focus on the risks of exposure to RCS. Such regularity encourages a culture of continuous improvement.

Training, implementation of NEPSI Good Practices and impact on workers

NEPSI data report that in 2014, a total of 155,000 employees, 88% of all employees potentially exposed to RCS, received training on general principles included in the NEPSI Agreement. Since 2008, when 75% of employees received training, the overall trend has been increasing. The increasing trends by sectors show an equal commitment of NEPSI members across all industries. In 2014, almost 115,000 employees were covered by information, instruction and training on Task Sheets, this made up 65% of all employees potentially exposed to RCS. Consistently increasing trends showed an improvement in this indicator of more than 12 percentage points.

Increased knowledge and awareness was the area where all stakeholders perceived the NEPSI Agreement had the greatest impact, including NEPSI members and experts. Trade unions also believe that the main impact of the NEPSI Agreement has been increased awareness among employers of the health risks of exposure to RCS, together with better emphasis on preventive measures to protect workers from RCS.

The implementation of NEPSI Good Practices is central to the Agreement. The NEPSI reporting system monitors the implementation of Good Practices by asking employers whether the following measures were implemented: 'technical measures to reduce generation/dispersion of RCS', 'organisational measures' and 'distribution and use of personal protective equipment'. **NEPSI data shows that since 2008, employers have increasingly applied a range of Good Practices:**

- The application of technical measures to reduce the generation and dispersion of RCS increased from 70% in 2008 to 76% in 2014;
- The application of organisation measures increased 59% in 2008 to 74% in 2014; and,
- The percentage of sites distributing technical protective equipment increased from 77% in 2008 to 80% in 2014.

Finally, the NEPSI Agreement should lead to overall improvements in workplace health and safety conditions. Overall, 61% of respondents to the online survey believed that the NEPSI Agreement was effective or very effective in improving working conditions, while 50% stated that other national measures where effective or very effective in improving working conditions. The fact that measures implemented through the NEPSI Agreement were deemed to be somewhat more effective than other national measures in improving workplace health and safety conditions was also confirmed by interviews with NEPSI members. **The bottom-up approach of the Agreement ensured commitment from employers, encouraging them to go beyond legislative requirements. The tailored tools (i.e. the Good Practice Guidance) provided practical guidance to implementing effective workplace changes and improving compliance with national legislation, which contains generic principles.**

Key recommendations arising from this study therefore relate to improving the availability of data on workplace exposure to RCS (which could be part of the NEPSI reporting system) and on occupational illnesses linked to workplace exposure to RCS. A number of improvements could also be made in the reporting system to increase transparency without betraying confidential information, as well as in linking reporting to sharing good practices. On the whole, the approach can be considered as innovative with regard to social partner actions aimed at improving workplace health and safety.

1 Introduction

ICF International was appointed by DG Employment, Social Affairs and Inclusion in May 2015 to conduct a *Study on the implementation of the autonomous agreement on workers' health protection through the good handling and use of crystalline silica and products containing it*, under specific service order VC/2015/0365 of the multiple Framework Contract "Provision of services related to evaluation, evaluative studies, analysis and research work, including support for impact assessment activities - Lot 2: analysis and research including impact assessment (VC/2013/0085).

1.1 Study objective

The objective of this project was to provide the Commission with a study on the implementation of the *Autonomous Agreement on Workers' Health Protection Through the Good Handling of Crystalline Silica and Products Containing it* (henceforth referred to as 'the Agreement' or 'the NEPSI Agreement'). The Commission intended to undertake an independent monitoring of the Agreement aimed at assessing the contribution of this instrument towards the achievement of the Community's objectives[9].

The main purpose of this assignment therefore was to:

- Assess the role of the signatories and their affiliated members as well as the actions undertaken by them, in the framework of the procedures and practices specific to management and labour, and of the Member States in the field of OSH;
- Assess the implementation of the Agreement;
- Assess the impact of the Agreement;
- Collect background information and data on exposure levels at company, industry, sector and country level at the time the Agreement was signed and today; and;
- Analyse the reporting system put in place by the signatory organisations.

The evaluation covered all EEA countries in terms of background literature, and looked in more detail at 12 countries (Belgium, France, Germany, Italy, Lithuania, Netherlands, Poland, Romania, Slovakia, Spain, Sweden and the UK), in addition, additional interviews were also carried out with labour inspectorates, experts and some NEPSI members in four countries (Austria, Cyprus, Finland and Ireland).

1.2 The NEPSI Agreement

1.2.1 The negotiation process and signatory organisations

Crystalline silica is a material that is naturally abundant and raw materials and products containing crystalline silica are used in a large variety of industries. Concerns have been raised about the health impact of exposure to respirable crystalline silica (RCS) which can be released as part of extraction or production processes.

In recognition of the risks associated with the exposure of workers to RCS in Europe, in June 2002, the European Commission's Scientific Committee for Occupational Exposure Limits (SCOEL)[10] concluded '*that the main effect in humans of the inhalation of respirable crystalline silica is silicosis. There is sufficient information to conclude that the relative lung*

[9] COM (2004) 557 – "Partnership for change in an enlarged Europe – Enhancing the contribution of European Social Dialogue"

[10] SCOEL SUM Doc 94-final on respirable crystalline silica, June 2003

cancer risk is increased in persons with silicosis. Therefore, preventing the onset of silicosis will also reduce the cancer risk. Any reduction of exposure will reduce the risk of silicosis.'

In parallel, in March 2002, the Commission Communication on *Adapting to change in work and society: a new Community strategy on health and safety at work 2002–2006* mentioned the possibility of extending the scope of the 'Carcinogenic agents' Directive. This was foreseen in the context of the ongoing adaptation of existing directives to changes in scientific knowledge, technical progress and the world of work[11]. It was considered that this change could potentially lead to the inclusion of crystalline silica in this Directive.

In June 2003, the Commission indicated that any future activity to set an exposure limit for crystalline silica would have to include social partner consultations. The Commission emphasised that the Treaty contained provisions on EU social dialogue that enabled social partners to negotiate Agreements. It also added that according to the treaty provisions, social partners can request their Agreement to be adopted by a Council Decision[12].

On 2 March 2004, the European Commission launched the first phase consultation of the social partners on the protection of workers from risks related to exposure to carcinogens, mutagens and substances which are toxic for human reproduction. Crystalline silica was listed as one of the most common exposures at the workplace together with other substances.

Following this consultation, IMA-Europe (the Industrial Minerals Association at EU level) informed the Commission that the European silica industry had developed a Good Practice Guide on the handling and use of respirable crystalline silica[13]. IMA-Europe was considering extending this Good Practice Guide to cover other industries concerned by exposure to crystalline silica, with the possibility of a European level framework Agreement on this issue. It was argued that this could be considered as an alternative to the inclusion of crystalline silica in the Carcinogens Directive.

According to Article 154 of the TFEU, social partners are free to begin negotiations at any stage during the two consultation phases. Therefore, in May 2005, trade unions and employer representatives from 14 different sectors launched the 'Negotiation Platform on silica' with the support of the Commission. Two working groups were established. The 'Steering' Working Group was responsible for the drafting of the Agreement and discussing political aspects while the 'Technical' Working Group drafted the technical annexes of the Agreement and particularly the Good Practice Guide. This Technical Working Group was supported by experts from the Health and Safety Executive (HSE) in the UK, relevant occupational health insurance bodies (*Berufsgenossenschaften*) in Germany and the Instituto National de Silicosis (INS) in Spain.

The 'Agreement on Workers' Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it'[14] was signed on 25 April 2006, involving 17 initial signatories:

Table 1.1 NEPSI Signatory organisations

Type of organisation	Sector	Organisation name
Employers' organisations	**Glass sector**	
	Flat Glass	Glass for Europe
	Glass Fibre	GlassFibreEurope

[11] European Commission 2002, COM (118), Communication of 11 March 2002 on a Community strategy on health and safety at work
[12] ETUI (2006) Will the Silica Agreement foil EU legislation?
[13] http://www.crystallinesilica.eu/114-what-are-regulatory-measures-taken-eu-level-iarc%E2%80%99s-monograph-publication
[14] http://www.nepsi.eu/agreement-good-practice-guide/agreement.aspx

Type of organisation	Sector	Organisation name
	Container Glass	FEVE
	Building materials	
	Precast Concrete	BIBM
	Cement	Cembureau
	Ceramics	Cerame-Unie
	Mortar Industry	EMO
	Insulation materials	EURIMA
	Natural Stone	EUROROC
	Mines/quarries/minerals	
	Mines	Euromines
	Industrial minerals	IMA-Europe
	Aggregates	UEPG
	Expanded Clays	EXCA
	Foundry	
	Foundry	CAEF
	Metal, Engineering and Technology-based Industries	CEEMET
Trade Union	IndustriALL-European Trade Union - formerly EMCEF and EMF	

Source: NEPSI website

After the conclusion of the NEPSI Agreement, the Commission launched the Second Stage Consultation of the Social Partners on the Protection of Workers from Risks Related to Exposure at work to Carcinogens, Mutagens and Substances Toxic for reproduction.

Subsequently, the Agreement has been extended to the expanded clay sector via the signature of the European Expanded Clay Association (EXCA) and, to date, it covers 18 European industry sectors. Other sectors are free to join the Agreement at any time. This Agreement constitutes the first multi-sectoral social dialogue Agreement at EU level.

The NEPSI Agreement is an autonomous agreement, therefore, it is implemented through the procedures and practices specific to management and labour in the Member States. Although, it is not binding in the same way as legislation, there is an official commitment from signatory social partners and their members to implement the Agreement at national level. In addition, Member States are free to transpose the Agreement in their national legislation if they wish so.

1.2.2 European social partners' view on the Agreement and the absence of the construction sector

The two trade union organisations that were signatories of the NEPSI Agreement were the European Mine, Chemical and Energy Workers' Federation (EMCEF) and the European Metalworkers' Federation (EMF)[15], subsequently merged under the name IndustriALL. The trade unions supported the Agreement as it was considered to be the best instrument to ensure early implementation of practical measures to reduce workers' exposure to RCS, without hindering the legislation of RCS as a carcinogenic agent and/or the adoption of an EU Occupational Exposure Limit (OEL). Trade unions deemed and still consider that binding measures at the EU level would complement the NEPSI Agreement. The European

[15] http://www.ima-europe.eu/sites/ima-europe.eu/files/publications/Reaching_agreement_on_crystalline_silica__LE__Aug_2006.pdf

Federation of Building and Woodworkers (EFBWW) and the European Trade Union Confederation (ETUC) did not wish to participate in the negotiations.

As far as ETUC was concerned, the organisation wanted RCS to be recognised as a carcinogen at EU level and was keen to see the adoption of an EU-level OEL[16]. Indeed, in its response to the second stage consultation of the social partners[17], ETUC emphasised the need for legislation on crystalline silica to ensure the health and safety of all EU workers in the spirit of the Framework Directive 89/391. ETUC also believes that EU legislation on RCS would generate synergies with the NEPSI Agreement and encourage new signatories[18].

A similar position was held by trade unions in the construction sector who did not participate to the negotiating process. The EFBWW was in favour of crystalline silica being recognised as a carcinogen in Directive 2004/37/EC on carcinogens and mutagens at work and thought that the NEPSI Agreement would constitute an obstacle to this[19]. The EFBWW was also in favour of a threshold value for respirable crystalline silica dust in line with the recommendations from the EU scientific committee on occupational exposure limits (SCOEL)[20]. By joining the NEPSI Agreement, the organisation felt it would diminish the political pressure to have binding legislation on RCS[21].

On the employer side, the European Construction Industry Federation (FIEC) did not join the Agreement for other reasons. The organisation found the NEPSI reporting inappropriate for the activity of the construction sector. It was argued that the ability to report requires a stable workplace which is not a feature of the construction sector characterised by mobile worksites. FIEC's position was also that companies in the construction sector in Europe already comply with the legislation and that the NEPSI reporting system would place additional burdens on them[22]. In addition, FIEC was reluctant to take part in the NEPSI Agreement as the Commission was working on a possible integration of RCS in the Directive 2004/37/EC on carcinogens or mutagens at work[23].

1.2.3 Objectives and content of the NEPSI Agreement

Objectives (Article 1)

The Agreement has three objectives:

- Protection of the health of employees and other individuals occupationally exposed at the workplace to respirable crystalline silica from materials/products/raw materials containing crystalline silica;
- Minimising exposure to respirable crystalline silica at the workplace by applying the Good Practices stipulated herein to prevent, eliminate or reduce occupational health risks related to respirable crystalline silica and;
- Increasing knowledge of potential health effects of respirable crystalline silica and about relevant Good Practices.

[16] EFBWW position on the European regulation of crystalline silica, 13 September 2012

[17] ETUC response to the Second stage of consultation of the social partners on the protection of workers from risks related to exposure to carcinogens, mutagens and substances toxic for reproduction.

[18] ETUC response to the Second stage of consultation of the social partners on the protection of workers from risks related to exposure to carcinogens, mutagens and substances toxic for reproduction.

[19] Information collected through stakeholders' interviews.

[20] EFBWW position on the European regulation of crystalline silica, 13 September 2012

[21] Musu. T and Sapir. M, ETUI (2006) Will the Silica Agreement foil EU legislation?

[22] Information collected through stakeholders' interviews.

[23] Information collected through stakeholders' interviews.

Scope (Article 2)

The NEPSI Agreement concerns the production and use of crystalline silica as well as materials/products/raw materials containing crystalline silica that may potentially lead to exposure to RCS. It applies to the following signatory sectors[24]:

- Aggregates
- Ceramics industry
- Foundries
- Glass industry
- Industrial minerals and metalliferous minerals industries
- Cement industry
- Mineral wool
- Natural stone industry
- Mortar industry
- Precast concrete industry

Ancillary activities such as handling, storage and transport but also mobile workplaces fall under the scope of the Agreement. The Agreement is applicable to all employers and employees directly or indirectly represented by the Parties to the Agreement. Employers are understood as individual companies in the above mentioned industries and the term employees indicates any employee that may be exposed to respirable crystalline silica at work regardless of their working patterns and contracts (part-time, fixed-term or posted workers).

Principles (Article 4)

As mentioned in Article 4 of the Agreement, cooperation of the Parties to the Agreement is key to enhancing knowledge of the health effects of exposure to RCS, in particular through research and the monitoring and dissemination of Good Practices[25]. In addition, by signing this Agreement the Parties agreed that the implementation of the 'Good Practices' will make an effective contribution to risk management by preventing or, where this is currently not achievable, minimising exposure to respirable crystalline silica through the application of appropriate prevention and protection measures in the application of Section II of Directive 98/24 on employers' obligations[26]. Finally, the Agreement states that in cases where national practices in force are shown to be more stringent than the requirements under the Agreement, the Employers and Employees will adhere to these national practices (non-regression clause)[27].

The Good Practice Guide (Article 5 to 7)

A Good Practice Guide[28] was included as an annex to the Agreement. The Good Practice Guide has been jointly adopted by all the signatories and represents a key tool to implementing the Agreement at site level. It provides an introduction to crystalline silica and its effects. It also guides companies in the risk assessment procedure and how to apply it.

Most importantly, the Good Practice Guide provides advice on how to apply the Agreement by providing task sheets. These task sheets are specific to the industries that signed the Agreement and contain several aspects of each activity where crystalline silica can be encountered. For instance, these sheets concern the issue of spray drying and spray glazing, shot-glazing in foundries or the grinding of glass. The task sheets can be updated and Annex 7 of the Agreement provides the procedure to do so. It states that employees or

[24] Annex 5 of the Agreement

[25] Article 4 (1) of the Agreement

[26] Article 4 (5) of the Agreement

[27] Article 4 (7) of the Agreement

[28] Good Practice Guide on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it.

employers can submit new or revised task sheets after discussion and approval from the other party. New or amended task sheets are to be submitted to the representative party accompanied by a justification for the insertion of this new document. The NEPSI Council is responsible for reviewing and approving the modification or the creation of task sheets and ensures outdated task sheets are removed. This procedure enables the Council and signatories to cover any aspect that may have not been mentioned in the Good Practice Guide and keeps these good practices up to date with recent changes. Employers may also organise training on the implementation of this Good Practice Guide.

Monitoring (Article 6)

The Agreement provides that each site must put in place a monitoring system for the application of the Good Practices. For this purpose, the employer must designate an employee for each site (e.g. the team leader of a site) to monitor the application of the Good Practices. The Agreement also states that an individual must also be designated by the employer in accordance with the obligations stemming from Article 7 of Directive 89/391 on protective and preventive services. This Article provides that 'the employer shall designate one or more workers to carry out activities related to the protection and prevention of occupational risks for the undertaking and/or establishment'. In the context of the Agreement, this person must monitor the application or non-application of the Good Practice regularly. S/he will also liaise with the person mentioned above according to a schedule/procedure set up under his/her responsibility after consultation with the works council of the company and workers representatives where applicable. Finally, employers must follow the relevant Dust Monitoring Protocol(s) as inserted in Annex 2 of the Agreement.

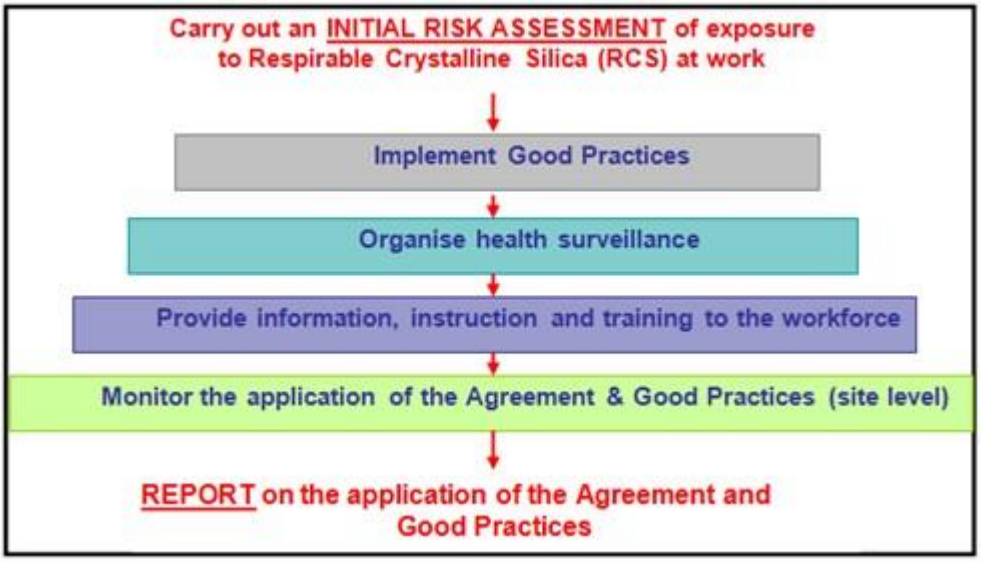
Reporting, Improvement (Article 7)

Employers must report the application or non-application of the Agreement and improvements made every second year through the individual that they designate in accordance with Article 7 of Directive 89/391 (starting in 2008). They must follow the reporting format that has been included in Annex 3 of the Agreement.

In the Agreement, the signatory parties stipulated that the number of non-application situations must progressively decrease per employer unless the number of non-application situations is such as not to allow for further improvement at which point the employer will make the best efforts to retain the status quo.

Finally, the Agreement provides that a list of sites which are repeatedly in a situation of non-application must be annexed to the consolidated report.

Figure 1.1 Main provisions of the Agreement



Source: http://www.nepsi.eu/agreement-good-practice-guide/agreement.aspx

The NEPSI Council (Article 8)

The NEPSI Agreement is based on the cooperation of the signatory parties. A key measure introduced by the Agreement related to the set-up of a Council in charge of supervising the implementation and interpretation of the Agreement. This Council, mentioned in Article 8 of the Agreement, resulted in the implementation of the NEPSI Council.

As mentioned in the Agreement and on the NEPSI Council's website, each signatory European industry sector association and trade union federation is represented on the bi-partite Council, composed of 30 Members, including four chairpersons. This ensures an equal number of representatives of the employers' and workers' delegations. Two permanent co-chairmen (from the producing industries) and two permanent vice-co-chairmen (from the downstream-user industries) are appointed among the employer and employee delegations and are in charge of chairing the NEPSI Council meetings[29]. In addition, the Council is assisted by a Secretariat as required by the Agreement.

In supervising the implementation of the Agreement, the NEPSI Council must review the reports on the application of the Agreement. On the basis of these reports, the Council must issue Summary Reports gathering information on the application of the Agreement per industry sector. Executive summaries of the reports starting from 2007 are also available on the NEPSI Council website.

In case of the non-application of the Agreement in an unjustified and systematic way, the Council is the body in charge of taking the appropriate measures.

In addition to its main task of supervising the application of the Agreement, the NEPSI Council is in charge of:

- Discussion and resolution of any issues of importance for the working of the Agreement;
- Resolution of any conflicts and interpretations issues under this Agreement, including those brought by individual parties, employers and employees;

[29] Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it, Article 8(3)
NEPSI Council: http://www.nepsi.eu/about-nepsi/nepsi-council.aspx

- Issuance of recommendations about possible revisions of the Agreement;
- Communication with third parties; and
- Adaptation of the Good Practices in accordance with Annex 7 on the procedure for the adaptation of the Good practices.

1.3 Structure of the report

The next chapters of this report are structured as follows:

- Chapter 2 provides an overview of the methodology
- Chapter 3 discusses work-related illnesses resulting from exposure to RCS
- Chapter 4 presents the coverage of the NEPSI Agreement in Europe
- Chapter 5 presents data on exposure to RCS and measurement
- Chapter 6 provides an assessment of the legal framework in relation to RCS
- Chapter 7 provides an overview of the implementation of the Agreement and the NEPSI reporting system
- Chapter 8 presents the impact of the Agreement
- Chapter 9 discusses overall conclusions and recommendations
- Annex 1 presents the data collected from national sources on work-related illnesses and exposure data
- Annex 2 includes the transnational literature review on health risks, sectors with high risk of exposure to RCS, evidence of impact reducing exposure and measurements

2 Methodology

2.1 Introduction

The information presented in this report is based on a range of sources including a transnational literature review, interviews with stakeholders at European and national level, twelve in-depth country studies, an online survey and analysis of the NEPSI reporting data.

A literature review of international sources and relevant studies on the subject of RCS was conducted to provide an overview of risk exposure, work-related illnesses and preventive measures to protect workers from exposure. A stand-alone paper has been produced integrating the results from the international literature review.

2.2 Stakeholder interviews at European level and in in-depth study countries

Interviews with the NEPSI signatory organisations at European level were conducted to gather information on the ongoing implementation of the Agreement and to facilitate access to relevant national stakeholders. Additionally, two interviews with representatives of the construction sector at European level were undertaken (the European Construction Industry Federation – FIEC and the European Federation of Building and Woodworkers - EFBWW).

Twelve countries were selected for an in-depth assessment of the implementation of the Agreement and its impact: Belgium, France, Germany, Italy, Lithuania, Netherlands, Poland, Romania, Slovakia, Spain, Sweden and the UK. The selection of the countries was based on a methodological assessment of presence of NEPSI members in Member States and geographical spread to ensure the coverage of Western countries, Eastern European economies, Baltic States and Nordic countries, thus also representing different industrial relations systems.

National research gathered information on the sectoral coverage of the NEPSI affiliates; legislation and other instruments in place to protect workers against risk of exposure to RCS, the implementation of the Agreement and its effectiveness.

Complementary to the 12 in-depth studies, interviews with labour inspectorates, experts and some NEPSI members were conducted in Austria, Cyprus, Finland and Ireland.

Due to the nature of the stakeholders consulted, i.e. NEPSI members (representatives of national industry and employers' organisations and individual employers), Labour Inspectorates, experts and trade unions and the fact that the sample achieved was uneven across groups of stakeholders, countries and sectors, the results of this aspect of the study will be presented clarifying the nature of the source (rather than the number of stakeholders expressing certain views).

The table below (Table 2.1) presents an overview of stakeholders consulted across Member States.

Table 2.1 Sample achieved of stakeholders consulted at national level[30]

Country	Labour inspectorate	Trade unions	NEPSI members (Employer organisations)	NEPSI Members (Companies)	Experts	Total
Countries selected for in-depth research						
BE		1	5	2	3	11

[30] Empty cells for in-depth countries represent stakeholders who have been contacted but did not respond or did not participate to the study

Country	Labour inspectorate	Trade unions	NEPSI members (Employer organisations)	NEPSI Members (Companies)	Experts	Total
DE	1	2	9	2	1	15
ES			5	1	1	7
FR			5	2	2	9
IT	1		3	3		7
LT	1	3	1		2	7
NL			3	1	2	6
PL	1	1	5	3	2	12
RO	1			1		2
SE	1	1	4	1		7
SK	1		1		2	4
UK	1	1	6	1	1	10
Other countries						
AT	1	1	2			3
CY	1					1
FI	1				1	2
IE	1					1
Companies without country allocation because direct members of EU organisations				8		8
Total	12	10	48	25	17	112

Source: ICF

2.3 Online survey of companies and employee representatives

An online survey of employer and employee representatives was carried out to assess the effects of the Agreement at site level. The online survey investigated whether the Agreement had an impact on the protection of workers exposed to RCS; minimising exposure to RCS at the workplace was achieved by applying the NEPSI Good Practices; knowledge about potential health effects of RCS was increased; and the extent to which the Agreement has contributed to improve the health and safety conditions in the workplace.

The target group for this online survey were employers and employee health and safety representatives in the sectors covered by the Agreement. NEPSI members at national levels were asked to disseminate the survey to their members (when the NEPSI member was a national association) or to their sites (when the NEPSI member was a company with multiple sites). Members of trade unions interviewed were also asked to disseminate the survey; furthermore, the introductory email to the survey contained a request to employer representatives to forward the link to their employee representatives at site level. To

increase the response rate, the survey was provided in 11 languages[31] and run from October to early December.

The majority of responses were provided by employer representatives, with only 1% of respondents coming from employee' representatives. Representatives of trade unions interviewed were asked to disseminate the survey and employers were asked to forward the survey to employee' representatives. In the report, wherever possible, the study team has sought to triangulate information obtained via the survey with information obtained from interviews to ensure a full consideration of the views expressed by different stakeholders on the different aspects of the study questions. Here it is worth reiterating that no significant differences in views emerged between employer and trade union organisations regarding the assessment of the implementation or impact of the Agreement.

A total of 202 employers and employee health and safety representatives of companies in the sectors covered by the Agreement started to complete the survey. However, 6 respondents answered fewer than 20% of the questions and these responses were therefore excluded from the final analysis. Figure 2.1 below provides an overview of the profile of respondents by country, sector and size of company.

For confidentiality reasons it proved not to be possible to use the database of companies reporting under the agreement, the study was required to adopt a snowballing methodology to contact possible respondents. The survey approach was not designed to achieve a representative sample of companies affiliated to the NEPSI network and employee representatives. The results presented in this study are therefore representative of respondents to the online survey only and cannot be generalised to the entire population of NEPSI members.

The respondents represented companies were located in 15 Member States, with two-thirds of responses coming from companies located in five countries: the UK (18%), Spain (15%), France (13%), Italy (11%), and Germany (10%).

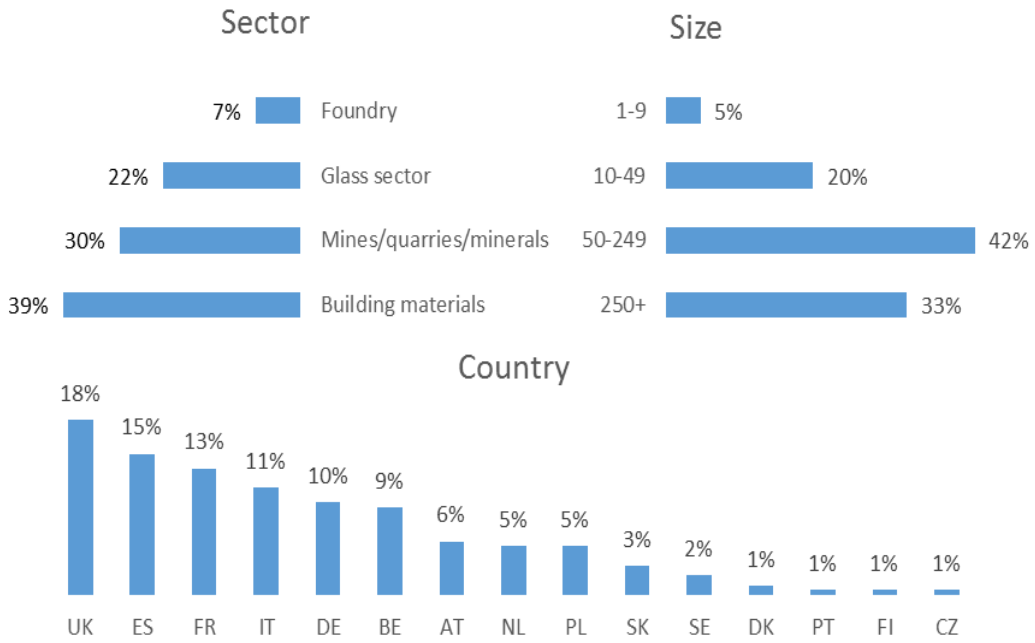
More than two in five companies were medium-sized. One-third of respondents represented large companies with more than 250 employees. One in four companies was small- (20%) or micro-sized (5%).

The majority of replies (91%) to the online survey came from representatives of companies in three sectors: building materials (39%), mines/quarries/minerals (30%), glass sector (22%). The two sectors of building material and mines/quarries/minerals represent the main sectors reporting to NEPSI, with respectively 33% and 55% of sites reporting.

Overall, the coverage of NEPSI members (organisations and companies) across sectors and countries (in relation to interviews and the online survey) was uneven and dependent entirely on voluntary participation. This led to sectors with a higher participation rate in this study than others and self-selection bias needs to be considered when reading the results e.g. participants (regardless the sector) are likely to be the 'best performers'.

[31] English, French, German, Spanish, Italian, Lithuanian, Dutch, Polish, Romanian, Swedish and Slovakian

Figure 2.1 The profile of respondents (N=196)



Source: ICF survey

2.4 Analysis of data from the NEPSI reporting system

Information collected through the NEPSI reporting system was also analysed. The NEPSI Council produces bi-annual reports providing results of the monitoring system in aggregate form by country (or groups of countries) and sectors. Since the focus of this study relates to the implementation of the Agreement by organisations affiliated to the NEPSI signatories in the EEA countries, voluntary reporting and non-EU countries were excluded from the analysis; this was possible only when data were not already aggregated. However, for the purpose of evaluating the overall effect of the Agreement, with for example positive spill-over effects, when deemed important this information was recorded.

Qualitative information on the recording system and country context included in NEPSI reports was also analysed.

Finally, EU-LFS data on employment in different sectors was used and information from the EU LFS ad-hoc module on health and safety has been analysed to provide an overview of the level of people with breathing or lung problems caused or made worse by work.

In this respect, it is worth noting that it is difficult to measure the coverage of the NEPSI Agreement in terms of employees, sectors across Europe and Member States, and therefore to assess the extent to which the Agreement protects a significant share of workers exposed to RCS. A precise assessment would require good data on a) the number of workers (potentially and actually) exposed to RCS in the workplace; b) the number of individuals employed in relevant sectors; the share of such employees covered by national members of the signatories to the NEPSI Agreement. However, a number of methodological issues do not allow for a clear mapping of employment and exposed workers across Europe and by sectors. The first methodological issue relates to different definitions of industry sectors for data on employment, exposure and the NEPSI sectors i.e. the NEPSI sectors cannot be mapped against EU-LFS data on employment and the limited available data on exposure.

The Agreement contains a confidentiality clause to protect the identity of companies reporting to the system. As indicated above, this limits the ability to disseminate the online survey to all companies reporting to NEPSI. Additionally, this affected the ability to fully

analyse the data produced by the NEPSI reporting system since in many cases information was aggregated at country level and/or sectoral level. As a consequence, it was not possible to fully assess the presence of NEPSI members across all Member States and to disaggregate data (e.g. data on employees potentially exposed) by country and/or sector,

3 Work-related illnesses resulting from exposure to RCS

What is the incidence of work-related illnesses resulting from exposure to RCS? This is a key evaluation question to assess the extent of the problem related to workplace exposure to RCS.

Exposure to RCS can cause permanent respiratory diseases including silicosis and lung cancer. The level of risk depends on the duration of exposure (how long), the intensity of exposure (how much) and the concentration of crystalline silica in the dust. Silicosis is one of the oldest known occupational diseases associated with the inhalation of dust. The inhalation and retention of dusts in the lungs is responsible for the group of lung diseases identified under the term pneumoconiosis. Pneumoconiosis caused by coal dust, asbestosis (caused by asbestos) and silicosis caused by RCS are the most common forms of pneumoconiosis. There is usually a delay of more than 10 years between the exposure to dust and the first symptoms of pneumoconiosis. However, in cases of high concentration and long exposure, symptoms can occur quickly such as in cases of acute silicosis. Silica has also been identified as a carcinogen i.e. there is evidence of increased cancer risk associated with industries and occupations where silica is handled. However, occupational exposure depends on multiple factors. For example, recent studies argue that shift work and sedentary work are possible contributing factors to work-related cancer (this also includes lung cancer). Furthermore, a number of substances and lifestyle factors contribute to the development of respiratory diseases such as lung cancer including fumes and smoke. It is therefore extremely difficult to make a causal link between occupational exposure to silica and respiratory diseases. As a result of this, while silicosis is recognised as an occupational illness in all Member States, this is not the case between lung cancer and exposure to RCS, as it is generally argued that no primary link can be established.

In 1997, IARC (International Agency for Research on Cancer) working party published its assessment of the carcinogenic risk of silica to humans[32]. It concluded that silica was associated with lung cancer, and assigned it a group 1 classification. This view was reaffirmed in a further review published in 2012[33]. However, unanswered questions remain relating to the mechanism that leads to the development of lung cancer. The issue of whether silicosis is a precursor to cancer has now been addressed, however, and found not to be correct[34].

The SHEcan project[35] states that 'based on the assumption that current trends in employment and exposure are maintained until 2030 and remain steady thereafter, the predicted numbers of lung cancer deaths in 2060 attributable to RCS would be 5,685. The lung cancers that might be attributable to RCS would have reduced to 1.265% of all lung cancer deaths in the exposed population'. By 2060 the introduction of an OEL of 0.05 mg/m3 would lead to reductions in the number of lung predicted lung cancer deaths and registrations to 337 and 345 respectively; an OEL of 0.1 mg/m3 would lead to a reduction in

[32] IARC Working Party on the Evaluation of Carcinogenic Risks in Humans; Silica, Some silicates, Coal dust and Para-Aramid fibrils. Lyon 15-22 October 1996 IARC Monog Eval Carcinog Risks Hum 1997; 68;1-475

http://monographs.iarc.fr/ENG/Monographs/vol68/mono68.pdf

[33] IARC Working Party on the Evaluation of Cancer Risks in Humans; Arsenic, metals, fibres and dusts; A Review of Human carcinogens Vol 100C Lyon 17-24 March 2009 2012

http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C.pdf

[34] Steenland, K., and Ward, E. Silica: A lung Carcinogen CA Cancer J Clin 2014; 64;63-69

http://onlinelibrary.wiley.com/doi/10.3322/caac.21214/full

[35] IOM Research Project: P937/8, May 2011. The SHEcan project, financed by the European Commission in 2008 and published in May 2011, aimed to assess the socioeconomic, health and environmental impacts of possible amendments to the European Carcinogens and Mutagens Directive (2004/37/EC) for 25 occupational carcinogens including RCS. Available at: http://www.occupationalcancer.eu/

the number of predicted lung cancer deaths and registrations to 818 and 838 respectively; an OEL of 0.2 mg/m3 would lead to a reduction in the number of predicted lung cancer deaths and registrations to 1,721 and 1,763.These estimates are based on the assumption of full compliance.

Due to the long latency period, statistics on health outcomes mainly reflect past working conditions. In Europe there are no harmonised statistics on silicosis and work-related cancer, this is because of differences in occupational diseases recognition criteria and compensation schemes.

The lack of harmonised statistics and different compensation schemes make it difficult to map the health outcomes of RCS. At national level, data are fragmented and different sources need to be examined to gather relevant data. The following paragraphs provide an overview of diverse data on work-related illnesses from European and national sources associated to different extents to workplace exposure of RCS.

It should be noted from the outset that a thorough assessment of the impact on health outcomes related to exposure to RCS would also require precise statistics (on employment and exposure to RCS) in sectors considered to be at high risk due to high numbers of exposed workers. According to CAREX, construction is the sector with the highest numbers of workers exposed accounting for 67.7% of all workers exposed, followed by manufacture of other non-metallic mineral products; other mining; manufacture of pottery, china and earthenware; manufacture of machinery except electrical; iron and steel basic industries; manufacture of fabricated metal products; metal ore mining; manufacturing of glass and glass products.

Therefore, monitoring exposure and concomitantly the health effects of exposure to RCS is not straightforward and does not readily contribute to an assessment of trends in these areas and indeed the measurement of the impact of any relevant legislation or guidance.

3.1 Work-related illnesses in selected European countries

This section provides an overview of the national data on work-related illness gathered from national sources in 12 Member States. Overall, collecting data on illnesses that may be linked to workplace exposure to RCS and interpreting the data gathered poses significant challenges. National frameworks and data are not comparable and a number of challenges need to be taken into account when attempting to identify the level and type of illnesses related to exposure of RCS.

When looking at evidence from register data on the incidence of work-related illnesses linked to exposure to RCS, it is important to highlight that official registers pertaining to OSH only contain data related to work-related illnesses that are officially classified as occupational diseases in the national context, in this specific case where the link between the exposure to RCS and the illness is officially recognised.

All national legal frameworks and insurance schemes officially recognise the link between exposure to RCS and silicosis. However, a clear link between exposure to RCS and the development of lung cancer is not recognised in national legislation. RCS is recognised as a carcinogenic substance only in Belgium (exclusively for sandblasting activities), the Netherlands and in Slovakia. However, even in these countries, this does not translate into an official classification of lung cancer as a work-related illness linked to workplace exposure to RCS, since multiple exposure factors (also outside workplaces) can contribute to the development of lung cancer.

Since silica is not considered as a carcinogenic substance following the European list[36], the link between lung cancer and exposure to RCS is not directly recognised by national legal frameworks, although there is a certain level of formal acknowledgement. For example, in the UK although there is no official recognition of RCS as a carcinogenic substance in the legal framework, HSE recognises the link between RCS and the development of silicosis, chronic obstructive pulmonary disease (COPD) and lung cancer amongst workers who are exposed. Much of HSE guidance concerning exposure to dust which contains RCS refers to the link between exposure and the development of these diseases. In Austria, crystalline silica is not classified as carcinogen; however, since 2013 cancer in connection to RCS is recognised as occupational a disease.

Data at national level are collected by different organisations and depend on a number of factors including health surveillance systems (both general health surveillance systems and health surveillance in case of risk of silicosis). For example, in the context of illnesses related to exposure, key factors are the ability of health professionals to identify the likelihood of developing illnesses on the basis of exposure levels i.e. whether workers are at risk of developing silicosis and/or other lung issues in relation to the exposure they are subject to; the ability of health professionals to assess the illness and the link with workplace exposure i.e. whether a worker is developing lung problems (solely and significantly) because of exposure in the workplace.

Additionally, national data are collected in diverse ways. For example, different types of illnesses are grouped together, and it is not usually clear whether illnesses are linked to exposure to RCS or other types of dust; trends over time are sometimes not comparable due to changes in the national framework and compensation schemes, etc.

An additional challenge of illnesses related to exposure to RCS and compensation schemes for registered occupational diseases, as indicated above, is that illnesses develop years after the exposure, only acute silicosis develops within 10 years of exposure. How and whether this is taken into account depends on the individual country.

In France, for example, time limits exist for claiming a potential case of acute silicosis and thresholds linked to the period of exposure i.e. a worker can only file a claim within six months of leaving the place of employment provided that the illnesses has been officially diagnosed and provided that the period of exposure was at least six months. For chronic silicosis, the threshold for claiming compensation is 35 years and the period of exposure required is at least five years. Because of these thresholds, workers have the right to professional follow ups i.e. health surveillance implemented every five years after workers leave the place of employment[37][38]. However, a worker cannot obtain the right to a post-professional follow-up without a certificate of exposure, and obtaining such a certificate years later may be a challenge, potentially making it more difficult to initiate a compensation procedure.

Declining trends in reported cases of silicosis and other pulmonary diseases recognised as linked to the exposure of RCS have been found in all countries studied and this is likely to be related to the decline in employment in sectors with historically high levels of cases of silicosis (e.g. mining). The figure below provides overall trends for Germany, the UK and France. The spike, observed in Germany in 2009 and 2011, of compensated cases is related to a new guideline for the medical examination of silicosis. This guideline now basically also allows for compensation for cases with low grades of silicosis (this is ILO 1/1 and higher).

[36] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[37] Table 25 of the general regime and table 22 of the agricultural regime

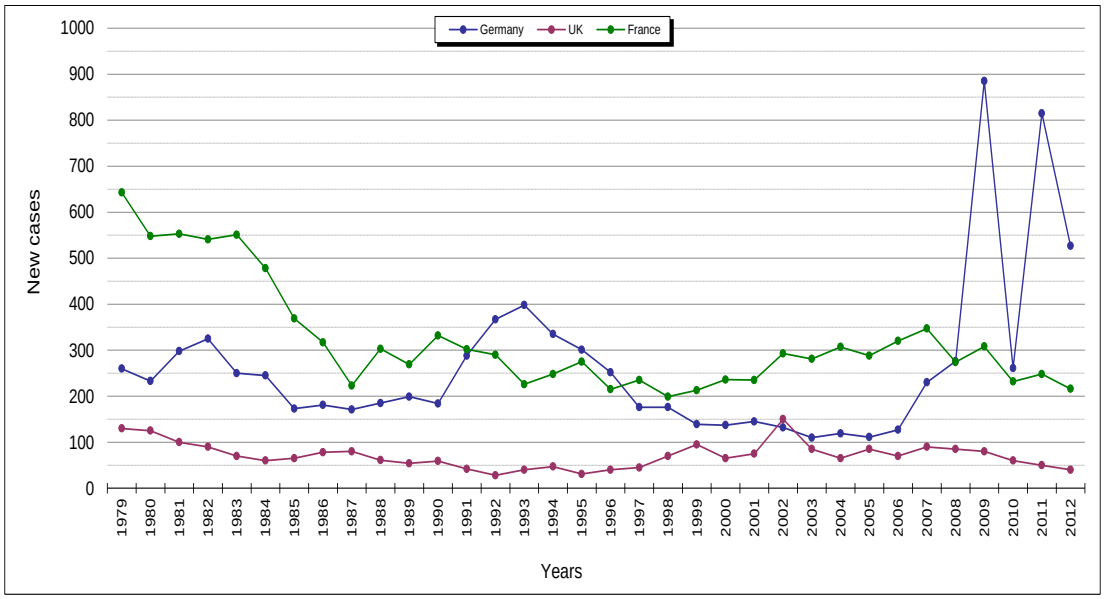
[38] Article D. 461-23 of the Social Security Code

Previously, compensation was only possible for severe silicosis with higher ILO classifications.

These trends are also confirmed in the other countries analysed in-depth in the study. See Annex 1 with detailed information on work-related illnesses collected in each country.

However, it is interesting to note that in Spain, new cases of silicosis have been diagnosed among active workers in new sectors such as the manufacturing of kitchen countertops or new work processes (e.g. sanding of jeans).

Figure 3.1 New cases of silicosis excluding coal workers



Sources: Germany: BK-DOK, Gewerbliche BGen Neue BK-Renten, 4101 Silikose. UK: Department for Work and Pensions (DWP). France: Statistiques nationales des maladies professionnelles pour les pneumoconioses dues à la silice (Tableau 25), CNAMTS, Direction des risques professionnels, Paris

3.2 Available control measures to prevent and limit exposure to RCS

Finally, this section focusses on available control measures that can prevent or limit exposure to RCS in the workplace. The ToR for this still calls for the provision of a list of control measures in place and a comparison of their effectiveness, as well as the state of the art in technology.

The discussion of control measures is highly technical and the selection of appropriate techniques and tools is dependent on the work process and therefore sector involved. The NEPSI good practice guidance contains tailored advice regarding this issue for specific sectors that will not be reiterated here. Annex 2 also includes more information from the literature review on this technical aspect of the study.

In this sector a summary of the information available in the literature is present. On balance, this focusses significantly on relevant techniques in sectors must prone to RCS exposure, therefore includes the construction sector, which is not covered by NEPSI.

Generally, speaking, exposure is controlled by a series of measures termed the General Principals of Prevention contained within Council Directive 89/391/EEC (as amended)[39]. In practice, the engineering controls for reducing exposure to RCS are local exhaust ventilation,

wet suppression of dust, and the use of Respiratory Protection Equipment (RPE). However, the use of engineering controls must take precedence in any exposure control strategy. RPE may be used in combination with other controls if they will not adequately control the risk alone.

4 Coverage of the NEPSI Agreement in Europe

A key evaluation question was to assess the NEPSI Agreement and its coverage across Europe and in Member States i.e. what is the level of coverage of the industry and the interested population across Europe, and what is the incidence of workplace exposure to RCS?

4.1 Methodological steps to assess the coverage of the NEPSI Agreement

A measurement of the coverage of NEPSI Agreement requires information in relation to the following four dimensions:

- The number of workers in Europe in the relevant sectors
- The number of workers covered by the NEPSI Agreement, by industry sector and country
- The number of workers exposed to RCS in Europe, by industry sectors and country
- The number of workers covered by the NEPSI Agreement and exposed to RCS, by industry sectors and country

This study attempted to collect information from European and national sources to assess the coverage of the Agreement on the basis of the dimensions presented in the figure below.

Figure 4.1 Framework to assess the coverage of the NEPSI Agreement

Source: ICF

Key methodological considerations need to be borne in mind when looking at the coverage of workers exposed to RCS.

The number of workers in Europe/Member States in a given sector cannot be considered as a proxy for the number of workers exposed or potentially exposed to RCS. Similarly, **the number of companies operating in a sector is not a proxy for companies with a risk of exposure**. For example, not all companies operating in the foundry sector have an exposure risk on their premises and/or in their work processes. In this specific case a distinction must be made between foundries that process ferrous metals where RCS is not present and the non-ferrous ones where sand is used and where the risk

of exposure to RCS exists. Among mineral wools, only glass wool is a concern with regard to crystalline silica since glass wool is manufactured using sand, while stone wool is not. After melting the raw material for glass wool, no crystalline silica remains, because it becomes an amorphous material. In the ceramic sector or in glass manufacturing, since only some parts of work processes involve the use of RCS, e.g. raw material storage, loading and transport, cleaning operation, the whole sector can similarly not be considered to be affected. Additionally, in companies where the risk of exposure is present only some workers are exposed, or at risk of exposure, while others are not, e.g. workers in sites with no presence of RCS, administrative staff working in offices separate from production processes etc.

Nevertheless, mapping industry sectors with risk of exposure in Member States and mapping the coverage of the NEPSI members in terms of employment and/or production provides useful insight on the extent to which the NEPSI Agreement covers sectors and workers that are at high risk.

Additional methodological considerations and challenges need to be taken into account when attempting to map the coverage of the NEPSI Agreement in terms of workers exposed to RCS across Europe.

- **Presence of NEPSI members across Member States**: Organisations signatory to the NEPSI Agreement are employer or industry associations (with the exception of IndustriAll) and companies; therefore, their presence across Member States depends primarily on the structure of national economies. The structure of industrial relations across Member States plays also a role on the level of affiliation of companies to national associations and consequently on the presence of NEPSI members.
- **An exhaustive mapping of NEPSI members in Member States was not possible:** precise information on the number of companies affiliated to national member organisations of NEPSI signatories (or directly company members among NEPSI signatories) was not available in each country. Employers' organisations at European and national level either do not always store information on their associated and/or information are not always updated. Only patchy information on the precise coverage of a sector by NEPSI members at Member State level is therefore possible (see also Table 4.6).
- **Data on exposure to RCS**: Data on workplace exposure to RCS is scarce, out-of-date and not comparable across Member States. At European level, the available sources of information on exposure to RCS are CAREX and the SHECan study based on CAREX data. At national level, few countries have national databases containing data on exposure to RCS. Where databases exist, the information is not publicly available for consultation. Such databases are either held by labour inspectors or public health and safety agencies, occupational health insurance bodies, universities or research institutes and material is either considered commercially sensitive or is simply not in the public domain. Additionally, the nature and content of the databases are extremely diverse due to a number of factors, including:
  - nature of data on exposure e.g. databases may contain numbers or estimates of workers exposed at a given time, exposure history of workers, information on sectors at risk of exposure, information on professional profiles at risk of exposure
  - methods of measurement used to estimate the exposure and sampling methods to carry out the measurements
  - substances measured vary across databases and often is not clearly identifiable, very rarely data are available relating purely to exposure to RCS. More often it refers to dust containing RCS and/or simply dust
  - purpose of the database e.g. some information is collected for insurance purposes by insurance authorities, other by labour inspectorates, occupational health physicians etc.

  - diversity of institutes (public and private) performing the measurements and diverse accreditation processes/rules in Member States

- **Comparability of exposure data**: For the reasons presented above, data from national sources is not comparable. Any attempt to simply compare data on exposure to RCS across countries from national sources is likely to be inappropriate and a prior ad-hoc methodological assessment is necessary. Similarly, comparisons of trends from the same sources are often difficult due, for example, to changes to national regulations, methods of measurements etc. For example, the update of the Spanish CAREX database, from 1990-93 to 2004 brought about an increase in the number of workers exposed of more than 800,000 people. Similarly, the comparison of CAREX French data between 1994 and the last update in 2010 shows additional 197,900 people exposed. The update of CAREX database in 2000-03 in Italy showed a decrease of number of workers exposed to RCS by 10%. The extent to which these changes are linked to reduced/increased exposure in workplaces or are partly related to methodological factors need to be considered.
- **Definition of industry sectors**: European and national data on employment and data on exposure to RCS follow different coding to define industry sectors, making the comparison of available data extremely difficult. EU-LFS employment data uses NACE Rev. 2 from 2008, CAREX is based on ISIC Rev.2, the SHECan study is based on NACE Rev. 1.1; while the sectors identified in the NEPSI Agreement do not follow international classifications. Additionally, the NEPSI data are self-assessed e.g. reporting employers decide in which sector to locate their company, which in in some cases is not clear-cut since companies operate across sectors, particularly big corporations. Therefore, mapping the sectors covered by NEPSI against other data, which follow international classifications, is a complex exercise that will always demand a degree of value judgment from researchers.

4.2 Mapping of NEPSI sectors against international industrial codes

The table below (Table 4.1) attempts to map the sectors used in the NEPSI Agreement with the sectors of the EU-LFS and CAREX (data on exposure to RCS). The table is built on assessments from the research team based on interviews with members of the NEPSI council where the type of activities of their members was discussed. In some cases, NEPSI members have clearly identified the sectors in which they are active according to NACE classification, i.e. CEEMET and Glass Alliance.

However, it is worth noting that in the case of the Glass Alliance, a paper produced by this organisation clearly explains the issues underpinning the mapping of the sector and the assessment of the coverage of exposed workers. The paper explains that the economic activity of glass manufacturing is classified under code 23.1 manufacture of glass and glass product of NACE Rev. 2. However, at four-digit level, there is no differentiation between manufacturing and shaping and/or processing of glass, except for flat glass (see Table 4.1). This is a crucial point because once the glass is formed there is no risk of exposure to RCS and all workers involved in the glass shaping and processing activities should not be considered as 'potentially exposed to RCS'. The paper concludes that using EU-LFS data and NACE classifications to estimate the number of workers potentially exposed to RCS leads to substantial overestimates. The paper also states that, for the above mentioned reasons, the estimates provided by the SHECan study are deemed by the organisation as incorrect[40].

[40] Glass Alliance (2014) Respirable crystalline silica in the glass industry http://www.glassallianceeurope.eu/images/cont/glass-alliance-europe-statement-on-respirable-crystalline-silica_file.pdf

Therefore, taking into account all the methodological limitations, the table below attempts to provide a mapping for the NEPSI sectors and clearly shows the complexity of this mapping exercise. Overlaps and gaps occur in all sectors and at all levels of the coding systems and employment data based on NACE, when used to assess the coverage of potentially exposed workers are likely to generate overestimations.

Table 4.1 Mapping of NEPSI sectors against EU LFS Nace Rev. 2 and ISIC Rev.2 used in CAREX

EU LFS (NACE Rev.2)[41]	Sector NEPSI Members	CAREX (ISIC Rev.2)[42]
Section C Manufacturing	Glass sector[43]	Major Division 3 Manufacturing
23 Manufacture of other non-metallic mineral products		36 Manufacture of Non-Metallic Mineral Products, except Products of Petroleum and Coal 369 Manufacture of other non-metallic mineral products
23.1 Manufacture of glass and glass products 23.11 Manufacture of flat glass 23.12 Shaping and processing of flat glass 23.13 Manufacture of hollow glass 23.14 Manufacture of glass fibres 23.19 Manufacturing and processing of other glass, including technical glassware	Flat Glass Glass Fibre Container Glass	362 Manufacture of glass and glass products
Section C Manufacturing	Building materials	Major Division 3 Manufacturing
23.2 Manufacture of refractory products 23.3 Manufactory of clay building material 23.4 Manufacture of other porcelain and ceramic products 23.5 Manufacture of cement, lime and plaster 23.6 Manufacture of articles of concrete, cement and plaster 23.7 Cutting, shaping and finishing of stones 23.9 Manufacture of abrasive and non-metallic mineral products n.e.c	Precast concrete Cement Ceramics Mortar Industry Insulation Materials Natural Stones	3692 Manufacture of cement, lime and plaster 361 Manufacture of pottery, china and earthenware 3699 Manufacture of non-metallic mineral products not elsewhere classified
Section B Mining and quarrying	Mines/quarries/minerals	Major Division: 2 - Mining and Quarrying
07 Mining of metal ores 08 Other mining and quarrying	Mines Industrial minerals	22 Crude Petroleum and Natural Gas Production 23 Metal Ore Mining

[41] http://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF/dd5443f5-b886-40e4-920d-9df03590ff91?version=1.0

[42] http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=8

[43] Glass Alliance (2014) Respirable crystalline silica in the glass industry http://www.glassallianceeurope.eu/images/cont/glass-alliance-europe-statement-on-respirable-crystalline-silica_file.pdf

EU LFS (NACE Rev.2)[41]	Sector NEPSI Members	CAREX (ISIC Rev.2)[42]
	Aggregates Expanded clays	29 Other Mining
Section C Manufacturing	Foundry	Major Division 3 Manufacturing
24 Manufacturing of basic metals 25 Manufacturing of fabricated metal products, except machinery and equipment 26 Manufacture of computer, electronic and optical products 27 Manufacturing of electrical equipment 28 Manufacture of machinery and equipment 29 Manufacture of motor vehicles, trailers and semi-trailers 30 Manufacture of other transport equipment 33 Repair and installation of machinery and equipment	Foundry Metal, Engineering and technology base-industries[44]	37 Basic Metal Industry 371 Iron and steel basic industries 38 Manufacture of Fabricated Metal Products, Machinery and Equipment 381 Manufacture of fabricated metal products, except machinery and equipment 372 Non-ferrous metal basic industries

Source: ICF

[44] CEEMET website provide a list of the sectors covered by the organisation http://www.ceemet.org/page/overview

4.3 Employment in Europe and presence of the NEPSI members

4.3.1 Level of employment in Europe in relevant sectors based on EU-LFS data

Table 4.1 above provides a mapping of the sectors as defined by NACE Rev. 2 code in the EU-LFS against the sectors signed up to the Agreement. As indicated above, it shows that a straightforward match is not possible, for example the glass and building materials sectors (as identified in the NEPSI Agreement) are included in large group of Manufacturing in NACE Rev. 2, which include other sectors and activities. The subgroups of the glass sector (as identified in the NEPSI Agreement) could be included in EU-LFS groups at two and three-digit level, similarly the subsectors in building materials.

Table 4.2 below provides an overview of number of workers in the EU28 and in selected Member States in the sectors that have been identified as potentially matching the NEPSI sectors. In many cases at three and four-digit level data are not available or cannot be published because of reliability issues. Therefore, the table below provides an approximate number of workers active in the sectors are potentially covered by the NEPSI Agreement. This study attempted to map the NEPSI sectors against international codes on the basis of the information provided by NEPSI members interviewed and information provided in the website of NEPSI organisations (see section above on mapping of the NEPSI sectors against international industrial codes)

Knowledge of the level of employment in the sectors covered by the NEPSI Agreement is important to provide an assessment of the workers that could be potentially exposed to RCS and understand how data on workers exposed relate to the employment in the sector. Although, it is important to reiterate that any assessment of the number of workers potentially exposed to RCS based on NACE leads to overestimates, since exposure to RCS occurs only in certain industrial processes and concern only workers involved in those processes.

The table below presents information on employment levels in the sectors identified in this study as covered by the NEPSI (see previous section on mapping of the NEPSI sector against the NACE code). In particular, the sectors from 24 to 33 have been clearly identified on the CEMET website as the industry sectors represented by the organisation. For the other sectors a judgement call was made on the basis of information collected in this study. Keeping in mind all these methodological issues, an approximation of the sectors identified as potentially including workers covered by NEPSI has been performed.

Across Europe approximately 36 million workers are employed in the sectors covered by the NEPSI Agreement. The largest numbers of workers among the in-depth countries analysed for this study are found in Germany (9,781,800), Italy (4,328,400), France (3,264,500), Poland (3,171,000), the UK (3,142,600) and Spain (1,974,300).

Table 4.2 Number of workers in selected sectors (as mapped again NEPSI sectors) in selected Member States and EU 28 (EU LFS 2014)

NACE Rev.2	BE	FR	DE	IT	LT	NL	PL	RO	SK	ES	SE	UK	EU28
23 Manufacture of other non-metallic mineral products	49,200	(230,600)	417,300	380,200	(13,900)	47,000	329,800	107,800	35,000	188,800	30,300	198,700	2,549,600
23.1 Manufacture of glass and glass products		26,646		44,784		4,645	44,452		3,675	16,622	2,428	37,535	
23.11 Manufacture of flat glass													
23.12 Shaping and processing of flat glass													
23.13 Manufacture of hollow glass													
23.14 Manufacture of glass fibres													
23.19 Manufacturing and processing of other glass, including technical glassware													
23.2 Manufacture of refractory products				6,248					(2,229)	(2,280)		(5,652)	
23.3 Manufactory of clay building material		7,198		34,674		3,180	19,880			23,959		12,535	
23.4 Manufacture of other porcelain and ceramic products		7,779		16,836			16,735	13,096	(2,366)	6,121		(9,754)	
23.5 Manufacture of cement, lime and plaster		10,550		12,119			(6,585)	(7,170)		9,119			
23.6 Manufacture of articles of concrete, cement and plaster		33,353		28,946		9,437	45,558	(7,686)	4,681	15,920	7,282	22,255	
23.7 Cutting, shaping and finishing of stones		13,794		43,109		(1,911)	20,311	12,049		17,433	(1,211)	(4,971)	
23.9 Manufacture of abrasive and non-metallic mineral products n.e.c		11,578		6,484		3,154	(8,946)			(3,136)	2,303	(8,565)	
Section B Mining and quarrying													
07 Mining of metal ores							41,700			(8,400)	11,500		119,000
08 Other mining and quarrying		(47,400)	78,000	42,700		(1,600)	51,700	16,200	6,900	37,500	4,300	30,200	433,400
24 Manufacturing of basic metals	70,300	(207,200)	496,000	359,000		43,200	190,000	109,100	57,200	147,200	59,000	200,200	2,316,800
25 Manufacturing of fabricated metal products, except machinery and equipment	93,400	(683,800)	1,734,100	1,051,900	21,800	155,600	613,600	235,100	122,400	398,400	129,000	498,200	7,152,600

NACE Rev.2	BE	FR	DE	IT	LT	NL	PL	RO	SK	ES	SE	UK	EU28
26 Manufacture of computer, electronic and optical products	34,400	(302,800)	1,032,200	266,000		51,100	159,600	113,900	54,400	73,400	40,200	357,400	3,074,100
27 Manufacturing of electrical equipment	30,000	(242,000)	591,200	361,900		37,800	262,400	143,000	62,300	128,100	41,600	148,700	2,620,600
28 Manufacture of machinery and equipment	90,400	(405,000)	2,427,200	930,400	(12,700)	153,200	275,600	119,600	101,100	248,600	130,600	515,900	6,380,700
29 Manufacture of motor vehicles, trailers and semi-trailers	90,300	(457,100)	2,274,400	418,800		38,600	500,200	350,600	180,600	413,400	111,500	365,600	6,179,000
30 Manufacture of other transport equipment	23,200	(352,400)	388,800	214,600		41,500	150,200	102,800	10,700	128,200	29,000	385,600	2,008,700
33 Repair and installation of machinery and equipment	24,000	(336,200)	280,000	302,900	(11,100)	75,600	212,600	133,600	21,900	193,200	36,900	442,100	2,501,600
Total Sum (of 23, 07, 08, 24, 25, 26, 27, 28, 29, 30, 33)	505,200	3,264,500	9,719,200	4,328,400	59,500	645,200	2,787,400	1,431,700	652,500	1,965,200	623,900	3,142,600	35,336,100

Source: Eurostat [lfsa_egan22d]. Note for data in brackets: (flag u in EU LFS), data with flag u can be published but only in brackets and with a warning on their reliability, aggregation with other lines is advised. Whether the cells are empty data were not provided by Eurostat and/or under the threshold for publication.

4.3.2 Presence of NEPSI Members in Europe

A major factor when assessing the coverage of the NEPSI Agreement is whether signatory organisations are present in a given country and/or sector. The presence of NEPSI signatories in European countries largely depends on the nature and presence of the industry (how important are different sectors in the different Member States; is a sector mainly represented by large or small companies etc.). Furthermore, the structure of industrial relations and the density of social partner organisations have an impact on the presence of NEPSI members, as countries with less developed industrial relations systems tend to have lower membership density. For instance, in Eastern European countries there is still a certain level of cultural resistance to the establishment of employers' associations, and it is therefore more difficult for European confederations to establish a presence in these countries.

Three sources of information have been used to identify in which countries the European confederations adhering to the NEPSI Agreement have members, this includes confederations' websites, the provision of national contacts by the European associations, and information from NEPSI reports. Table 4.3 provides and overview of the countries where a member was identified at national level, in the cells without blue shading no members were identified. Overall, European confederations who signed the NEPSI Agreement have at least one member in all Western European countries, the Eastern European countries where the associations are most likely to be represented are Poland and the Czech Republic.

However, this provides information only on the potential geographical coverage of the Agreement but not on the organisational density of these member bodies at national level. It is also important to note that not all members take part in regular reporting as required by NEPSI when no risk from exposure to RCS is identified, and the size of industries differ across countries; therefore in some countries there are a very limited number of members. Table 4.4 provides an overview of the number of sites reporting to the NEPSI Agreement, this represent a more coherent assessment of the presence of reporting of companies across countries. However, it is not always possible to provide a clear overview by country since data are provided in an aggregated format due to confidentiality issues. The highest presence of NEPSI members reporting in line with the NEPSI Agreement can be found in the largest European economies, the UK, France, Germany, Italy and Spain. The presence of reporting sites in Eastern European countries and the Baltic countries is often relatively low and varies across sectors; Poland, the Czech Republic and Hungary appear to have a high number of reporting sites, however data for Eastern European countries is often aggregated which indicates a low number of reporting sites within each country. Similarly, data for the Nordic countries are provided in an aggregated format for Finland and Sweden. Norway reports voluntarily.

This information makes clear that all NEPSI members have a strong presence in the largest economies in Europe. A relatively significant presence is also found in the Nordic countries as a group.

Table 4.3 Presence of NEPSI members in Member States

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	LI	IS	NO
UEPG	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■		■	■	■	■	■	■	■	■		■	■
CEMBUREAU	■	■	■		■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■		■			
IMA-Europe	■	■	■	■	■	■	■	■		■	■	■		■	■	■					■	■	■	■	■		■	■			■
Euromines	■	■			■	■	■		■	■	■	■		■							■	■	■		■		■	■			
EMO	■	■			■	■				■	■	■			■	■					■	■	■		■	■		■			
BIBM	■	■				■	■			■	■	■			■						■	■	■		■			■			■
EuroRoc *	■	■	■		■	■			■	■	■	■		■	■	■						■	■		■			■			■
Cerame-Unie	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
EXCA	■	■			■	■	■	■			■	■		■	■	■		■		■	■	■	■	■	■	■	■	■	■	■	■
CAEF	■	■	■		■	■	■			■	■	■	■	■	■	■	■			■	■	■	■	■	■	■	■	■	■	■	■
CEEMET	■	■			■	■	■			■	■	■	■			■	■		■	■	■	■	■	■	■	■	■	■	■	■	■
GlassFibre	■	■	■		■	■	■	■	■	■	■	■		■	■	■		■	■	■	■	■	■	■		■	■	■	■			
ESGA **	■	■	■		■	■	■	■	■	■	■	■		■	■	■		■	■	■	■	■	■	■		■	■	■	■			
EURIMA	■	■	■		■	■	■	■	■	■	■	■		■	■	■		■	■	■	■	■	■	■		■	■	■	■			
FEVE	■	■	■		■	■	■	■	■	■	■	■		■	■	■		■	■	■	■	■	■	■		■	■	■	■			
Glass for Europe***																															
IndustriALL	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■

*Source: ICF with information from information from NEPSI report (sites reporting), contacts provided and associations' websites. Note: *No data available on the number of sites reported by country in the 2013-2014 NEPSI reports; **ESGA withdrew from the Agreement in 2014; ***Members are large companies with sites across Europe. The blue shading represents countries were at least one member was identified.*

Table 4.4 Number of sites reported by country

Aggregates		Cement		Ceramics		Foundry		Glass		Industrial Minerals		Mining Industry		Mortar		Precast Concrete	
UEPG		CEMBUREAU		CERAME-UNIE/EXCA		CAEF/CEEMET		GlassFibre/ESGA/EURIMA/FEVE		IMA-Europe		EUROMINES		EMO		BIBM	
FR	862	IT	77	DE	182	DE	203	DE	63	DE	107	CZ	107	DE	89	DE	215
UK	706	DE	49	ES	147	FR	173	FR	40	FR	100	EL	42	UK	75	UK	119
DE	610	ES	43	IT	113	UK	93	IT	38	IE, UK	91	SE, NO	20	ES	58	FR	97
ES	272	FR	31	UK	111	ES	52	ES, PT	30	ES	84	DE, NL	19	FR	58	BE	81
FI, SE	201	UK	23	FR	100	SE	52	IE, UK	24	DK, FI, SE	67	FI	18	NL, SE	34	NL	78
EL, HR, IT, RO, SK	78	EL	15	BE, LU, NL	84	IT	45	BE, LU, NL	20	IT	57	PL	14	PT	18	SE	48
IE	66	PL	14	CZ	37	PL	34	PL	15	BE	31	AT	11	FI, PL	12	AT	26
BE	56	BE	13	PT	31	CZ	27	BG, EL, RO, SI, SK	10	BG, HU, RO, SK	25	ES, IE, UK	10	AT, CZ, IT, SI	11	ES	13
AT	51	RO	13	AT	28	AT	25	CZ	9	AT	24	BG, EE, HU	8*			FI	3
PT	50	AT	12	HU, SI	22	FI	22	DK, EE, FI, LV,	7	CZ	15					IT	n.a*
NO	50	PT	8	EE, PL	19	NL	18	AT, HU	6	PL	13						
CZ, HU, LV, PL, SI	34	SE	5	FI, SE	15	PT	16			NL	12						
NL	33	BG	4	DK	14	BE	14			PT	9						

Aggregates		Cement		Ceramics		Foundry		Glass		Industrial Minerals		Mining Industry		Mortar		Precast Concrete	
UEPG		CEMBUREAU		CERAME-UNIE/EXCA		CAEF/CEEMET		GlassFibre/ESGA/EURIMA/FEVE		IMA-Europe		EUROMINES		EMO		BIBM	
BG	9	CZ	4	BG, RO, SK	11	NO	14			CY, EL	5						
						HU	13			NO	37*						
						SI	10										
No figures in 2014 for: LV, IT - Voluntary: NO		Voluntary: HR, NO				Voluntary: NO				Voluntary: NO * data include also Peru, USA, Switzerland, Turkey		*data include also Turkey				IT data for 2012:96, *no longer a member since 2013	

Source: NEPSI Council 2013-2014 National Reports. Note: EUROROC stated in the report that only one company working with quarts stone was found, the few small sized companies working with products falling under the Agreement decided in most cases to apply water flash cutting systems, companies that are not in the economic position to apply such system have been advised to stop the handling of the products in question and buy finished products.

The NEPSI reporting system contains information on the number of sites reporting and employees working at reported sites (Table 4.5). Due to confidentiality issues data by country are provided (in many cases) in an aggregated form, therefore this is the maximum level of disaggregation that can be presented.

In 2014, a total of 439,268 employees were reported to the NEPSI system. Compared to the total number of workers in EU 28 in relevant sectors, as identified above, this is a very small fraction. However, calculating a simple proportion would be methodologically incorrect and misleading since, as it has been already discussed, not all NEPSI members report to the system (mainly in sectors and companies with no presence of RCS), not all companies operating in a sector are members of employers' organisations, the sectors are not directly comparable; and finally the level of employment cannot be used as a proxy for the number of employees potentially at risk.

Table 4.5 Number of sites, reporting sites and reported employees in the NEPSI reporting system by NEPSI members (2014)

NEPSI Sectors		NEPSI Organisations	Number of sites	Number of reported sites	Number of reported employees
Mines/quarries/minerals	Aggregates	UEPG	2,991	2,493	34,262
	Expanded Clays	EXCA	14	14	983
	Industrial Minerals	IMA-Europe	596	564	22,827
	Mining Industry	EUROMINES	249	207	48,169
Building Materials	Cement	CEMBUREAU	330	330	36,761
	Ceramic	CERAME-UNIE	911	771	92,364
		EURIMA	48	45	7,047
	Mortar	EMO	337	265	8,864
	Precast Concrete	BIBM	690	520	40,322
Foundry	Foundry	CAEF/CEEMET	797	533	89,812
Glass sector	Glass	FEVE	148	146	40,181
		Glass for Europe	41	41	12,751
		Glass Fibre	15	15	4,925
Total			7,167	5,944	439,268

Source: NEPSI Council 2013-2014 National Reports (data do not include voluntary reporting)

4.3.3 Coverage of employment in relevant sectors by the NEPSI members

As described in previous paragraphs, it is extremely complex to measure the coverage of the NEPSI Agreement purely on the basis of quantitative data on employment and data collected through the NEPSI reporting system. Another avenue pursued by this study is the assessment of the density of membership at national level i.e. how many companies are associated in a given sector and country. This was done through interviews with NEPSI members (at European and national level) and a desk review of literature and data.

Representatives of European confederations and national organisations have been asked to provide information and/or estimates on the coverage of their organisations. The qualitative information from NEPSI reports on the coverage of the sector has also been used[45].

Table 4.6 shows in the last column information on the structure of the sector and the estimates collected. Estimates were sometimes provided in relation to production, employment or companies, in sectors characterised by small companies it is more difficult to provide any estimate. **Overall, it seems that the NEPSI signatories cover most of the sector in their country either in terms of production of employment; this means that the number of companies and or workers not covered by the Agreement is likely to be relatively low**. For example, the two confederations in the glass sectors cover almost 100% of total production in Europe. The cement industry is entirely covered by the confederation affiliated to the NEPSI Agreement. In the insulations materials sector, the NEPSI members cover 90% of the production. In the foundry sector the association covers 100% of the European market. The subsectors of mines/quarries/minerals estimate proved difficult to come by. The same was true for the precast concrete and natural stone sectors, due to fact that it is mainly micro and small companies that operate in these sectors.

An important omission mentioned during interviews on the coverage of the associations member of NEPSI is that smaller enterprises (small SMEs or micro-enterprises) tend not be members of national associations mainly for financial reasons. Another important category of workers that are not covered by these associations are self-employed workers who, according to interviews, play an important role in some sectors, mainly those with micro and small companies.

[45] No national sectorial study on density of employers' organisations has been identified.

Table 4.6 Coverage of NEPSI organisations at EU level

Sector	Organisation name	Members type	Structure of the sector, information on employment covered and estimates of sectoral coverage
Glass sector			
Glass Fibre	GlassFibreEurope	Companies (7 in total)	**Large companies, the 7 members cover almost 90% of EU production.** In 2014 the federation covered approximately 20,000 employees across Europe
Container Glass	FEVE	Companies	Average size of companies is approximately 150-200 employees with roughly 44,000 employees across Europe. Three large multinationals cover 80% of European production. **FEVE covers almost 100% of the production sector.**
Building materials			
Precast Concrete	BIBM	National associations (members only in Western Europe and Nordic Countries) (There are no associations in the sector in Eastern European countries with the exception of Poland)	Mainly micro and small companies. Across Europe there are approximately 7,000 production plants with an average of 20-25 employees and a total of approximately 150,000 workers. A couple of large companies operate in the sector, but they cover only 5% of the EU production. **BIBM covers approximately one quarter of the sector in terms of workers**
Cement	Cembureau	National associations With the exception of countries where only one company operates in the sector (LT, LU, NL, SE)	Large companies, primarily five multinational groups. **Cembureau members cover 100% of the sector.**
Ceramics	Cerame-Unie	National associations (39) and companies (20) Associations covers 9 different sectors amongst which there is no exposure to RCS	SMEs represent 80% of the sector. In East European countries, members are more likely to be companies while in Western Europe national associations are predominant. **The association covers around 70%-80% in terms of employment.**
Mortar Industry	EMO	National associations (10) and companies (4)	Covers 12 EU countries mainly based in Western Europe. The big players in the sectors are based in FR and DE. **The EU association covers 50% of EU 27 and 70% of the mortar production at EU level.**
Insulation materials	EURIMA	Companies (9) Only 3 companies have a risk of exposure to RCS	The industry is dominated by 9 large companies with sites across the EU. **The 9 companies represent the 90% of the sector.**

Natural Stone	EUROROC	National associations	Micro enterprises with approximately 3-5 employees, only few companies have more than 100 employees. **Representativeness varies**; in some countries the national associations cover only a small proportion of companies (e.g. EL around 5%)
Mines/quarries/minerals			
Mines	Euromines	National associations and companies	Industry structure varies across countries with small and large companies dominating in different counties. The risk of exposure to RCS depends on the mineral extracted; therefore some companies do not have this risk. The coverage varies on the basis of the metal extracted **in many cases Euromines cover 100% of the EU production** (bauxite, chromium, gold, iron ore, silver, titanium, uranium, slate, barytes, potash, fluorspar) in others such **coals and aggregates 50% of employees are covered**.
Industrial minerals	IMA-Europe	National associations	Small and medium enterprises but also few large multinational companies. Around 500 mineral companies or groups operating 750 plants in Europe and employ 42,500 employees.
Aggregates	UEPG	National associations with the exception of three countries (ES, SI, EE) where members are companies	Structure of the sector differs between countries, in some countries there are mainly micro and small companies while in others few large companies cover most of the production but are organised in small sites across the country. Also the risk of exposure to RCS varies greatly across countries since it depends on the nature of the materials processed. Difficult to estimate coverage in countries with small family-run companies.
Expanded Clays	EXCA	12 companies in 11 countries (BE, CZ, DK, FI, DE, IT, NO, PL, PT, SE, UK)	Overall the sector is very small, half of the company members are part of the same group while the remaining are independent companies. Members represent **95% of production in Europe**.
Foundry			
Foundry	CAEF	National associations/federations	More than 80% of companies in this sector are small enterprises with less than 150 employees. Three countries (DE, FR, IT cover 50% of European production) and with ES, PL, UK all 6 countries cover 75% of

			European production. The association covers **almost 100% of the sector in Europe**.
Metal, Engineering and Technology-based Industries	CEEMET	CEEMET covers 23 countries of which 21 are in Europe. Membership largely covers the entire spectrum of metal industries, including fabricated metal goods, mechanical engineering, electrical and electronics industry, transport industry (automotive, ships and aircraft) and instrument engineering.	Members are national employers' organisations and federations, representing 200,000 member companies across Europe, the vast majority of which are SMEs, providing employment for 35 million people.

Source: ICF European level interviews with NEPSI Council members and websites

Table 4.7 presents the information collected in this study on the national coverage of NEPSI members by sector. Information was provided in those countries where employer organisations are better organised, while for other countries no information was provided. **Overall, the representativeness of organisations varies by sector and country. However, overall, the national associations involved in the NEPSI Agreement tend to cover most of the national industries, either with reference to employment, companies or market**. For example, in the precast concrete sector the coverage of the sector is around 85% in Belgium, 75% in France, 70% in the Netherlands and 70% in Spain. In the cement sector, in Belgium the association represents the large majority of the sector, in Germany covers 98% of employment, in Italy 83% of the national production of cement, in Poland 100% of the sector, in the UK 100% of Portland cement. In the ceramics sector, in Italy the association covers the majority of the sector, in the Netherlands around 99% of the sector. In the natural stone sector, in Germany the association represents about 80% of the sector. In the aggregates sector, in Belgium the association represents 85% of the production, in Spain 75%-80% of the market, in France 86% of the sector turnover, in the Netherlands 40% of the sector, in Sweden 85% of production, in Slovakia 49% of employees and in the 90% of British producers. In the foundry sector, in Belgium the association represents 90% of employment, in Italy 90% of the sub-sector of ferrous metals and 40% of non-ferrous sub-sector; in the Netherlands the association covers approximately 60% of the industry.

Table 4.7 National coverage of NEPSI members

NEPSI sectors	Information on national coverage
Precast Concrete	■ Belgium - The association represents the large majority of the sector (85% of the sector's turnover), a total of 80 members and 110 sites. The majority of SMEs and especially micro-enterprises. ■ Germany - Only 4 to 5 regional associations out of the 9 existing are affiliated to NEPSI. Only 2 take part in the reporting process. The Association for Construction Materials, Stone and Soil represent 22,000 in the concrete product manufacturing sector with 6000 sites reporting in NEPSI (90 companies). ■ Spain - The association covers around 25% of the companies in the sector and 70% of the market. ■ France - The association represents 75% of the sector (12,000 employees out of the total 18,000 employees), primarily micro-enterprises. Only 12 sites out of 700 have more than 300 employees. ■ The Netherlands - The association covers around 70% of the sector. Represents 90 out of 200 companies and 5,000 out of 7,000 total employees Companies from 10 to 600 employees ■ Poland - The association gathers several significant producers but it is difficult to assess their share in the total employment in the sector. ■ Sweden - The association represents 6,500 employees ■ UK - The UK association represents 8,000 workers working in 65 companies. This is 80% of the companies of the precast concrete industry
Cement	■ Belgium - The association represents the large majority of the sector. It has 3 members (large multinational companies) with 13 sites in BE. ■ Germany - The association represents 98% of employment in the sector. It has 22 company members out of the 23 existing ■ Spain - The association covers most of the sector. It has 9 members. They are large companies with 32 sites ■ Italy - The association covers 83% of the national production of cement. There are 27 companies in Italy and 10 are affiliated ■ Poland - The association represents 100% of the sector. ■ UK - The association represents 5 companies which equals to 100% of Portland cement in the UK.
Ceramics	■ Germany - The association represents 35,000 employees. ■ Spain - The association represents around 50 member companies. ■ Italy - The association covers the majority of the sector (members are the main companies). It represents 175 companies out of the 223 existing ■ The Netherlands - The association covers 99% of the sector with 21 national and multinational companies (43 sites).
Natural Stones	■ Germany - The association represents about 80% of the sector. It has 150 members (around 6500 employees). ■ Sweden - The association represents 1,200 employees spread between 120 member companies.
Minerals	■ Belgium - The Company interviewed was the biggest company in the sector. ■ Spain - The lime association has 14 members out of the total 19 companies. It covers 90% of the production. ■ France - The lime association has 15 members (48 sites). Composed of both large groups and small businesses. The association of silica producers represents 8 companies, 44 sites and around 2,000 workers. ■ Italy - The association has 12 member companies. Difficult to estimate the coverage of companies in the mining sector – The associations affiliates mainly companies in the oil industry, therefore big multinational companies operating across sectors. ■ Poland - The lime association has 7 members (leading producers and SMEs). ■ Sweden - The lime association has 5 company members. ■ The UK - The mineral association has 485 members, his organisation includes several sectors such as aggregates, cement, precast concrete, mortar, sand etc. The other association (sand) has 7 companies (21 sites) representing 362 workers. This represents the vast majority of the

	sector. Non-members companies are smaller companies.
Aggregates	■ Belgium - The association represents 85% of the production in Belgium (2,840 workers). A total of 55 companies (SMEs and large companies) and 75 production sites. ■ Spain - The association represents 55% of the sites (around 1,000-1,100 sites) and 75%-80% of the market. Micro-enterprises tend not to be affiliated. ■ France - The national association represents 86% of the sector turnover. ■ The Netherlands - The association represents 40% of the sector. It has 10 members. ■ Poland - The association has 36 member companies. ■ Sweden - The association represents 3,000 employees in 70 company members (represents around 85% of production) ■ Slovakia - The association is the only one affiliated in the country. It represents 49% of employees in the sector. ■ The UK - The association represents 90 aggregates producing companies which equals to 90% of British producers.
Expanded clays	■ Belgium - The company represents the biggest player in the sector. ■ Spain - The association covers 80% of companies. Around 10% of companies in the sector do not hold any employers' membership. ■ Sweden - The company has 45 employees. ■ The UK - The association only has two member companies.
Foundry	■ Belgium - The association represents 17 sand foundries out of the 24 existing in Belgium. It is 90% of employment in the sector (2,139 workers) ■ Germany - The association has 600 members with around 80,000 employees in 40,000 sites. ■ Italy - The association represents 90% of the sub-sector of ferrous metals and 90% of the production, 40% of non-ferrous sub-sector. Affiliates are the biggest companies but the sector is characterised by SMEs. ■ The Netherlands - The association covers approximately 60% of the industry. ■ Poland - The national association has 62 companies. ■ Sweden - The company represents around 9,000 employees in 200 companies. ■ The UK - The association represents about 30% of the sector. Most of the members are large companies

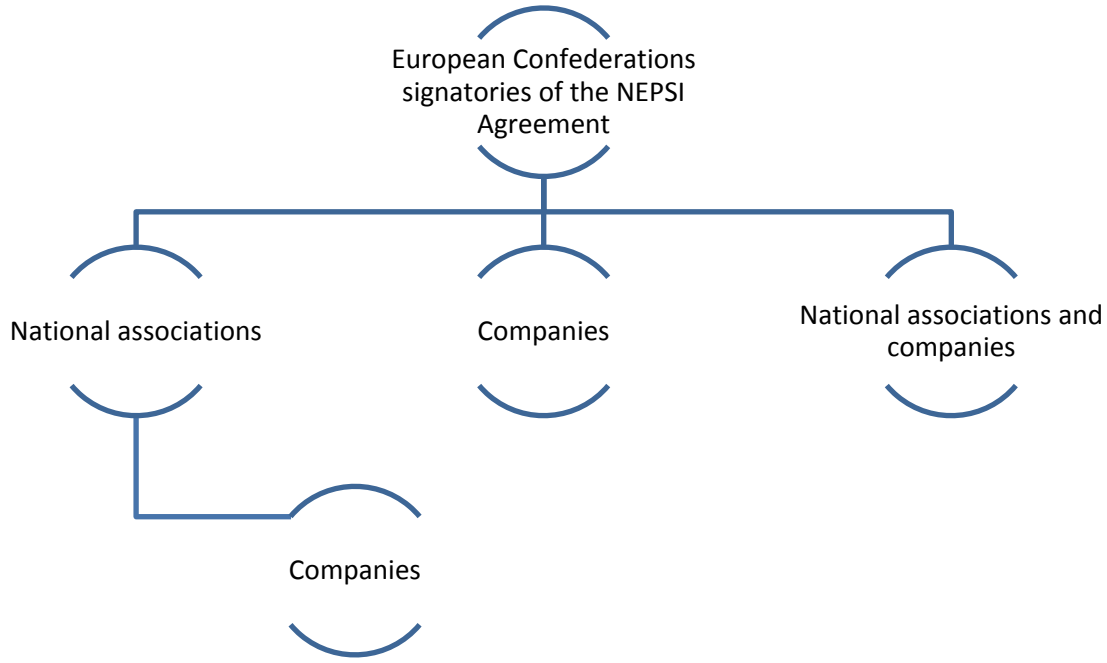
Source: ICF interviews with NEPSI Members and associations' website

The nature of signatory members of the NEPSI Agreement varies. Members of the European confederations can be national associations or companies, or both. Figure 4.2 provides a graphical representation of the nature of NEPSI organisations.

On this basis, two major problems encountered in the collection of information need to be discussed; in the case of companies, it is methodologically incorrect to assess the level of membership at national level but companies may be able to estimate the share of the market covered in terms of production at national and/or European level. In the case of national associations, these rarely hold and/or monitor data on their members and information on their coverage of employment in the sector. The difficulties linked to aligning NESPI sectors with readily available employment data and the quality of other (non-comparable) data also make it difficult for national organisations to assess their coverage.

An issue that frequently arises during discussions with national organisations about their coverage is the sector in which they operate. National organisations often cover different sectors (including those not covered by the NEPSI Agreement). A similar issue of overlap at company level also came up during interviews, i.e. a number of large companies and multinational groups are affiliated to several associations because of the nature of their activity, which extend across several NEPSI sectors. Most make the effort to avoid double counting in their NEPSI reporting.

Figure 4.2 Scheme of possible membership of NEPSI members



Source: ICF

5 Measurement of and data on exposure to RCS in the workplace

Key to discussing the health risks of RCS among the population of workers is occupational exposure to RCS. As previously indicated, not all workers in a given sector, company and site are actually exposed to RCS. To assess exposure, it is important to be aware of the basic mechanisms of measuring exposure, since methods of measurement can impact levels of exposure measured. This section therefore first provides a brief overview of key techniques to measuring occupational exposure to RCS before discussing available exposure data.

5.1 Measurement of personal exposure to airborne respirable silica

The accurate and precise measurement of exposure of workers to respirable crystalline silica is essential to estimate the risk of disease formation (the greater the exposure, the greater the risk of disease), demonstrate compliance with any national occupational exposure limit, and to demonstrate effectiveness of any engineering controls applied to reduce exposure. Exposure measurement will also identify trends in exposure over time and calculate how effective new technology and work processes are in controlling exposure.

Accuracy and precision are particularly important when demonstrating compliance with occupational exposure limits because failure to comply may result in formal action against the employer. For example, in the UK, the Workplace Exposure Limit for respirable silica is 0.1mg/m3, and is considered by the UK regulator as the lowest level, that can be accurately and precisely measured using the current sample collection and analytical techniques. Exposure limits below 0.1mg/m3 are not therefore considered appropriate because of the limitations of the available techniques, but some Member States have adopted lower Occupational Exposure Limits.

Personal exposure monitoring will give the best estimate of exposure as the sampling device is carried by the workers as they undertake their daily work tasks. Static or area sampling can also be used to estimate exposure, but is not as reliable because the sampler stays in one place during the sampling period while the workers move about the workplace. In practice, a combination of both personal and static sampling is likely to be used to complement each other. . Personal exposure measurements also allow researchers to gather epidemiological data on exposure concentration and disease formation over time.

It is therefore essential that the method chosen gives the required level of accuracy and precision to allow for comparison between results to enable employers and researchers to demonstrate the points raised above.

Annex Two to the NEPSI Agreement[46] contains a description of a sampling methodology based upon various European standards[474849].The method refers to personal and static sampling techniques and suggests that as a minimum the technique used must assess the exposure of the workers to respirable dust. It is respirable dust that reaches the gas exchange region of the lung where it causes inflammation and subsequently disease. The sampling devices used must conform to the appropriate particle collection performance

[46] Agreement on Workers health protection through the good handling, and use of crystalline silica and products containing it 25th April 2006 http://www.nepsi.eu/media/2097/agreement%20-%20english%20.pdf

[47] EN 689 Workplace atmospheres-Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, 1995, CEN

[48] EN 481 Workplace atmospheres-Size fraction definitions for measurement of airborne particles, 1993, CEN

[49] EN 1232 Workplace atmospheres-Pumps for personal sampling of chemical agents-Requirements and test methods, 1997

standards and that jobs should be segregated by function. Sampling should be carried out over a full shift and the number of samples taken should give a representative assessment of worker exposure. The samples should be analysed to identify the quartz content by either X-ray diffraction or IR spectroscopy. Full records must be kept and the laboratory should belong to a quality control system and/or be accredited.

The method described uses a size selective sampling head, usually a cyclone, which collects the respirable fraction of the dust by spinning the airflow, thereby removing the larger particles from the airstream so that the smaller respirable particles are collected on a filter, which is then sent for laboratory analysis. Other samplers, such as the IOM and CIS samplers[50], use foams to collect the various fractions simultaneously.

Researchers have explored the variation between sampling heads in collecting representative samples[51]. Significant variations were found between different types of samplers.

Work has been carried out across Europe to determine whether monitoring data collected in different Member States are compatible and can be used in epidemiological studies[52]. Our study looked at data collected by institutions from Switzerland, Austria, Finland, and Germany and concluded that while the measurement conventions, sampling and analytical methods were comparable, there were significant differences between the measurement strategies. The conclusion therefore was that the exposure levels for comparable tasks would similarly vary between countries.

In addition, direct reading instruments are available for monitoring real-time exposures to respirable dust. Some companies use these to monitor exposures from continuous processes e.g. truck loading. These devices work on the principle of light scattering, but they will not identify the composition of the dust[53].

The two principal methods of analysis to determine the concentration of respirable silica collected using a respirable dust sampling head is either on filter X-ray diffraction[54] or IR spectroscopy[55]. The IR method is suitable for a concentration range of 10ug to 1mg on a 25mm filter. The detection limit for the method is as follows, qualitatively 0.006mg/m3 and quantitative 0.02mg/m3 for a 500 litre sample[56].

Both methods of analysis appear to be capable of detecting quartz at levels below 0.1mg/m3, meaning the method could be employed to measure Occupational Exposure Limits set at lower concentrations.

[50] General methods for sampling and gravimetric analysis of respirable, thoracic and inhalable dust MDHS 14/4 HSE 06/14 http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs14-4.pdf

[51] Verpaelle, S and Jouret, J. A comparison of the performance of samplers for respirable dust in workplaces and laboratory analysis for respirable quartz. Ann. Occup. Hyg., Vol 57 No1 pp54-66 2013 http://annhyg.oxfordjournals.org/content/early/2012/07/17/annhyg.mes038.full

[52] Gabriel S., Mattenklott S.M., Van Gelder R., Steinle P., Rüdin P., Neiss N., Ressler C., Johansson A., Linnainmaa M., Dahmann D., Fricke H. Comparison of the determination and evaluation of quartz exposure and exposure levels at workplaces across Europe Gefahrstoffe - Reinhaltung der Luft 74 (2014) Nr. 9-Septemberhttp://www.dguv.de/medien/ifa/de/pub/grl/pdf/2014_136.pdf

[53] Walsh P, Evans P, Lewis S, Old B, Greenham L, Gorce JP, Simpson P and Tylee B Technical Guide on Direct Reading Devices for Airborne and Surface Chemical Contaminants Technical Guide Series No 15 (3rd Edition) BOHS 2012 www.bohs.org/TG15/

[54] NIOSH 7500: Silica, crystalline by XRD. http://www.cdc.gov/niosh/docs/2003-154/pdfs/7500.pdf

[55] NIOSH 7602: Silica, crystalline by IR. http://www.cdc.gov/niosh/docs/2003-154/pdfs/7602.pdf

[56] MDHS 101/2: Crystalline silica in respirable airborne dusts- Direct-on-filter analyses by infrared spectroscopy and X Ray diffraction HSE 02/15 http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs101.pdf

Error in determining exposure has two components: sampling error and analytical error. It is clear from earlier references that samplers can vary in performance, as can laboratories in their ability to perform accurate and precise sample analysis.

Clearly, there are a number of approaches in measuring exposure to RCS across European Member States, which may result in the data being incomparable (for more information on measurement and sampling techniques see Annex 2).

5.2 RCS exposure data

A recent EU OSHA report published in 2014[57] highlights that in relation to preventing occupational cancers, it is important to gather information on the levels of exposure in occupations, jobs and tasks. The report is the most current review of available data sources on exposure to carcinogens and work-related cancer and states that '*information on the extent of exposure to carcinogenic agents and factors in Europe is worryingly out of date*'.

The EU OSHA report identifies available sources of data on exposure to carcinogens including RCS.

Three types of sources provide information on exposure to carcinogens:

- national registers
- exposure measurement databases
- exposure information systems

National registers: National registers of exposure to selected carcinogens have been established in some European Member States, , including the Finnish Register of Workers Exposed to Carcinogens (ASA Register), the Italian Information System for Recording Occupational Exposures to Carcinogens (SIREP) and the German ODIN Register. Other national registers exist in Poland, Slovakia and the Czech Republic. All provide information on a pre-set selection of suspected or proven carcinogens, although some systems are more developed than others. A common drawback is that they do not collect information on all relevant carcinogens and occasional and low exposure tend to be underreported.

Exposure measurement databases: Some ad-hoc databases and studies on measurement on concentration of carcinogens in workplaces exist across Europe. These include the MEGA database in Germany, the international ExpoSYN database which covers 19 countries (the major contributing countries for personal measurement were Germany, the UK, France, Norway and Canada)[58], the COLCHIC and SCOLA databases in France. The COLCHIC collects the data on occupational exposure to chemicals collected by the regional health insurance funds and the national institute for research and safety.

Exposure information systems: While the previous two sources of data are based on **notifications** of exposed workers or workplaces or workplace measures another group of sources includes information on **estimations** of numbers of exposed workers and their level of exposure to selected carcinogens.

5.2.1 The CAREX database

According to EU OSHA (2014), the International Information System on Occupational Exposure to Carcinogens (CAREX), established in the mid-1990s, is still '*the most comprehensive information system on carcinogen exposures in Europe*'. But the report also concludes that updating CAREX should be a priority. The system contains information on

[57] EU OSHA (2014) Exposure to carcinogens and work-related cancer: a review of assessment methods https://osha.europa.eu/en/tools-and-publications/publications/reports/report-soar-work-related-cancer

[58] Peter S. et al. (2011) Development of an exposure measurement database of five lung carcinogens (ExpoSYN) for quantitative retrospective Occupational exposure assessment Ann. Occup. Hyg., pp. 1–10 http://annhyg.oxfordjournals.org/content/early/2011/10/11/annhyg.mer081.full.pdf

numbers of exposed workers in 55 industries and 15 Member States. It has been recently updated in Finland, Italy and Spain. Estonia, Latvia, Lithuania and the Czech Republic have been recently added. To date this is still the most complete system and has been used in the assessment of the global burden of work-related cancers by the WHO in 2005[59], the assessment of the burden of occupational cancer in the UK in 2008[60] and the SHEcan project financed by the European Commission in 2008 to assess the socioeconomic, health and environmental impacts of possible amendments to the European Carcinogens and Mutagens Directive (2004/37/EC) for 25 occupational carcinogens including RCS[61].

Box: Methodology of the CAREX database

The CAREX database was designed with support from the European Commission to provide selected exposure data and documented estimates of the number of workers exposed to carcinogens by country, carcinogen, and industry in an effort to address the lack of exposure data to carcinogens in the workplace. During the first phase, from 1990 to 1993, estimates were produced. The value of prevalence considered the most valid (usually the mean of the US and Finnish values) was used as the default value. In a second phase held in the summer 1997, a network of national experts assessed these estimates in view of their similarity or discrepancy to the perceived exposure patterns in their own countries. The CAREX system enabled these experts to select appropriate 'first-phase' estimates or to generate and document modifications of these estimates. The database has not been updated since.

Table 5.1 provides an overview of the number of workers exposed in Europe by industry sector as measured by CAREX. Workers in the construction sector represent 67.7% of all workers exposed to RCS. Sectors with the highest numbers of workers exposed are construction (2,325,149), manufacture of other non-metallic mineral products (221,476), other Mining (144,767), manufacture of pottery, china and earthenware (105,214), manufacture of machinery except electrical (84,295), iron and steel basic industries (76,781), manufacture of fabricated metal products (74,170), metal Ore Mining (57,717), manufacture of glass and glass products (48,912), manufacture of transport equipment (39,924).

In the table below, the shaded rows show the sectors covered by the NEPSI Agreement. These sectors have been identified on the basis of the mapping exercise of NEPSI against international codes as described above.

Table 5.1 Estimates of workers exposed to Silica Crystalline by sector (CAREX)

	EU 19	% on Total EU 19
Construction	2,325,149	67.7
Manufacture of other non-metallic mineral products	221,476	6.4
Other Mining	144,767	4.2
Manufacture of pottery, china and earthenware	105,214	3.1
Manufacture of machinery except electrical	84,295	2.5
Iron and steel basic industries	76,781	2.2
Manufacture of fabricated metal products	74,170	2.2

[59] Driscoll, T., Nelson, D., Steenland, K., Leigh, J., Concha - Barrientos, M., Fingerhut, M., Prüss-Üstün,A., 'The global burden of diseases due to occupational carcinogens', Am J Indust Med 48, 2005, p. 419–431.

[60] Rushton, L., Hutchings, S., Brown, T., 'The burden of cancer at work: estimation as the first step to prevention', Occup Environ Med 65, 2008, pp.789 – 800.

[61] http://www.occupationalcancer.eu/

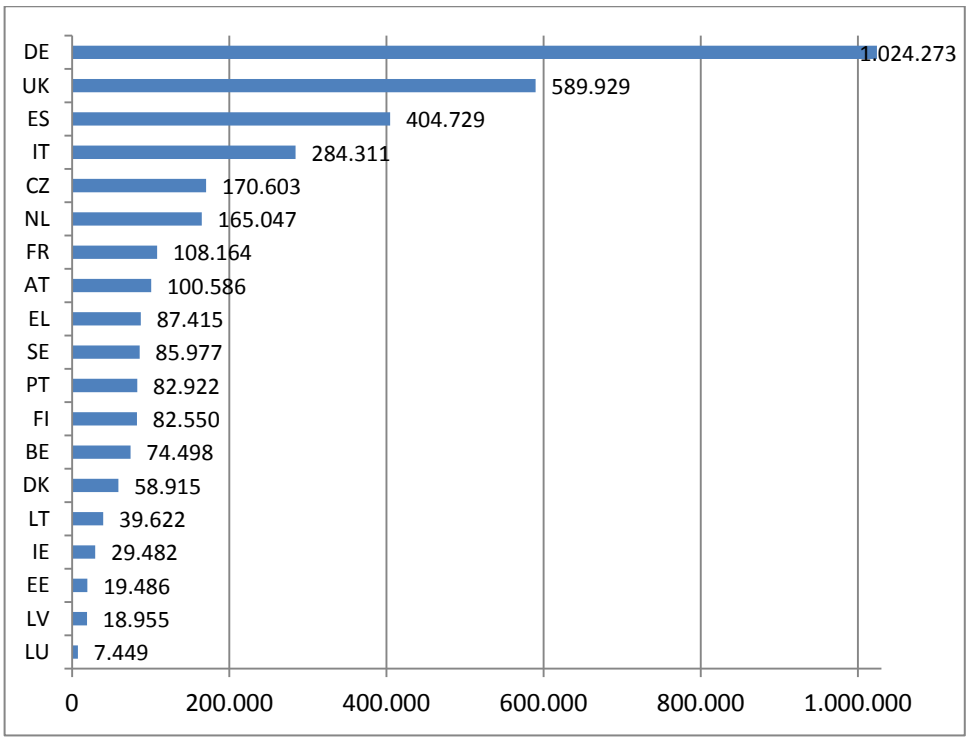
	EU 19	% on Total EU 19
Metal Ore Mining	57,717	1.7
Manufacture of glass and glass products	48,912	1.4
Manufacture of transport equipment	39,924	1.2
Land transport	34,791	1.0
Manufacture of other chemical products	32,712	1.0
Agricultural and hunting	31,600	0.9
Electricity, gas and steam	23,179	0.7
Manufacture of instruments, photographic and optical	16,614	0.5
Sanitary and similar services	15,320	0.4
Non-ferrous metal basic industries	10,366	0.3
Manufacture of plastic products not elsewhere classified	9,820	0.3
Other manufacturing industries	8,842	0.3
Manufacture of electrical machinery, apparatus, appliances	6,758	0.2
Manufacture of miscellaneous products of petroleum	6,371	0.2
Manufacture of industrial chemicals	5,908	0.2
Water transport	5,388	0.2
Research and scientific institutes	4,576	0.1
Services allied to transport	4,309	0.1
Crude Petroleum and Natural Gas Production	4,112	0.1
Wholesale and retail trade and restaurants and hotels	4,000	0.1
Manufacture of rubber products	3,549	0.1
Education services	3,450	0.1
Printing, publishing and allied industries	3,298	0.1
Air transport	2,933	0.1
Medical, dental, other health and veterinary services	2,600	0.1
Food manufacturing	2,596	0.1
Manufacture of wearing apparel, except footwear	2,496	0.1
Manufacture of textiles	2,247	0.1
Manufacture of furniture and fixtures, except primary of	2,217	0.1
Manufacture of leather and products of leather	1,763	0.1
Manufacture of footwear	1,248	0.0
Personal and household services	1,000	0.0
Petroleum refineries	867	0.0
Manufacture of paper and paper products	600	0.0
Manufacture of wood and cork products	300	0.0
Water works and supply	250	0.0
Financing, insurance, real estate and business services	200	0.0
Beverage industries	121	0.0
Coal mining	100	0.0

	EU 19	% on Total EU 19
Tobacco manufacture	7	0.0
Total EU 19	3,434,913	100.0

Source: Carex http://www.ttl.fi/en/chemical_safety/carex/countries/pages/default.aspx

On the basis of CAREX data, the European countries with the highest numbers of workers exposed to RCS include Germany, the UK, Spain and Italy. These are also the countries that represent the largest economies in Europe. I is also important to note that in terms of workforce, Germany and Italy cover the high share in EU 28 of the sector of manufacture of other non-metallic mineral products, one of the sectors with highest numbers of workers exposed)[62]. Differences across countries are difficult to interpret, but r it can be suggested that a number of factors affect the estimates. These include the diversity of the profile of industries present in each country as well as the specific methodologies of estimation procedures used by national experts[63]. The estimates of the construction industry also drive differences across countries. For example, the number of workers exposed to RCS in the construction industry in Germany is 720,930, in Spain 301,629 while in France this drops to 21,894 workers. However, these estimates do not reflect the size of the industry in terms of employment; for example, the number of workers in the construction sector in France in 2005 (before the economic crisis) totalled 1,747,343 while in the Netherlands it was 482,531.

Figure 5.1 Number of workers exposed to Silica Crystalline by country



Source: Carex http://www.ttl.fi/en/chemical_safety/carex/countries/pages/default.aspx

5.2.2 SHEcan data on exposure

The SHEcan study[64], financed by the European Commission to assess the impact of possible amendments to the Directive 2004/37/EC, built on CAREX data to provide update estimates on exposure. With reference to the topic of RCS the key objective of the study was to assess the technical feasibility and the socioeconomic, health and environmental impacts of setting an OEL for RCS of 0.05, 0.1 or 0.2 mg/m3.

[62] http://ec.europa.eu/eurostat/statistics-explained/index.php/Manufacture_of_other_non-metallic_mineral_products_statistics_-_NACE_Rev._2

[63] Occupational exposure to carcinogens in the European Union in 1990-1993 http://www.ttl.fi/en/chemical_safety/carex/Documents/1_description_and_summary_of_results.pdf

[64] IOM Research Project: P937/8, May 2011

The study highlighted that action should be taken to update data on exposure e.g. CAREX and provide additional data on intensity of exposure.

The main sources of information to estimate prevalence of exposure were the EU-LFS and structural business statistics, CAREX, WOODEX with estimates for wood dust exposure and information from stakeholders such as trade associations. The report states that information from CAREX and other sources were combined with data from the EU-LFS to obtain estimates of exposure prevalence.

The methodology used to provide estimates on prevalence of exposure to RCS is clearly presented in the report: "*the prevalence of exposure to RCS was estimated from the Finnish CAREX estimate of 2007, the Spanish CAREX of 2004, the Italian CAREX of 200-2003. The proportion of exposed workers in each industry was taken from each of these three CAREX estimates and the average proportion exposed across all three countries was found for each industry. The average proportion of exposed workers was applied to information on the number of employees in each industry obtained from the structural business statistics and the labour force survey available on the Eurostat database. The average proportion of exposed workers was multiplied by the number of workers employed in each industry in each country in 2006 to estimate the number of exposed workers in each industry and country.*"

The study estimated that approximately 5,300,000 employees in the EU were potentially exposed to RCS in 2006. A total of 4,112,824 (78%) of these workers were in the construction sector. Although, the study does not specify whether the number of employees provided includes all workers, i.e. employees and self-employed, but it can assumed from the report that it includes all workers.

The report provides a comparison of the number of workers exposed with the NEPSI data for 24 Member States (Table 5.2). The SHEcan study estimates that the number of employees potentially exposed to RCS and reported to NEPSI cover 23% of the estimated number of exposed workers in the sectors covered by the NEPSI Agreement. Despite methodological considerations that need to be taken into account when reading the estimated coverage, the SHEcan study provides updated estimates (based on CAREX data) of exposed workers and covers a larger number of countries than CAREX. This can therefore be considered the most updated source of information.

Table 5.2 Number of employees potentially exposed to RCS reported to NEPSI in 2008 and the number of workers estimated to be exposed in NACE 10, 11, 12, 13, 14 and 26 from CAREX and Eurostat Data (SHEcan data)

Country	Exposed employees reported to NEPSI[65], 2008	Estimated number of exposed workers using CAREX and Eurostat, 2006	Ratio of NEPSI estimate to CAREX estimate (%)
AT	3,605	13,637	26
BE	6,771	10,798	63
BG	366	21,839	2
CZ	4,727	39,679	12
DK	762	6,532	12
EE	463	2,235	21
FI	5,374	5,952	90
PT	22,230	58,113	38

[65] The table reports the wording as presented in the SHEcan study, however the wording used by the NEPSI network for this specific indicator is 'employees potentially exposed'.

DE	43,140	110,053	39
EL	2,971	11,245	26
HU	1,329	11,497	12
IE	1,970	4,985	40
IT	10,440	78,472	13
LV	147	3,126	5
PT	118	1,105	11
NL	5,132	10,655	48
PL	3,145	97,352	3
PT	3,831	25,904	15
RO	2,321	37,730	6
SK	452	7,028	6
SI	1,111	3,224	34
ES	16,675	94,564	18
SE	6,611	11,186	59
UK	20,515	51,234	40
Grand Total	164,206	718,145	23

Source:SHEcan Report, IOM Research project P937/8, May 2011

The sectors covered by the NEPSI Agreement as identified by the SHEcan study include NACE REV. 1.1: 10, 11, 12, 13, 14, and 26. The report concludes that the number of exposed workers estimated for these sectors is '*markedly higher*' than the numbers reported in NEPSI, likely because NEPSI is '*voluntary therefore there are likely to be many workers who are exposed to RCS who do not work for employers that are within the NEPSI network*'. While it is true that NEPSI is voluntary and a certain number of workers and companies are not covered by NEPSI members, some methodological considerations need to be borne in mind when interpreting this information.

As previously explained, the mapping of the NEPSI sectors against international codes (i.e. NACE Rev. 1.1., NACE Rev 2, ISIC Rev.2) is a complex exercise and will always contain a degree of value judgement by the research team, In addition, using the level of employment in sectors identified by NACE to estimate the number of workers potentially exposed will always lead to overestimations (to a large extent) because exposure to RCS concerns only certain industrial processes and only workers involved in those processes. The information provided by Glass Alliance is a clear example of this, where the risk of exposure to RCS involves only the process of forming the glass, whereas activities related to the shaping and processing of glass do not produce RCS. The sectors classified under the NACE code that cover the glass sector activities do not make a distinction between manufacturing and shaping and/or processing, meaning a large proportion of workers not at risk of exposure are wrongly classified as potentially exposed[66].

Another important consideration for the purpose of this study is that the SHEcan study provides information on NEPSI exposed employees by country. It is not clear how disaggregated numbers by country have been identified, since in many cases data produced by NEPSI members are aggregated by country due to confidentiality reasons. The data provided by the NEPSI network to the research team of this study did not allow for disaggregation of numbers by country.

[66] Glass Alliance (2014) Respirable crystalline silica in the glass industry http://www.glassallianceeurope.eu/images/cont/glass-alliance-europe-statement-on-respirable-crystalline-silica_file.pdf

Other exposure data collected at national level as part of this study are summarised in Annex 1.

6 The EU acquis and national legislation

This section presents the legal framework in relation to exposure to RCS at both EU and national level in the selected countries. An overview of the methods of measurements in Europe and in selected European countries is also provided. This section seeks to answer to the following study questions:

- What instruments are in place in the Member States to regulate exposure to RCS?
- To what extent has the Agreement had an impact on national legislation?

6.1 The EU acquis on health and safety in the workplace and RCS

6.1.1 General OSH legislative framework in Europe and relevant instruments in the context of this study

In accordance with Article 153 TFEU, the EU is responsible for supporting and complementing the activities of the Member States in the improvement of the working environment to protect workers' health and safety. In pursuance of this goal, the European Framework Directive 89/391/EEC, sets out the general framework for health and safety at work. The Directive elaborates under Article 6.1 and 6.2 that employers must - within the context of their responsibilities - take the measures necessary for the safety and health protection of workers by implementing prevention measures '*avoiding risks; evaluating risks that cannot be avoided; combating risks at source; adapting the work to the individual, especially as regards the design of work places, the choice of work equipment and the choice of working and production methods, with a view, in particular, to alleviating monotonous work and work at a predetermined work-rate and to reducing their effect on health'*. Furthermore, employers must '*develop a coherent overall prevention policy which covers technology, organization of work, working conditions, social relationships and the influence of factors related to the working environment*'. In addition to the obligation for companies to put in place a risk assessment stemming from this Directive, a Guidance on risk assessment at work[67] was released in 1996 to help Member States and the management and labour to undertake their duties relating to the risk assessment procedure contained in Directive 89/391/EEC.

This 'Framework Directive' also constitutes the basis for the elaboration of other, more specific instruments in the area of health and safety at work. Several Directives adopted on the basis of Directive are of relevance for this study.

- Directive 89/686/EEC on personal protective equipment ensures that the design and manufacture of personal protective equipment is subject to essential health and safety requirements. This is also another key Directive which helps building a framework for ensuring that workers are adequately protected against health hazards at work.
- Directive 98/24/EC of 7 April 1998 on the risks related to chemical agents at work constitutes the fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC. This Directive aims at ensuring the protection of the health and safety of workers from the chemical agents which they can be in contact with. Under this Directive, the employer must take the necessary preventive measures and risks must be eliminated or reduced to a minimum following the hierarchy of prevention measures. If the risk assessment undertaken by the employer reveals a risk to the health and safety of workers, the employer must take the specific protection, prevention and monitoring

[67] https://osha.europa.eu/en/topics/riskassessment/guidance.pdf

measures. The employer has the obligation to ensure that the risk is eliminated or as low as possible.

- Directive 2004/37EC (repealing Directive 90/394/EEC) on exposure to carcinogens or mutagens at work is the sixth individual Directive taken on the basis of this European 'Framework Directive'. It provides protection for workers against the risks related to the exposure to carcinogen or mutagen substances at the workplace. It present sets limit values for three carcinogens, not including crystalline silica. Employers have several obligations under this Directive. They must first eliminate or replace the carcinogen or mutagen by a substance that is not or is less hazardous. The substitution of the substance is mandatory and failure to do so cannot be justified by high costs for the company. If replacement is 'technically impossible', the employer must ensure that the carcinogen is manufactured or used in a closed system. If the employer cannot do so, s/he must ensure the level of exposure of workers is 'reduced to as low a level as is technically possible'.

In 2014, the European Commission launched the EU Occupational Safety and Health Strategic Framework 2014-2020. It aims to better protect workers in the EU from work-related accidents and disease. One of the main challenges identified by the EU in the framework of this Strategy is the improvement of the prevention of work-related diseases by tackling existing, new and emerging risks. More specifically, the Commission underlines the specific attention that needs to be paid to occupational cancers, diseases caused by asbestos, lung diseases, skin diseases, asthma and other chronic conditions. In its Communication, the Commission also emphasises that social dialogue is one of the key instruments to meet this challenge.

Dangerous substances and chemicals are also regulated by several instruments at EU level. These instruments are more targeted at consumers but also cover substances used at the workplace. The REACH Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals was adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals. The REACH Regulation applies to all chemical substances and requires companies to identify and manage the risks linked to the substances they manufacture and market in the EU. Companies are responsible for demonstrating to the European Chemical Agency how the substance can be safely used, and communicating risk management measures to the users[68]. However, crystalline silica does not fall into the scope of the REACH Regulation as it is not considered as a chemical substance under this Regulation. Indeed, crystalline silica is commonly found in nature as sand and the REACH Regulation exempts from its scope 'minerals which occur in nature, if they are not chemically modified'. As a result, the use of crystalline silica by companies does not have to be registered and thus flagged to the relevant authority.

The European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures of 16 December 2008 known as the CLP Regulation requires suppliers to classify, label and package hazardous substances according to the requirements of the Regulation, which ensures that hazards are described and labelled in the same way worldwide[69]. RCS is covered by this piece of legislation as it was self-classified under CLP as this is further explained below.

6.1.2 Classification of Respirable Crystalline Silica

Following the definition provided in the Chemical Agents Directive (CAD), crystalline silica is recognised as a hazardous chemical agent which is defined as '*any chemical agent which*

[68] http://echa.europa.eu/regulations/reach/understanding-reach
[69] http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/index_en.htm

meets the criteria for classification as hazardous within any physical and/or health hazard classes laid down in Regulation (EC) No 1272/2008 (CLP Regulation) whether or not that chemical agent is classified under that Regulation[70].' RCS responds to this criterion as mixtures and substances containing crystalline silica (fine fraction), whether in the form of an identified impurity, additive or individual constituent, are voluntarily classified by producers as:

- STOT RE 1, if the crystalline silica (fine fraction) concentration is equal to, or greater than 10%; Danger text: Causes damage to organs through prolonged or repeated exposure
- STOT RE 2, if the crystalline silica (fine fraction) concentration is between 1 and 10%. Warning text: May cause damage to organs through prolonged or repeated exposure

In these two cases, the product containing the thresholds of crystalline silica mentioned above will show the following pictogram:

However, if the crystalline silica (fine fraction) content in mixtures and substances is 1%, no classification is required.

It is worth noting that this classification only applies to the fine fraction of quartz and cristobalite. The IMA-Europe Position Paper of on Classification and labelling of crystalline silica (fine fraction)[71] justifies this by the fact that scientific research showed that only fine fraction of crystalline silica may cause health effects[72].

Under the Carcinogens Directive (Directive 2004/37EC), a carcinogen is defined as a substance or mixture that meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation)[73]. Crystalline silica placed on the market is self-classified in accordance with CLP Regulation as carcinogen category 1A or 1B for quartz and cristobalite[74]. Furthermore, since 1997, the International Agency for Research on Cancer (IARC) recognises crystalline silica (i.e. quartz and cristobalite) human carcinogen (Group 1). The European Commission's Scientific Committee for Occupational Exposure Limits (SCOEL)[75] also concluded that *the main effect in human of the inhalation of respirable silica dust is silicosis. There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis*. Even though, RCS has been self-classified as carcinogenic, Directive 2004/37/EC does not impose a binding OELV on respirable crystalline silica. Despite the SCOEL recommendation an OEL threshold of 0.05 mg/m3, there is no OEL legally enforced at EU level and no harmonisation has really occurred as this will be explained in the Section on the national

[70] CAS number for quartz : 14808-60-7; CAS number for cristobalite: 14464-46-1

[71] IMA-Europe Position Paper of on Classification and labelling of crystalline silica (fine fraction

[72] http://www.crystallinesilica.eu/120-what-classification-and-labelling-crystalline-silica-fine-fraction-under-clp-regulation

[73] Article 2(a)(i) of Directive 2004/37/EC of the European Parliament anof the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

[74] European Chemical Agency, C&L Inventory. Available at: http://echa.europa.eu/information-on-chemicals/cl-inventory-database

[75] SCOEL SUM Doc 94-final on respirable crystalline silica, June 2003

legislative frameworks. Even though RCS has been self-classified as carcinogenic, it is not fully covered by Directive 2004/37/EC as it is not in the list of carcinogens for which a mandatory OELV applies in all EU countries. Despite the SCOEL recommendation of on an OEL threshold of 0.05 mg/m3, there is no OEL legally enforced at EU level and no harmonisation has occurred, as explained in the Section on the national legislative frameworks.

6.2 The legislative framework on health and safety in the workplace and RCS in selected European countries

6.2.1 National OSH regulation and recognition of RCS as carcinogenic

The NEPSI Agreement has three objectives described in more detail in the following chapters. In short, they consist of:

- Achieving better protection of employees exposed to RCS
- Minimising the occupational exposure to RCS via the application of the NEPSI Good Practices
- Increasing knowledge of the health effects of exposure to RCS

As a result, the NEPSI Agreement was not intended to impact the legal framework of EU Member States but rather to provide practical tools to minimise exposure, increase awareness raising on RCS and thus better protect employees who are exposed. Indeed, Article 4 (6) of the NEPSI Agreement does mention that the A*greement is without prejudice to the Employers' and Employees' obligation to comply with national and EU law in the area of workers' health and safety.*

As discussed in the section on the Implementation of the Agreement, the implementation of the NEPSI Agreement generated the production of non-binding tools such as toolboxes, awareness-raising campaigns and guidance by employers' organisations.

As mentioned above, the EU provides a general OSH legal framework that all Member States had to implement via the OSH 'Framework Directive'. As a result, all the selected Member States now have a general legal framework covering OSH which also requires a risk assessment to be performed (in accordance with the 'Framework Directive'). Similarly, RCS is covered by the Chemical Agent Directive and it can be noted that this is the classification that applies to the Member State studied thanks to the implementation of this Directive in national legislation. But because there is no binding OEL at EU level, different OEL can be observed at national level.

One of the key differences is whether Member States have recognised RCS as a carcinogen or not. Three Member States of the 12 studied recognise RCS as a carcinogenic agent. In Belgium, the situation is unusual because RCS is partially recognised as carcinogenic as it only concerns sandblasting activities. In Slovakia, however, RCS is considered as a carcinogen and therefore must be substituted wherever possible and/or the exposure must be reduced for the workers involved. This also involves applying protective measures and health monitoring, employee information and training requirements among other things. In the Netherlands, RCS is listed in the Carcinogens at work Regulation since 1994, which means that exposure should be avoided where possible, and reduced as much as feasible where no alternative material is available.

In those countries where RCS is not officially recognised as carcinogen, the issue of the carcinogenic effect of RCS has also been discussed. For instance, in Sweden the link between exposure to RCS and lung cancer is mentioned in some guidance documents[76] . Similarly, in Spain, some regional protocols on health at work recommend following the regulation on carcinogenic agent at work concerning the data management and occupational risk assessment results for RCS. In Germany, it was argued that it was not quartz as a substance in itself that was linked to the risk of cancer, but the way it was handled during manufacturing processes in the workplace. As a result, the use of RCS (in particle form

[76] Silica - stone dust in the working environment (AFS 2015:2) https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/kvarts---stendamm-i-arbetsmiljon-afs-20152-foreskrifter/

capable of entering alveoli) is mentioned as carcinogenic in the TRGS 906, which are technical guidelines providing a register of carcinogenic tasks/processes, but RCS is not included in the TRGS 905 - the list of recognised carcinogenic substances.

In Poland, even though RCS was listed among potential carcinogen substances in the Minister of Health ordinance from 1996[77], it is no longer officially recognised as a carcinogen. The Ordinance was repealed and replaced by the Minister of Health Regulation from 1 December 2004, which does not recognise RCS as a potential carcinogen[78].

In Italy, RCS is not officially recognised as a carcinogenic agent, although its e link to the risk of cancer is mentioned in official documents and websites. Although is not officially classified as a chemical agent, employers with risk of exposure to RCS in their premises are required to follow the risk assessment for chemical agents. In Italy, companies are compelled to pay a premium for work-related illness and there is an extra premium for companies with employees exposed to RCS and asbestos 'premium for risk silicosis and asbestosis'[79]. A list of the work-processes for which the extra premium is compulsory is available[80].

Finally, the UK recognises the link between RCS and the development of silicosis, COPD and lung cancer among workers who are exposed. Much of HSE guidance concerning exposure to dust containing RCS refers to the link between exposure and the development of these diseases. However, RCS is not listed as a carcinogen within Schedule One of the COSHH Regulations. RCS is not assigned as Carcinogen within EH40 for Workplace Exposure Limits. This is because it is not included within Chemicals (Hazard Information, and Packaging for supply) Regulations 2009, and therefore is not assigned the various risk phrases indicating it is carcinogenic.

In relation to the recognition of RCS as a type of substance, two trends can again be observed. While some Member States recognise RCS as a chemical agent, others qualify RCS of hazardous substance or agent. More details are provided in the table below.

Table 6.1 Classification of RCS in the 10 countries studied

Member State	RCS recognition as a substance	RCS recognised as a **carcinogenic**
BE	**Chemical agent**[81]	**Yes (partially)** But it was recognised as carcinogenic only in the context of

[77] Rozporządzenie Ministra Zdrowia i Opieki Społecznej z dnia 11 września 1996 r. w sprawie czynników rakotwórczych w środowisku pracy oraz nadzoru nad stanem zdrowia pracowników zawodowo narażonych na te czynniki (Ordinance of the Minister of Health from 11.09.1996 on carcinogens in work environment and on monitoring of health of workers exposed to carcinogens) (Dz. U. Nr 121, poz. 571 z późn. zm.), http://isap.sejm.gov.pl/DetailsServlet?id=WDU19961210571

[78] Rozporządzenie Ministra Zdrowia z dnia 1 grudnia 2004 r. w sprawie substancji, preparatów, czynników lub procesów technologicznych o działaniu rakotwórczym lub mutagennym w środowisku pracy (Ordinance of the Minister of Health from 1.12.2004 on carcinogens and mutagens in work environment) (Dz. U. Nr 280, poz. 2771 z późn. zm.), http://archiwum.ciop.pl/10641.html

[79] Decreto del presidente della Repubblica 1124/1965, capo VIII http://www.inail.it/internet/default/Normativa/Bancadatinormativa/Normativanazionale/DecretoPresidenteRepubblica/p/dettaglioBDN/index.html?wlpnormativa_wcmplaceholder_1_contentDataFile=N1968586297&wlpnormativa_wcmplaceholder_1_contentRegionTemplate=RT_DETTAGLIO_NORMATIVA&_windowLabel=normativa_wcmplaceholder_1#

[80] http://www.inail.it/internet/default/Normativa/Bancadatinormativa/Normativanazionale/DecretoPresidenteRepubblica/p/dettaglioBDN/index.html?wlpnormativa_wcmplaceholder_1_contentDataFile=N1968586297&wlpnormativa_wcmplaceholder_1_contentRegionTemplate=RT_DETTAGLIO_NORMATIVA&_windowLabel=normativa_wcmplaceholder_1#

[81] Royal Decree of 11 March 2002 on the protection of the health and safety of workers against the risks related to chemical agents at work

		sandblasting activities[82].
DE	**Hazardous material[83]**	**No** But it was argued that it was not quartz as a substance in itself which was link to the risk of cancer, but the way it was handled during manufacturing processes in the workplace.
ES	**Chemical agent[84]**	**No[85]** But some regional protocols on health at work[86] recommend to follow the regulation for carcinogenic agent at work concerning the data management such keeping all medical records and risk assessment results of the workplace during 40 years after the worker is no longer expose to RCS.
FR	**Hazardous chemical agent[87]**	**No** But France recognises the European list[88].
IT	**Hazard substance to be assessed following the risk assessment for chemical agents**	**NO** **Official documents mention the link between RCS and cancer**
LT	**Chemical agent[89]**	**No[90]**
NL	**Carcinogenic substance**	**Yes** RCS is listed in the Carcinogens at work Regulation since 1994[91] The Dutch government has inserted crystalline quartz on the list of carcinogenic substances.
PL	**Agents Harmful to Health in the Working Environment[92]**	**No** It used to be listed among potential carcinogen substances in the Minister of Health ordinance from 1996[93]. But the text

[82] Royal decree of 2 December 1993 regarding workers' protection against the risks linked to exposure to carcinogenic and mutagenic agents at work

[83] The hazardous materials regulation (Gefahrenstoffverordung) of November 2010

[84] http://www.insht.es/InshtWeb/Contenidos/Documentacion/LEP%20_VALORES%20LIMITE/Valores%20limite/Limites2014/FINAL%20-%20Web%20v5%20-%20LEP%202014%20-%2029-01-2014.pdf

[85] The Royal Decree 665/1997 of 12 May on workers' protection of exposure to carcinogenic agents at the work establishes the agents that are carcinogenic and that are linked to the work.
http://www.insht.es/InshtWeb/Contenidos/Normativa/TextosLegales/RD/1997/665_97/PDFs/realdecreto6651997de12demayosobrelaprotecciondelostra.pdf

[86] http://www.guiasalud.es/GPC/GPC_487_Protocolo_silicosis.pdf

[87] Title 1 of Book IV, 4th Part of the Labour code regarding the chemical risks

[88] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[89] https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143

[90] Regulations 97/406 (2001) About the protection of employees from the chemical and carcinogenic substance (Nuostatai Nr. 97/406 (2001) DĖL DARBUOTOJŲ APSAUGOS NUO CHEMINIŲ VEIKSNIŲ DARBE NUOSTATŲ BEI DARBUOTOJŲ APSAUGOS NUO KANCEROGENŲ IR MUTAGENŲ POVEIKIO DARBE NUOSTATŲ,0 https://www.e-tar.lt/portal/lt/legalAct/TAR.313208361D5D/UOoavNmMtJ

[91] Arbeidsinspectie, 1994
http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.532.4297&rep=rep1&type=pdf

[92] http://www.ilo.org/dyn/natlex/docs/ELECTRONIC/99664/119046/F512545540/POL99664%20Pol.pdf

[93] Rozporządzenie Ministra Zdrowia i Opieki Społecznej z dnia 11 września 1996 r. w sprawie czynników rakotwórczych w środowisku pracy oraz nadzoru nad stanem zdrowia pracowników zawodowo narażonych na te czynniki (Ordinance of the Minister of Health from 11.09.1996 on carcinogens in work environment and on

		has been repealed and RCS no longer considered as a potential carcinogen since December 2004[94].
RO	**Chemical agent[95]**	**No**
SE	**Hazardous substance**	**No** There are specific guidance and regulation on quartz dust. But the link between exposure to RCS and lung cancer is mentioned in regulations[96].
SK	**Chemical agent[97]**	**Yes[98]** The Decree on protection of employees from risks associated with the exposure to carcinogenic and mutagenic agents at work sets since 2006 the threshold limit value for RCS, which is recognised as an established carcinogen for humans
UK	**Substance hazardous to health[99]**	**No** RCS is not listed as a carcinogen within Schedule One of the COSHH Regulations[100].

Source: ICF

6.2.2 National legislation regarding control of exposure to RCS

When looking at national legislation and guidance regarding the protection of workers from exposure to RCS in the workplace, it is important to bear in mind that all Member States have implemented the EU legislative framework outlined above. The table below summarises the key legislative texts identified at national level that govern the protection of workers from exposure to RCS, with legislation on relevant OELs discussed in a separate sub-section.

monitoring of health of workers exposed to carcinogens) (Dz. U. Nr 121, poz. 571 z późn. zm.), http://isap.sejm.gov.pl/DetailsServlet?id=WDU19961210571

[94] Rozporządzenie Ministra Zdrowia z dnia 1 grudnia 2004 r. w sprawie substancji, preparatów, czynników lub procesów technologicznych o działaniu rakotwórczym lub mutagennym w środowisku pracy (Ordinance of the Minister of Health from 1.12.2004 on carcinogens and mutagens in work environment) (Dz. U. Nr 280, poz. 2771 z późn. zm.), http://archiwum.ciop.pl/10641.html

[95] http://www.inspectmun.ro/site/Legislatie/Legislatie%20SSM%20engleza/GD%201218%20on%202006.pdf

[96] Silica - stone dust in the working environment (AFS 2015:2) https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/kvarts---stendamm-i-arbetsmiljon-afs-20152-foreskrifter/

[97] Decree of the Government of the Slovak Republic on protection of employees from risks associated with the exposure to chemical agents at work (No. 355/2006 Coll.)

[98] Decree of the Government of the Slovak Republic on protection of employees from risks associated with the exposure to carcinogenic and mutagenic agents at work (No. 356/2006 Coll.)

[99] Control of Substances Hazardous to Health Regulations 2002 (COSHH)[99]

[100] Control of Substances Hazardous to Health Regulations 2002 SI no. 2677 www.legislation.gov.uk/uksi/2002/2677/contents/made n

Table 6.2 National legislation governing the protection of workers from exposure to RCS in the study countries

Country	Relevant national legislation
BE	Law of 4 August 1996[101] on the welfare of workers during the execution of their work is the basis in the field of safety and health at work. The royal decree of 11 March 2002 on the protection of the health and safety of workers against the risks related to chemical agents at work (transposition of CAD). It includes as an Annex the list of OELVs. The royal decree of 2 December 1993[102] classified RCS as a carcinogenic agent but only in the framework of sandblasting.
DE	The hazardous materials regulation (*Gefahrenstoffverordung*) of November 2010 (last amended in 2015) regulates protection of workers from hazardous agents and sets out the obligation of employers to minimise exposure of hazardous materials and to minimise dust. The hazardous materials regulation has an annex of dust regulations which are more concrete in several Technical Rules for Hazardous Substances (*Technische Regeln für Gefahrstoffe - TRGS*). Quartz, cristobalite and tridymite (respirable fraction) are classified as 'carcinogenic – category 1' in the so-called MAK value list. The Committee on Hazardous Substances (*AGS*) classified tasks leading to the exposure of workers to RCS quartz and as carcinogenic in the TRGS 906 from 2005. This is a technical guideline that provides a register of carcinogenic tasks in line with paragraph 3, section 2 of the hazardous agents regulation. However, RCS is not included in the TRGS 905 (only in TRGS 906), as it was argued that it was not RCS as a substance in itself that posed a cancer risk, but the way it was treated during manufacturing processes in the workplace. Between 1972 and 2005, an occupational exposure limit of 0.15mg/m³ for RCS applied in Germany, but this has since been suspended. For substances without an occupational exposure limit other assessment criteria of exposure are to be established by the employer. For RCS, the assessment criteria of 50 µg/m³ decided by Committee on Hazardous Substances in November 2015 will be included in the Technical Rules for Hazardous Substances 559 - TRGS 559[103]. To monitor whether protection to limit the exposure of RCS is sufficient, employers can use information on exposure of RCS for different work-related tasks outlined in TRGS 559 as a yardstick. The TRGS 559 contains a list **of** RCS exposure measurements for dusk and RCS for specific tasks across sectors and establishes levels of RSC exposure (1- low exposure, 2 medium exposure, 3- high exposure) for each task.
ES	Law 31/1995 on Risk Prevention[104] is the pillar of the Spanish health and safety system. Silica is not recognised as a carcinogenic agent at work by the Spanish legislation[105]. Some regional protocols on health at work[106] recommend to follow the regulation for carcinogenic agent at work concerning the data management: keeping all medical records and risk assessment results of the workplace during 40 years after the worker is no longer expose to RCS. Several regulations are in place to ensure that prevention measures are implemented at the workplace.

[101] Loi du 4 août 1996 sur le bien-être des travailleurs lors de l'exécution de leur travail

[102] Arrêté royal du 2 décembre 1993 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents cancérigènes et mutagènes au travail

[103] Ausschuss für Gefahrstoffe (AGS), Technische Regeln für Gefahrstoffe 559, available here: http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS-559.html

[104] http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasPublicaciones/LegisNormalizacion/TextosLegales/Ficheros/lprw-lprl-en-consolidado%20-CON%20CARATULA%20SIN%20NIPO.pdf

[105] The Royal Decree 665/1997 of 12 May on workers' protection of exposure to carcinogenic agents at the work establishes the agents that are carcinogenic and that are linked to the work.

http://www.insht.es/InshtWeb/Contenidos/Normativa/TextosLegales/RD/1997/665_97/PDFs/realdecreto6651997de12demayosobrelaprotecciondelostra.pdf

[106] http://www.guiasalud.es/GPC/GPC_487_Protocolo_silicosis.pdf

Country	Relevant national legislation
	■ Order ITC 2585/2007 Complementary Technical Instruction 2.0.02[107] of the General Regulation of the Mining Safety Rules. This legislation established the requirements that mining/extractive companies need to follow to guarantee adequate safety levels at the workplace. It also established the levels of exposure in the mining sector. The Order also regulates other relevant aspects such as the medical tests that are required to carry out. ■ The UNE EN 481 on workplace atmospheres of 1995 develops the size fraction definitions for measurement of airborne particles. ■ The Order TAS 1/2007 of 2 January adopts the model for professional claims and the process for the elaboration and transmission of data in the electronic database CEPROSS. Additionally, the Order regulates the occupational exposure limits for the mining and extractive industries. ■ Order TIN 1448/2010 of 2 June which creates a database with personal information for the PANOTRATSS programme[108]. ■ Royal Decree 374/2001 of 6 April on the protection of health and safety of workers from risks related to chemical agents at work. The Ministry of Health published in 2001 (updating a 1991 version) a protocol on health surveillance procedures on Silicosis and other pneumoconiosis[109]. This protocol is of mandatory compliance at the workplace and provides guidelines for the health and safety measures.
FR	Crystalline silica is recognised as a hazardous chemical agent. Therefore, Title 1 of Book IV, 4th Part of the Labour code regarding the chemical risks applies for silica. It is then completed with some general and specific decrees, the most important being notably a decree of 2003 regarding the prevention of chemical risk[110], a circular of 2010 regarding the control of the chemical risk in the workplace[111] and a decree of 1997 regarding the protection of workers exposed to RCS[112]. Crystalline silica has a binding occupational exposure limit value.
IT	Legislative Decree 626/94 (DLgs 624/94) and the Unified Text No 81/2008 (which unified the DLgs No 81/2008 with the DLgs No 106/2009) implementing EU framework Directive 89/391/EEC DLgs No 81/2008 (art 224-225), Chapter I 'protection from chemical agents', Title IX Other relevant decrees include ■ Ministerial Decree 14 January 2008 'List or work-related diseases for which is compulsory the reporting under art. 139 of the Presidential Decree 1124/1965 ■ Ministerial Decree 9 April 2008 New tables of work-related diseases in industry and agriculture ■ DLgs No 81/2008 ■ Legislative Decree 272/1999 (forbids the use of silica sand in sand 'dry' blasting operations on ships)
LT	In Lithuania, the key health and safety legislation is the Labour Code and the Law on Safety and Health at Work (2003). There are no specific references to the RCS in the law regulating the monitoring and research on occupational diseases (2004)[113], in the 2002 law regulating dangerous workplaces[114] and in the 2001 laws regulating chemical[115] and biological health and safety risks.[116]

[107] https://www.boe.es/boe/dias/2007/09/07/pdfs/A36828-36833.pdf

[108] Non-Traumatic Diseases Caused by Work-Related Injuries of the Social Security.

[109] http://www.msssi.gob.es/ciudadanos/saludAmbLaboral/docs/silicosis.pdf

[110] Décret n° 2003-1254 du 23 décembre 2003 relatif à la prévention du risque chimique et modifiant le code du travail

[111] Circulaire DGT 2010/03 du 13 avril 2010 relative au contrôle du risque chimique sur les lieux de travail

[112] Décret no 97-331 du 10 avril 1997 relatif à la protection de certains travailleurs exposés à l'inhalation de poussières siliceuses sur leurs lieux de travail

[113] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=424936

Country	Relevant national legislation
PL	In the case of RCS, the currently binding Occupational Exposure Limit (OEL) was published in the ordinance of the Minister of Labour and Social Policy from 6 June 2014. The employers' duty to provide safety at work is specified in article 15, section 1 of the Labour Code which also includes the requirement to carry out risk assessment.
RO	The national legislation which provides for provisions regulating exposure to RCS, risk assessments and/or specific control and monitoring procedures in Romania is the following: ■ OSH Law no.319.2006 updated in 2012; ■ Government Decision no. 1218/2006 on setting the minimum OSH requirements for providing workers' protection against risks related to exposure at chemical agents ■ Government Decision no. 1048/2006 on the minimum OSH requirements for the use of individual protection equipment by the workers (with Annex 2 – Guiding Non-exhaustive List of the protection equipment and Annex 3 – Guiding Non-exhaustive List of activities and activity sectors requiring the use of individual protection equipment) Government Decision no.355/2007 on the monitoring of workers' health – Fiche no.115 on RCS, Fiche 117 on dust with insignificant content of silica (less than 5%) (lignite, glass, artificial mineral fibres etc.).
SE	The latest amendments to the regulation and general advice on silica in the work environment (2015:2) took effect from November 2015 and replaces the existing regulation on silica (1992:16) from 1993. The RCS regulation complements other regulation in the work environment field, namely: ■ Systematic Work Environment Management (AFS 2001:1) ■ Occupational Exposure Limit Values (AFS 2011:18) Chemical Hazards in the Working Environment (AFS 2011:19), as amended in 2014:43.
SK	Labour Code (Act No. 311/2001 Coll.) imposes an obligation on employers to ensure occupational health and safety of employees and to apply necessary preventative measures and a suitable OSH management system. Act on safety and health at work (No. 124/2006 Coll.) further develops and specifies the obligations placed on employers in relation to safe working environments and risks prevention, and regulates consultations with employee representatives regarding OSH. The Decree of the Government of the Slovak Republic on protection of employees from risks associated with the exposure to chemical agents at work (No. 355/2006 Coll.) regulates employers' obligations pertaining to risk assessment, risk prevention, specific protective and preventive measures, health monitoring and employee awareness requirements. It defines occupational exposure limit values for quartz, cristobalite, and tridymite and inert dust. The Decree of the Government of the Slovak Republic on protection of employees from risks associated with the exposure to carcinogenic and mutagenic agents at work (No. 356/2006 Coll.) regulates the employers' obligations to assess risks associated with the exposure to carcinogenic or mutagenic factors, replace the use of such agents and/or reduce the exposure of workers, to apply protective measures and health monitoring, employee information and training

[114] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=369037

[115] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=145860&p_query=&p_tr2=

[116] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=140647&p_query=&p_tr2=

Country	Relevant national legislation
	requirements, etc. The decree sets since 2006 the threshold limit value for crystalline silica, which is recognised as an established carcinogen for humans.
UK	In the UK, the principal piece of legislation that regulates health and safety in workplaces is the Health and Safety at Work etc. Act 1974 (HSAWA)[117]. The Chemical Agents (98/24/EC)[118] and the Carcinogens and Mutagens Directive (2004/37/EC)[119] are both implemented by the Control of Substances Hazardous to Health Regulations 2002 (COSHH)[120] as amended. There are no specific regulations that apply to the exposure to RCS. COSHH are goal-setting regulations, which apply to all substances falling within the definition of a substance hazardous to health. Silica falls within that definition and therefore the COSHH framework applies to exposure to RCS that arises from or in connection with work. Supporting COSHH is an Approved Code of Practice (ACOP)[121], this has a quasi-legal status, and has greater weight than mere guidance. Essentially, an employer does not have to follow the ACOP, but must meet the same standard as required by the ACOP. Workplace Exposure Limits (WELs) for some of the substances covered by COSHH are published by Health and Safety Executive in EH 40[122]. RCS has a limit value but is not assigned as Carc within EH40 for Workplace Exposure Limits. This is because it is not included within Chemicals (Hazard Information, and Packaging for supply) Regulations 2009, and therefore is not assigned the various risk phrases indicating it is carcinogenic.

Source: ICF based on national research for this study

[117] Health and Safety at Work etc. Act 1974 Chapter 37 www.legislation.gov.uk/ukpga/1974/37

[118] Directive 98/24/EC Risks related to chemical agents at work
https://osha.europa.eu/en/legislation/directives/75

[119] Directive 2004/37/EC Carcinogens and mutagens at work
https://osha.europa.eu/en/legislation/directives/directive-2004-37-ec-carcinogens-or-mutagens-at-work

[120] Control of Substances Hazardous to Health Regulations 2002 SI no. 2677 www.legislation.gov.uk/uksi/2002/2677/contents/made

[121] Control of Substances Hazardous to Health Approved Code of Practice and Guidance L5 6th Edition HSE 2013 www.hse.gov.uk/pubns/priced/l5.pdf

[122] EH40/2005 Workplace Exposure Limits HSE 2nd Edition 2011 www.hse.gov.uk/pubns/priced/eh40.pdf

6.2.3 National legislation on OELs

The EU has not set any OEL for RCS. As a result, Member States are free to set their own limit value (or not)[123]. Although the 2003 recommendation of 0.05 mg/m3 from the SCOEL's is not binding, more than half of the countries tend to respect this recommended OEL. Twelve of 24 (BE, DK, EE, FI, FR, EL, IT, LT, NL, NO, PT, RO, ES, SE) countries for which information was available had a limit of 0.05 mg/m3 for Cristobalite and Tridymite. The situation differs for OELs for Quartz as the majority of Member States are above the SCOEL recommendation and only Finland, the Netherlands and Portugal set the value below or equal to 0.05 mg/m3 as illustrated in the table below.

Table 6.3 Occupational Exposure Limits in mg/m^3 8 hours[124] TWA – Respirable dust – in EU 27[125] + Norway & Switzerland

Country/Authority (See caption p.2)	Inert dust	Quartz (q)	Cristobalite (c)	Tridymite (t)
Austria / I	5	0,15	0,15	0,15
Belgium / II	3	0,1	0,05	0,05
Bulgaria / III	4	0,07	0,07	0,07
Cyprus/ IV	/	10k/Q[126]	/	/
Czech Republic/ V		0,1	0,1	0,1
Denmark / VI	5	0,1	0,05	0,05
Estonia		0,1	0,05	0,05
Finland / VII		0,05	0,05	0,05
France / VIII	5	0,1	0,05	0,05
Germany/IX	0,5	/[127]	/	/
Greece/X	5	0,1	0,05	0,05
Hungary		0,15	0,1	0,15
Ireland/ XI	4	0,1	0,1	0,1
Italy/ XII	3	0,05	0,05	0,05
Lithuania/ XIII	10	0,1	0,05	0,05
Luxembourg/ XIV	6	0,15	0,15	0,15
Malta / XV[128]	/	/	/	/
Netherlands/ XVI	5	0,075	0,075	0,075
Norway/XVII	5	0,1	0,05	0,05
Poland	0,3	0,3	0,3	0,3

[123] SCOEL SUM Doc 94-final, June 2003

[124] The measurement unit is cubic metre of air expressed as a mass concentration, ideally this should be sampled over an entire eight hours shift.

[125] Missing information for Latvia.

[126] Q : quartz percentage – K=1

[127] Germany has no more OEL for quartz, cristobalite, tridymite. Employers are obliged to minimize exposure as much as possible, and to follow certain protective measures.

[128] When needed, Maltese authorities refer to values from the UK for OELVs which do not exist in the Maltese legislation.

Country/Authority (See caption p.2)	Inert dust	Quartz (q)	Cristobalite (c)	Tridymite (t)
Portugal/XVIII	5	0,025	0,025	0,025
Romania/XIX	10	0,1	0,05	0,05
Slovakia		0,1	0,1	0,1
Slovenia		0,15	0,15	0,15
Spain/ XX	3	0,05	0,05	0,05
Sweden/XXI	5	0,1	0,05	0,05
Switzerland/XXII	6	0,15	0,15	0,15
United Kingdom/XXIII	4	0,1	0,1	0,1

Source: IMA-Europe. Date: January 2014

Table 6.4 Additional details regarding OEL legislation in EU Member States, Norway and Switzerland

Country		Adopted by/Law denomination	OEL Name (if specific)
Austria	I	Bundesministerium für Arbeit und Soziales	Maximale ArbeitsplatzKoncentration (MAK)
Belgium	II	Ministère de l'Emploi et du Travail	
Bulgaria	III	Ministry of Labour and Social Policy and Ministry of Health. Ordinance n°13 of 30/12/2003	Limit Values
Cyprus	IV	Department of Labour Inspection. Control of factory atmosphere and dangerous substances in factories, Regulations of 1981.	
Czech Republic	V	Governmental Directive n°441/2004	
Denmark	VI	Direktoratet fot Arbeidstilsynet	Threshold Limit Value
Finland	VII	National Board of Labour Protection	Occupational Exposure Standard
France	VIII	Ministère du Travail	Valeur limite de Moyenne d'Exposition
Germany	IX	Bundesministerium für Arbeit	Maximale ArbeitsplatzKoncentration (MAK)
Greece	X	Legislation for mining activities	
Ireland	XI	2011 Code of Practice for the Safety, Health & Welfare at Work (CoP)	
Italy	XII	Associazone Italiana Degli Igienisti Industriali	Threshold Limit Values (based on ACGIH TLVs)
Lithuania	XIII	Dėl Lietuvos higienos normos HN 23:2001	Ilgalaikio poveikio ribinė vertė (IPRV)
Luxembourg	XIV	Bundesministerium für Arbeit	Maximale ArbeitsplatzKoncentration (MAK)
Malta	XV	OHSA – LN120 of 2003, www.ohsa.org.mt	OELVs
Netherlands	XVI	Ministerie van Sociale Zaken en Werkgelegenheid	Publieke grenswaarden http://www.ser.nl/en/oel_database.asp

Country		Adopted by/Law denomination	OEL Name (if specific)
			x
Norway	XVII	Direktoratet for Arbeidstilsynet	Administrative Normer (8hTWA) for Forurensing I ArbeidsmiljØet
Portugal	XVIII	Instituto Portuges da Qualidade, Hygiene & Safety at Workplace NP1796:2004	Valores Limite de Exposição (VLE)
Romania	XIX	Government Decision n° 355/2007 regarding workers' health surveillance. Government Decision n° 1093/2006 regarding carcinogenic agents (in Annex 3: Quartz, Cristobalite, Tridymite).	OEL
Spain	XX	Instrucciones de Técnicas Complementarias (ITC) Orden ITC/2585/2007	Valores Limites
Sweden	XXI	National Board of Occupational Safety and Health	Yrkeshygieniska Gränsvärden
Switzerland	XXII		Valeur limite de Moyenne d'Exposition
United Kingdom	XXIII	Health & Safety Executive	Workplace Exposure Limits

Source: IMA-Europe. Date: January 2014

In its Opinion of 5 December 2012, the Commission's Advisory Committee for Safety and Health ('ACSH')[129] stated that a binding OEL at 0.1 mg/m3 8-hour time weighted average (8hr TWA), measured as respirable dust, is justified for RCS. It also recognised that several legal possibilities to adopt this OEL exist such as the Chemical Agents Directive (CAD) or the Carcinogens or Mutagens Directive (CMD).

6.2.4 Enforcement and compliance

The question of enforcement of health and safety legislation and control of the level of exposure of workers to RCS is fundamental to understanding the national context. Only very limited information was available, but in the countries where interviews took place with labour inspectorates, it was found that enforcement of the legislation on controlling exposure to RCS is difficult to achieve. It usually requires spot checks run by labour inspectorates, which do not always have the capacity to visit every site in the country.

Other factors that also need to be considered, as demonstrated by Slovakia, where the labour inspectorate reported capacity problems resulting from the high number of sites per inspector, and also that many of the operations are seasonal. The finding that resource constraints limit enforcement efforts is echoed in the CADimple study on the implementation of CAD at the workplace level[130]. In case of controls, the labour inspectorate may carry out check measurements and impose fines if his/her results do not match the results submitted by the employer. Public health authorities do not record data on controls and sanctions related specifically to RCS[131]. In 2014, authorities carried out a total of 19,607 inspections (19,513 in 2013) and imposed 10 fines (20 in 2013) for infringement of provisions governing

[129] ACSH is a tripartite committee consisting of the Member States, Employers and workers representatives.

[130] Kooperationsstelle Hamburg IFE GmbH (2010); Contract to analyse and evaluate the impact of the practical implementation in the workplace of national measures implementing CAD; https://osha.europa.eu/en/legislation/directives/75

[131] The reason is the settings of the information system in use (Automatised system of risk classification).

protection of workers from chemical agents[132]. In the UK, health and safety inspectors have a number of formal enforcement options available under the HSWA (Health and Safety at Work Act) to remedy contraventions of the Act and regulations made under the Act. An improvement notice can be issued requiring defects to be remedied within a specific period. A prohibition notice can be issued to prevent an activity that could cause serious personal injury, and therefore must stop immediately the notice is issued.

Few estimates are available on compliance with relevant health and safety regulations[133] and none are specific to RCS. It is generally estimated that compliance rates are roughly between 30-40%.

In term of the effectiveness of existing legislation, it can therefore be considered that compliance remains an issue and can be affected by a number of things such as:

- Awareness raising
- Clarity of guidance on the existence and implementation of legislation
- Frequency of inspections and level of sanctions

The above-mentioned CADimple study also emphasises the importance of raising awareness and, particularly, of improved guidance on risk assessment, as well as enhanced technical understanding of the risks of chemical agents and the benefits of control processes in enhancing the implementation of CAD. It also calls for inspection regimes to be improved.

As discussed in subsequent sections, the NEPSI agreement had a particularly important role to play in raising awareness and providing a practice tool for the implementation of existing legislation.

The dearth of good comparable data on exposure to RCS and occupational illnesses linked to RCS, as well as the absence of impact assessment studies showing impact over time of any legislative changes linked to the control of exposure of workers to RCS, make it challenging to conduct a meaningful assessment of the impact of different national regulations on health outcomes (and therefore their effectiveness).

The only judgement that can be made on the basis of existing research (and, as highlighted below, as a result of the survey carried out for this study) is that improvements in raising awareness and delivering clear guidance and practice tools can have an impact on company practice. The implementation of better control mechanisms and work organisation/production design is key to improving health outcomes.

[132] Annual reports of the departments and sections of preventive occupational medicine of the Public Health Authority of the Slovak Republic and the regional public health authorities.

[133] For instance a study in the UK on compliance with health and safety regulations among SMEs found compliance rates between 19 – 61%; http://www.hse.gov.uk/research/rrpdf/rr366.pdf

7 The Agreement and its implementation

The first step to evaluate the Agreement relates to the assessment of its implementation. The implementation of the Agreement required several actions to be taken at European and national level by European and national organisations, as well as companies. This chapter provides an overview of the implementation of the Agreement at European and national level.

7.1 Logic model of the evaluation of the NEPSI Agreement

The logic model below provides an overview of activities and changes expected to occur to implement the Agreement and following the implementation of the Agreement. This evaluation did not attempt to assess the human and financial resources linked to the Agreement (i.e. the monetary costs of implementing activities at European and national level and the number of people involved). A major element of this evaluation study relates to the assessment of the implementation of the Agreement and what actions have been taken at different levels to ensure the application of its principles across Europe, i.e. the outputs. This chapter provides an account of the content and implementation of the Agreement and the next chapter considers with the impact. Because of the nature of the Agreement and the implementation of the reporting system, the impact chapter also provides a detailed account of activities implemented at company/site level e.g. implementation of good practices and training.

Figure 7.1 Logic model for the evaluation of NEPSI Agreement

Source: ICF

The following sections provide an assessment of information gathered via interviews with European associations, national associations and affiliated companies, plus an analysis of the NEPSI reports (quantitative indicators and qualitative information), NEPSI website and NEPSI documents such as the Good Practices Guidance and other documents available on the reporting system.

7.2 Implementation of the Agreement

The following paragraphs respond to the overall evaluation questions: to what extent do instruments/actions taken comply with the provisions of the Agreement? To what extent the

NEPSI Council fulfils its mission? More specific evaluation questions are also included under each subheading.

7.2.1 Actions taken to implement the Agreement

Which actions have been taken by the NEPSI Council, by the signatories and their national affiliate members, and by companies to implement the Agreement? Which actions have been taken by other national bodies/public authorities to implement the Agreement?

A first step in the implementation of the NEPSI Agreement was establishing the NEPSI Council. Indeed, a NEPSI Council composed of 30 members was set-up in 2007 representing each European signatory organisation of the NEPSI Agreement. It includes four chairpersons, with an equal number of representatives from the employers' and workers' organisations. It has two permanent co-chairmen and two permanent vice-co-chairmen, who are appointed from within the Employer and Employee delegations to chair NEPSI Council meetings.

Rules have also been adopted and the NEPSI Council takes decisions by consensus or, if this cannot be achieved, a double majority of 75%. The Council is also supported in its tasks by a Secretariat, which assures relations with public institutions, the press or the general public on its behalf[134].

Once the NEPSI Council was set-up, it started a wide range of implementation activities.

In 2007 the Council took charge of the following actions:

- Dissemination/advertisement of the Agreement
- Translation into 20 languages
- Set up of the NEPSI website
- Road shows performed by the NEPSI Secretariat and aimed at a wide range of stakeholders (Health and Safety Institutes, European and national authorities, company management, health and safety practitioners, occupational physicians, works councils, etc.)

In 2008, the Agreement was promoted by the Council with two national workshops to raise awareness. New task sheets on portable tools in dry conditions were drafted and one on portable tools in wet conditions was under preparation at the time of the drafting of the report.

In 2010, two workshops were organised in order to promote the Good Practice Guide and nine new task sheets were developed. The Bulgarian and Romanian versions of the Agreement were also made available as these countries had joined the EU in 2007.

In 2012, the NEPSI Council organised five workshops with the help of the European and national sector associations to promote the Agreement at national level. It was also represented in two events organised by the European Commission, DG Employment and a presentation was given during the European Liaision forum organised by DG EMPL on 19 May 2011.

In 2014, the NEPSI Council carried out other dissemination activities including:

- Translating the NEPSI Executive Summaries into several languages
- Drafting additional task sheets for the Good Practice Guide
- Issuing a success story article in the DG EMPL newsletter and its dissemination during the European Thematic Liaison Forum of DG EMPL in December 2013
- The partnership with EU-OSHA on 'Working together for risk prevention'
- Discussion between the NEPSI and the construction sector

[134] http://www.nepsi.eu/about-nepsi/nepsi-council.aspx

In 2015, further actions were taken to continue disseminating the Agreement:

- Production of a 14-minute video in English explaining the issue of RCS and the NEPSI Agreement with the help of a grant from the European Commission. Versions will be also available in French, German, Spanish, Czech, Polish, Swedish, Romanian, and Italian.
- A power point presentation explaining the reporting system has been developed and is available on the NEPSI website.

A major step in the implementation of the Agreement was the NEPSI website. It contains various materials for NEPSI national members to access, the main documents available include:

- A direct link to the Agreement and the Good Practice Guide in 22 languages
- NEPSI Reading Guidelines
- NESPI Executive summaries
- NEPSI leaflet
- NEPSI video
- NEPSI Training PowerPoint Presentation
- NEPSI Council Contacts List
- NEPSI Questions and Answers

Thanks to the grant from the European Commission, the NEPSI website will be updated during 2016 and a conference celebrating the 10 year Anniversary of the Agreement will be held on 16 June 2016.

The NEPSI Executive Summaries represent a key source of information concerning the implementation of the Agreement and adoption of Good Practises at site level.

The website contains a 'Highlight and news' box to notify members of the latest news.

Figure 7.2 Highlights and news box on the NEPSI website homepage

Source: NEPSI website – Last accessed on 19/04/2016

As mentioned earlier, the NEPSI Council also supports national organisations and companies by answering any questions about the reporting system. It also delivers the consolidated NEPSI reports.

7.2.2 Actions taken by national organisations to implement the Agreement

Actions taken at EU level are key to ensure that national NEPSI members do implement the Agreement at their level and provides them with helpful tools to do so. Implementation at national level is fundamental since it often relates to the delivery of activities that will directly impact on workers. Overall, similar tools and methods have been used to implement the NEPSI Agreement across the different Member States:

- **Dissemination activities: National organisation have taken several** actions to disseminate the NEPSI Agreement to their members. A first step entailed disseminating the Agreement and its Good Practice Guide through newsletters, emails and organisations' websites. National organisations also developed factsheets; brochures and guidance and were also sent to members.
- **Training activities**: National organisation also arranged face-to-face and online training sessions to explain the NEPSI Agreement and the reporting system. More commonly, modules on exposure to RCS were added to existing OSH training and specifically to new training. For instance, in Belgium a national association organised a day around quartz dust and the use of the NEPSI good practice guide.
- **Awareness-raising initiative**s: National organisations arranged workshops and conferences to raise awareness among members at sectoral level. In Belgium, RCS study days were organised by a national association in 2008. Approximately 100 people took part i.e. two people per company, bringing together executives and blue-collar workers. National organisations reported that the issue of RCS is continually mentioned in their national health and safety committees to maintain a high level of awareness.
- **Other activities at national level**: Some of the national associations interviewed adapted relevant parts of the Good Practice Guide to the needs of their sector and/or used it to adapt already existing instruments (i.e. the job description fiches in France - *fiches de poste*) which were converted into PDF and disseminated to all sites. In the Netherlands, a national organisation launched a measurement campaign to coincide with the launch of the Agreement. Some actions have also been taken to disseminate the Agreement outside the signatory parties. In Italy, an official presentation of the Agreement was sent to all national Authorities (Ministries, Regional and provincial Labour Inspectorates, National Insurance Authority etc.). A Belgian organisation suggested integrating a reference to the NEPSI Agreement in their collective Agreement thus raising the debate to the national agenda. In Germany, a 'Silica Round Table' was set up at national level between employers, trade unions and employers' liability insurance. In the Netherlands, one association produced a syllabus in Dutch for its members with all the relevant information on silica dust prevention and abatement.

According to interviews with NEPSI members, labour inspectors, experts and trade unions no actions were taken by other national bodies or public authorities to implement the Agreement. It is worth reiterating that this Agreement was signed by a number of industries with the aim of implementing its principles among its members and there was not requirement for external bodies to take any actions.

The assessment of trade union activities at national level proved to be difficult. Trade unions are more involved at company level; employers interviewed reported that the implementation of the Agreement consistently involved work councils where employees are represented. However, work councils are not systematically set up in small companies, the threshold to set up a work council varies across countries.

7.2.3 Actions taken by companies to implement the Agreement

Companies that are direct members of European confederations were interviewed and an online survey was conducted (results of the online survey are presented in the impact chapter). The implementation of the Agreement at company level required changes to workplace procedures and management processes to ultimately achieve its objectives i.e. short-term outputs necessary for medium and long-term outcomes to occur, for example the introduction of new training modules at company level is a measure that needs to be undertaken to implement the Agreement in order to ultimately increase knowledge and awareness among managers and employees, and thus one of the expected (short-term) outputs of the Agreement which can lead to health improvements in the longer term. The impact section will provide a detail assessment of the outputs and outcomes resulting from

the implementation of the NEPSI Agreement. Therefore, this section will briefly provide an account of actions taken by companies, while a more coherent assessment of activities is provided in the chapter on impact of the Agreement.

- The implementation of the 2-year cycle of the reporting system was the primary action taken to fulfil the requirements of the Agreement
- Conducting the specific risk assessment identified by the Good Practice Guidance
- Training provided to employees and contractors or specific modules added on the issue of RCS controlling measures
- Cooperation with external medical surveillance institutes to ensure a correct implementation of the NEPSI requirements
- Other activities reported include for example adding symbols on Personal Protective Equipment (PPE), housekeeping audits at departmental levels, acquisition of new machines following the NEPSI Good Practices Guide, and changes to collective and individual protective equipment

Some companies reported that the NEPSI Agreement and its Good Practices did not generate any particular implementation activities from their side as internal procedures already existed that met the requirements of the Agreement and the Good Practice Guide. This was particularly true in large multinationals where global standards in terms of exposure to RCS and dust in general were already in place.

7.3 The reporting system

This sub-section responds to the evaluation question: what are the key features of the reporting system put in place by the signatories and their national affiliate members?

The reporting of data collected at site level to the NEPSI Council is a key feature of the NEPSI Agreement. The requirement for NEPSI national members to report every two years is enshrined in Article 7 of the NEPSI Agreement. To facilitate this exercise, a reporting format was inserted in Annex 3 of the Agreement when it was first signed. The annex contained similar reporting sheets with the indicators integrated in a table (Table 7.1).

Table 7.1 Information contained in the NEPSI reporting system

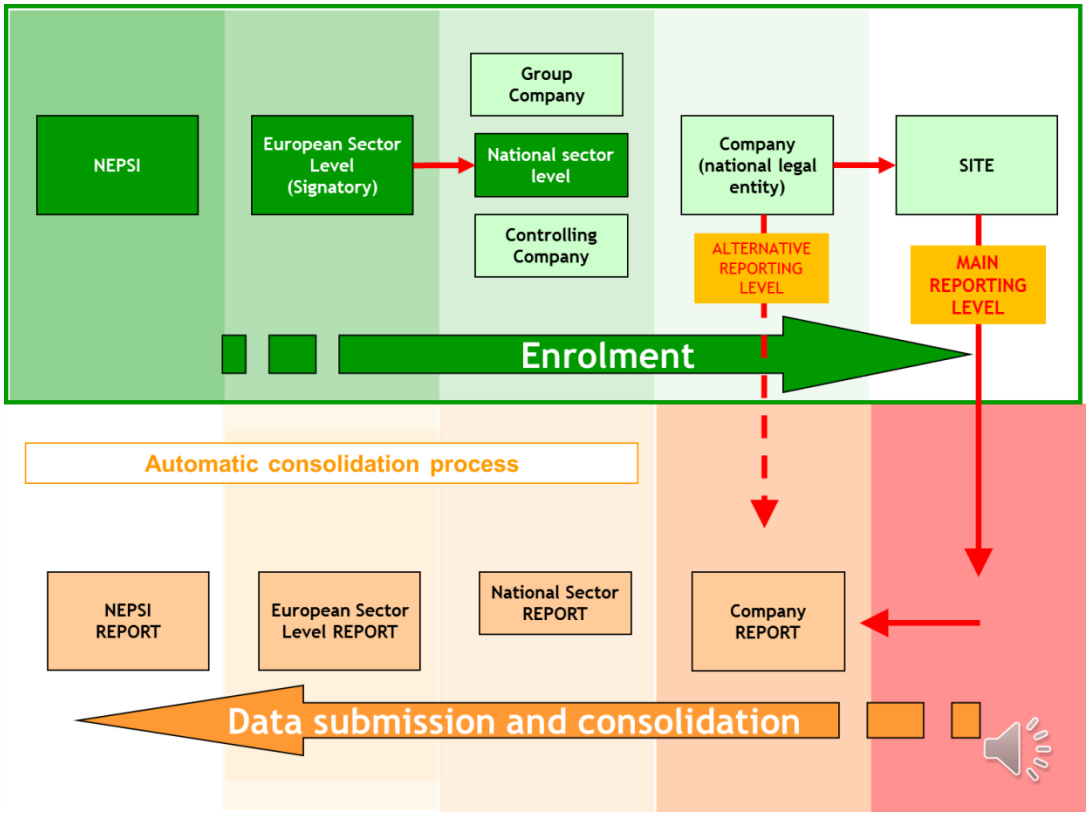
Indicators
Section 1:General information
Number of sites
Number of reported sites
% of reported sites
Number of reported employees
Section 2: Exposure risk
Number of employees potentially exposed to RCS
Section 3: Risk Assessment and Dust Monitoring
Among the number of employees potentially exposed to RCS, number of employees covered by risk assessment
Among the number of employees potentially exposed to RCS, number of employees covered by exposure monitoring
Among the number of employees potentially exposed to RCS, number of employees requiring Health Surveillance Protocols for Silicosis
Section 4: Health surveillance
Among the number of employees potentially exposed to RCS, number of employees covered by generic health surveillance protocol

Indicators
Among the number of employees potentially exposed to RCS, number of employees covered by generic health surveillance protocol for silicosis
Section 5: Training
Among the number of employees potentially exposed to RCS, number of employees covered by information, instruction and training on General Principles
Among the number of employees potentially exposed to RCS, number of employees covered by information, instruction and training on Task Sheets
Section 6: Good Practices
Technical measures to reduce generation/dispersion of fine particles of source
Organisation measures
Distribution and use of Technical Protective Equipment
Key Performance Indicators
% of employees potentially exposed to RCS
% covered by risk assessment
% covered by exposure monitoring
% with risk assessment requiring health surveillance protocol for silicosis
% covered by generic health surveillance
% covered by health surveillance protocol for silicosis
% covered by information, instruction and training on General Principles
% covered by information, instruction and training on Task Sheets
Additional key performance indicator
% of those identified as requiring health surveillance protocol for silicosis covered

Source: NEPSI reports

The reporting system builds on a cascading invitation process launched by the NEPSI Council level down to site level and involving the signatory EU Sector Associations, national employers' organisations and companies as illustrated in the figure below (Figure 7.3).

Figure 7.3 Information cascade in the NEPSI reporting



Source: Presentation available on the NEPSI website

In 2008, the NEPSI Council switched to an online reporting system to facilitate and harmonise the reporting procedure. Interviews with organisations and companies at EU and national level underlined the teething problems with the online system, Feedback from sites and national organisations was addressed and the problems were sorted out in by the next reporting cycle.

Given the geographical coverage of national NEPSI members, it was important to maximise the response rate by ensuring that the online reporting platform was available in every language. This has been achieved by the NEPSI Council, with the reporting platform now available in 22 languages. There is also a dedicated page on the NEPSI website with guidance on the reporting system in the form of slides and PDF available in 22 languages[135].

The aim of the online reporting system was to reduce the workload for the sites or organisations reporting and also to ensure that the same instructions and guidance were provided to all. The online reporting platform is open for two months. In addition, a helpdesk can be contacted by email for any technical issues, but it is not clear when this service began operating.

Table 7.2 Timeframe of the 2014 NEPSI reporting

Date	Step
Autumn 2013	Preparation of the 2014 Reporting and Communication
15 January – 14 March	NEPSI Reporting system opened – collection of data

[135] http://www.nepsi.eu/reporting/guidances.aspx

Date	Step
2014	
March – May 2014	Follow-up of the data collection and checks of the quality and completeness of the information provided Preparation of the draft NEPSI 2014 Summary Report
18 June 2014	Tenth meeting of the NEPSI Council

Source: NEPSI Council 2014 Summary Report

The online reporting phase starts with the NEPSI Council launching the top-down invitation process. Two separate e-mails are sent, one containing a hyperlink to access the system and the other containing a Member log-in password. Each EU Sector Association can enrol its respective members (both national associations and companies). This procedure is repeated until a company enrolls its site(s). At that point, when a site logs onto the system, it is asked to complete its report or to reject the invitation. Data need to be reported at several levels: site, company, country (national association) and sector (EU association) level. To do so, EU and national NEPSI members are free to organise themselves. Table 7.3 provides the overview of the different levels of reporting.

Table 7.3 Levels involved in the NEPSI reporting process

Level	Member Type	Description
Level 1	NEPSI Council	The European Network on Silica representing the signatories of the Agreement
Level 2	EU Sector Association	One of the 16 signatory European Sector Associations
Level 3	Group Companies	A Company: Directly Member of an EU Sector Association AND owning one / several Controlling Companies (see below
Level 4	National Sector Association	A National Sector Association representing one of the sectors involved
Level 5	Controlling Company	A Company: Member of an EU Sector Association OR a National Sector Association AND Owning one/several Companies (see below)
Level 6	Company	A Company owning one/several industrial sites where the Agreement is applicable
Level 7	Site	An industrial site where the Agreement is applicable

Source: NEPSI Guidance on reporting available in the website. Note: The levels highlighted in blue are mandatory. Levels left in white can be used or not depending on the structure of companies or on the membership of associations.

Although the majority of companies report directly into the system, in some cases the national association takes responsibility for entering the data into the online database. In these cases associations send either an Excel sheet or a paper form to its members. Once it has received their response, the association enters the data into the system. The choice of a paper version was aimed at sites within sectors characterised by micro business, potentially less experienced with IT systems. To encourage reporting and to maximisethe chance of a

response, associations send both the link to the online portal and a paper version. National associations usually perform checks on data entered from their members to ensure consistency across years (and to reduce the potential of double counting where companies are members of more than one association). In some cases, it was reported that national associations with fewer members organised a meeting to help finalise reporting, clarify gaps or misunderstandings.

The reporting method differs according to the size of companies reporting. In the case of small companies with one site, the procedure is straightforward as only one site enters the system. For large companies with several sites the process is either centralised at national level, when sites are located in the same country, or when sites are located in different countries, data are centralised first at national level and then at headquarters level.

7.3.2 Coverage of the reporting system

This sub-section responds to the evaluation question: what is the coverage of the reporting system?

This evaluation cannot provide a precise assessment of the number of companies/sites reporting to the NEPSI system as percentage of the number of companies/sites affiliated to the national organisations. Chapter 5 on coverage of the NEPSI Agreement provides a detailed account of the methodological issues in assessing the level of membership of national associations, as well as issues related to the uneven presence of risk of exposure across members. However, interviews with national associations revealed that overall a high proportion of members with an exposure risk report to the NEPSI system. Similarly, companies interviewed stated that all sites with a risk of exposure to RCS report to the system.

The NEPSI data contain information on the number of sites and the number of reported sites. Table 7.4 below shows that the overall percentage of sites reporting is relatively high across all Member States and sectors. Sectors with lowest percentages are usually those characterised by small companies.

Table 7.4 Percentage of reported sites in the NEPSI reporting system

Aggregates		Cement		Ceramics		Foundry		Glass		Industrial Minerals		Mining Industry		Mortar		Precast Concrete	
UEPG		CEMBUREAU		CERAME-UNIE/EXCA		CAEF/CEEMET		GlassFibre/ESGA/ EURIMA/FEVE		IMA-Europe		EUROMINES		EMO		BIBM	
FR	84%	IT	100%	DE	88%	DE	64%	DE	100%	DE	100%	CZ	88%	DE	80.9%	DE	42%
UK	99%	DE	100%	ES	93%	FR	60%	FR	100%	FR	100%	EL	67%	UK	100.0%	UK	99%
DE	76%	ES	100%	IT	65%	UK	69%	IT	100%	IE, UK	100%	SE, NO	95%	ES	17.2%	FR	99%
ES	49%	FR	100%	UK	90%	ES	46%	ES, PT	100%	ES	100%	DE, NL	100%	FR	96.6%	BE	100%
FI, SE	99%	UK	100%	FR	73%	SE	98%	IE, UK	100%	DK, FI, SE	100%	FI	67%	NL, SE	100.0%	NL	100%
EL, HR, IT, RO, SK	82%	EL	100%	BE, LU, NL	95%	IT	96%	BE, LU, NL	100%	IT	100%	PL	71%	PT	83.3%	SE	52%
IE	80%	PL	100%	CZ	81%	PL	62%	PL	100%	BE	100%	AT	100%	FI, PL	100.0%	AT	100%
BE	100%	BE	100%	PT	77%	CZ	95%	BG, EL, RO, SI, SK	100%	BG, HU, RO, SK	100%	ES, IE, UK	80%	AT, CZ, IT, SI	94.7%	ES	92%
AT	88%	RO	100%	AT	93%	AT	64%	CZ	100%	AT	96%	HU, TR	75.00% *			FI	67%
PT	46%	AT	100%	HU, SI	68%	FI	100%	DK, EE, FI, LV, SE	100%	CZ	100%					IT	n.a*
NO	100%	PT	100%	EE, PL	95%	NL	94%	AT, HU	100%	PL	100%						
CZ, HU, LV, PL, SI	94%	SE	100%	FI, SE	93%	PT	63%	Non EU countries	100%	NL	100%						
NL	79%	BG	100%	DK	100%	BE	0%			PT	100%						

Aggregates		Cement		Ceramics		Foundry		Glass		Industrial Minerals		Mining Industry		Mortar		Precast Concrete	
UEPG		CEMBUREAU		CERAME-UNIE/EXCA		CAEF/CEEMET		GlassFibre/ESGA/ EURIMA/FEVE		IMA-Europe		EUROMINES		EMO		BIBM	
BG	100%	CZ	100%	BG, RO, SK	82%	NO	64%			CY, EL	100%						
		NL	100%			HU	92%			NO	100.00 %*						
		IE	100%			SI	100%										
		HU	100%														
		FI	100%														
		SI	100%														
		NO	100%														
		LU	100%														
		LV	100%														
		EE	100%														
		HR	100%														
		DK	100%														
		RS	100%														
		TR	100%														
No figures in 2014 for: LV, IT - Voluntary: NO		Voluntary: HR, NO				Voluntary: NO				Voluntary: NO * data include also Peru, USA, Switzerland, Turkey		Voluntary: TR. No 2014 data available for BG, EE				IT data for 2012:96, *no longer a member since 2013	

Source: NEPSI Council 2013 - 2014 Reports

7.3.3 Efficiency and effectiveness of the reporting system

This sub-section responds to the evaluation question: to what extent is the reporting system efficient and effective?

Information related to the efficiency and effectiveness of the reporting system was gathered via interviews with NEPSI members at EU and national level (national associations and companies), the online survey and analysis of the qualitative information contained in the NEPSI reports (part of this section concerns the remarks on the reporting process).

Most of the national members interviewed deemed the online reporting system user-friendly, clear and efficient. Support from the NEPSI Council was commonly valued as very good by NEPSI national members. Most of the interviewees appreciated the prompt reply and the quality of the explanations given to them. For instance, there were some requests for clarification concerning whom to include in 'employees exposed to RCS'. Following discussion among the NEPSI Council, satisfactory guidance on this point was provided to the national members. Telephone interviews with large companies also confirmed that current NEPSI reporting is considered effective and efficient. A moderate 41% of respondents to the online survey assess the reporting system as very efficient (6%) and rather efficient (35%).

EU organisations and national members also highlighted that reporting can result in significant extra work for very small companies that need to be engaged and supported in the form-filling process. SMEs are often unfamiliar with the complexity of the system and it has been reported that small companies are also less likely to participate in potential training organised by their national association, because of lack of human and financial resources. In large companies, reporting does not create an issue because there is often one dedicated person in charge of NEPSI reporting.

An issue mentioned in relation to the reporting process is that some large companies are members of several national associations affiliated to NEPSI. In this case, companies are required only to report to one association and need to notify the other organisations what they are doing. However, it is unclear how these cases are fed into the system as the national organisation not selected may register the member as 'not reported' when it has reported elsewhere. Another point highlighted by NEPSI interviewees was that initially it was not possible to record all sites of the same company in one report, which was seen as an unnecessary administrative burden. It is how possible, however, to enter information from different sites onto the same webpage.

7.3.4 Monitoring of the implementation of the Agreement

This sub-section responds to the evaluation question: has a system been put in place specifically to monitor the implementation of the Agreement at national level? To what extent are the implementation instruments/actions taken binding for signatories and their national affiliated members?

The Agreement in Article 6 specifically envisaged a monitoring system at site level to assess the application of the Good Practices. For this purpose, the employer must designate an employee for each site. From interviews with companies directly affiliated to the NEPSI confederations, it seems that companies do have designated managers (usually health and safety managers) in charge of the implementation of the Agreement across sites and in charge of NEPSI reporting.

In addition, another layer of monitoring exists at national and European level to monitor reporting to the NEPSI system and the implementation of the Agreement at site level.

Monitoring reporting to the NEPSI system at national level is the first layer of ensuring that all member sites report back, either to their national organisation or to headquarters or directly into the reporting system. National organisations are the bodies in charge of monitoring at

national level and a dedicated person is usually appointed to monitor reporting. An initial communication is usually sent in advance to companies supposed to report to notify them of the upcoming reporting period. Reminders are then sent as the deadline approaches. Some national associations highlighted that they also follow-up with sites that have not reported to understand any difficulties they may have encountered.

In addition to monitoring at national level, EU NEPSI members are also responsible for ensuring that their national members do actually report. Members of the NEPSI Council that are EU organisations usually liaise with their national associations by sending reminders of the reporting deadline. Companies in direct membership of the NEPSI Council liaise directly with the person at headquarters who sends out reminders at national level.

Separate from monitoring NEPSI reporting (i.e. whether companies report to the NEPSI system or not) is monitoring whether companies apply NEPSI principles on the ground (i.e. whether Good Practices are implemented, changes are made at site levels, training, measurement of exposure, etc.). This level of monitoring is not set out in the Agreement, although implementation actions taken by national associations are not binding, so it is reasonable that national associations and/or European confederation put in place activities to verify reporting.

This evaluation found that this level of monitoring is not in place and very few national organisations include assess what is done in relation to the NEPSI Agreement in their visits to their members.

7.3.5 The consolidated NEPSI reports

The NEPSI reports are the final product of the NEPSI Council; and are prepared every two years following the end of reporting. Since 2007, two distinct reports are produced every two years collating information at national level[136] (i.e. data for each national NEPSI European confederation in each country) and a Summary Report with more aggregated data. Because information collected via NEPSI reporting is confidential, these reports are not publicly available and only the Executive Summary is available online.

Article 8 of the NEPSI Agreement states that the NEPSI Council must issue a "summary Report at the latest by June 30 of the following year summarising application, non-application and improvement, stating the level of application/non-application per industry sector, the reasons therefore and issuing recommendations related thereto". The same article also requires the NEPSI Council to forward the Summary Report to the Parties and their members, the European Commission and the national authorities responsible for workers' safety.

The NEPSI report collating the National Reports provides a detailed overview of all the data reported by NEPSI members at national level and by sector. The nine main sectors of the NEPSI signatories are represented (aggregates, cement, ceramics, foundry, glass, industrial minerals, mining industry, mortar and precast concrete). The report contains a short foreword and a summary of the NEPSI results. The rest of the report contains data from the reporting system. National data is organised by sections where each section represents one sector. Within these sections, data is broken down by country. Even though each section is dedicated to one sector, data from several organisations are often merged. For example, the section on the Glass sector aggregates data from six different organisations (GlassFibreEurope, AISBL, ESGA, Eurima, FEVE and Glass for Europe). Data is also sometimes aggregated by country, with between two to five countries grouped together.

[136] The detailed reports are sent by national organisations and companies to the consultancy company in charge of the management of the database.

The Summary Reports present an analysis of the National Reports and also contain qualitative information at national and sectoral level. The section on 'Important remarks' also provides details about factors that may have impacted the results of the reporting system. The report also contains a short section on 'the way forward' which focuses on possible improvements to the current system.

As stated in Article 8 of the Agreement, the NEPSI Council must cascade down the Summary Reports. This provides a clear view of the state of play and a comparative assessment of trends. National associations reported that they receive the NEPSI reports which they then forward to their members. It is unclear, however, how consistent this process is. Some of the companies interviewed complained that they have not received any feedback following the reporting system.

Companies seem interested in receiving more feedback on the results of the Agreement and sharing of Good Practices. Some of the suggested activities to ensure more effective feedback include meetings organised at national level and/or sectorial level to discuss the findings of the reporting system. Some national associations reported that they provide detailed feedback at their annual meeting on health and safety, which could be a useful practice to implement more widely.

7.4 Areas for improvement in the monitoring system and implementation of the Agreement

This sub-section responds to the evaluation questions: what are the areas for improvement in the monitoring system? What are the areas for improvement in the implementation of the Agreement?

Some areas for improvement have been identified by this study. These relate to the NEPSI Reports, the quantitative data reported, i.e. NEPSI indicators, the qualitative information collected via the reporting system, and the monitoring of the Agreement.

7.4.1 NEPSI Reports

NEPSI reports provide the results of the monitoring system in aggregate form by country and sectors. Detailed reports from the NEPSI Council are an important part of the assessment of trends. The impact of such reporting depends on the quality of the information provided in the reports, the way the information is aggregated and the comparability of the information between years.

However, this assessment of the data included in the NEPSI reports reveals some issues in the way the data are presented. Inconsistences have been confirmed during in-depth analysis of the reports and need to be taken into account when interpreting the data.

The structure of data in the 2014 NEPSI report (which includes national data and aggregates of national data, with some variation in the coverage and scope of country aggregates) has created challenges for the analysis of data by country, sectors and trends (i.e. between 2008 and 2014) with a significant impact on the interpretation of the data.

One of the issues identified is that the method of grouping country information varies significantly across years. This means that for the same organisation in different years the same country information can be provided individually or aggregated with other countries, meaning it is impossible to isolate the information by country. It seems feasible that detailed reporting by country and per year can be produced by NEPSI members, but confidentiality of data needs to be taken into account.

Moreover, the criteria underpinning the grouping of information and countries are not clear and/or consistently applied. F example, the issue of confidentially (the NEPSI reports state that the threshold is five sites reporting, i.e. if one organisation has less than five sites,

reporting in a given country data are then aggregated) is not necessarily the main reason for grouping information across countries.

The number of countries covered by the NEPSI members also varies across years because the NEPSI network is evolving over time, with new countries and/or organisations joining while others leave. In addition, data for EEA countries are provided together with data outside Europe e.g. Turkey, Peru etc. and/or countries that report on a voluntary basis. When this data are aggregated with EEA countries, it has implications for the assessment of the results for EEA countries and since the information cannot be disaggregated, it is not always possible to isolate the results for EEA countries. Finally, it appears that data are not systematically available for all the years under consideration (2008, 2010, 2012 and 2014).

These issues in the quantitative data make it difficult to interpret the data presented in the NEPSI reports. It is likely that more qualitative data would be needed to put these numbers into perspective. But, as explained below, the existing qualitative information does not focus on detail and is therefore hardly usable.

7.4.2 Quantitative information i.e. the NEPSI indicators

Because information given to the NEPSI is self-reported and there is no provision in the Agreement for monitoring what actually happens at site level, there is no process of quality control of the quantitative indicators.

Since data are self-reported, it is also impossible to assess the accuracy of the information where there is, for example misunderstandings of the reporting process or misinterpretation of the information required. The system is based on trust between organisations and companies. The majority of national associations believed that the quality of data was trustworthy and no further control was needed.

However, some of the companies interviewed suggested that more detailed information of what is implemented on the ground would provide real added value. This emerged primarily in relation to the section on implementation of Good Practices where the indicators refer only to whether a Good Practice is implemented or not, making it impossible to identify which NEPSI good practices are implemented. This makes it difficult to collect information on what kind of measures have been put in place by the site, whether they are adapted and whether there were difficulties in implementing them.

The correct interpretation of the NEPSI indicators (e.g. number of employees, confusion between "potentially exposed" and "exposed" workers) was the main issue highlighted by some interviewees. Although a NEPSI Guidance is available on the website, there are still problems deciphering what information needs to be provided. For example, some companies did not report workers as covered by risk assessment since this was not carried out close to the reporting period, but these workers should have been included as covered.

These misinterpretations are not widespread, however, and do not seem to have significant impact on the results. They are more common among sites newly reporting and where there has been a change in managers responsible, emphasising that continuous communication is key to ensuring correct reporting.

Interviewees have highlighted that the reporting system does not include an indicator to identify sites were the risk of exposure to RCS is not present. This is a problem for large companies that are not at risk no of exposure in all their premises.

Another indicator that could be added to the system relates to the number of companies, so that the system generates statistics on number of sites reporting but also number of companies reporting.

Interviewees also reported that technical issues related to the incompatibility of NEPSI online reporting with a particular Internet browser made it difficult for them to enter their data. In the qualitative information of the NEPSI reports, some members mentioned that they did not

take part in the reporting because of the known technical problems with the online reporting system.

7.4.3 Qualitative information

As mentioned above, there is a need to integrate more qualitative information into the NEPSI reporting system. However, the analysis of this data shows there is room for improvement in the way this information is collected.

The qualitative data are presented in the reports under specific sub-themes: 1) remarks on the reporting process; 2) Are there any notable National Obligations with regard to RCS? 3) Information on initiatives organised to promote/explain the NEPSI SDA (Social Dialogue Agreement); 4) Can you give an estimate of the number of employees covered by the report compared to the total workforce in the sector? 5) Any other comments.

The analysis of the comments provided in the qualitative textbox of the NEPSI Reports has shown that there is a lack of common understanding of the questions and that the added value of this exercise is questionable. Indeed, in most cases, the question may be too broad, which leads to different interpretation so that data is not comparable across sectors at EU level. For example, regarding the question on 'Information on initiatives organised to promote/explain the NEPSI Agreement', some organisations report that:

- *"training has been organised in the cement companies" or that*
- *"most of companies organise events to inform and train the employees on a regular basis".*

The first sentence on training does not provide any information on the number of training events organised, the attendance rate and the profile of the attendees (SMEs or large companies), whether they were targeted at the NEPSI Agreement or only a module of a broader training on health and safety. In the second sentence concerning the regular events organised to inform and train employees, little information is provided, making it impossible to understand whether these measures were actually initiatives organised to promote the NEPSI Agreement.

Some national NEPSI members recognised that the qualitative information would be an invaluable source to put quantitative data into context. However, qualitative information is separate from quantitative information and makes it difficult to interpret the numbers extracted from the NEPSI reporting. For instance, a reduction in the number of sites can be seen for a particular organisation from a particular country in the National Reports. One would assume that this is due to a lack of involvement of the national association or discouragement from sites. However, the qualitative information available can indicate that sites have canceled their membership to the national association, which explains the fall in the number of sites reporting. Nonetheless, this information is not available in the National Reports and the reader would have to consult the Summary report to get the necessary information which is not always sufficiently detailed.

Overall, qualitative questions lack detail for most of the organisations and therefore cannot be used.

8 Impact of the Agreement

This study attempted to assess the effectiveness of the Agreement through the following evaluation questions:

- Are the implementation mechanisms suitable to meet the objectives of the Agreement?
- To what extent is the Agreement effective in improving working conditions, health and safety at the workplace?
- To what extent are the other mechanisms in place in the Member States to regulate exposure to crystalline silica effective in providing employers and workers with a framework to identify and prevent or manage problems related to exposure to RCS?
- To what extent the implementation of the Agreement has contributed to the achievement of the Union objectives with regard to occupational health and safety?

8.1 Theoretical framework of changes expected by the implementation of the NEPSI Agreement

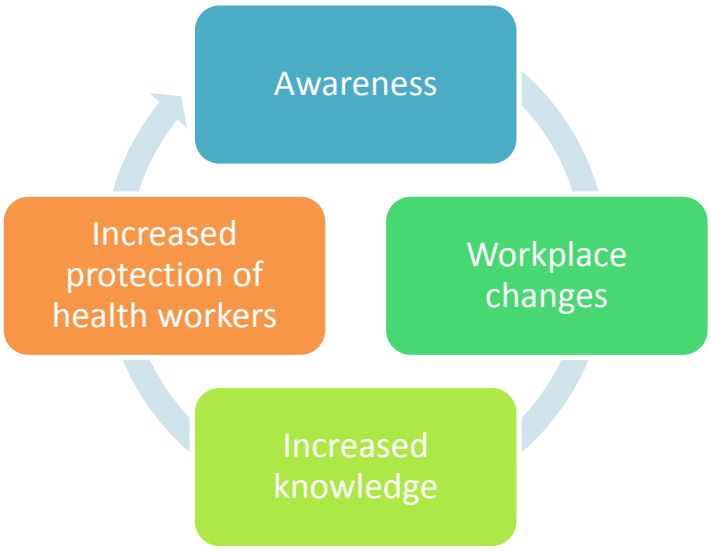
The impact of the Agreement, and the assessment of results achieved, need to be measured against the background of the original intention and its intended goals. Therefore, to disentangle the impact of the NEPSI Agreement at different levels, it is important to reiterate its original objectives, which relate to the protection of workers exposed to RCS by minimising exposure by applying the Good Practices annexed to the Agreement and increasing the awareness of workers of the risks of exposure to RCS and Good Practices.

Objectives of the NEPSI Agreement as per Article 1:	**Protection of health of employees** and other individuals occupationally exposed at the workplace to RCS from materials/products/raw materials containing crystalline silica **Minimisation of exposure** to RCS at the workplace by **applying the Good Practices** stipulated in order to prevent, eliminate or reduce occupational health risks related to RCS **Increasing the knowledge** about potential health effects of RCS and about Good Practices

The figure below provides a schematic representation of the overall approach of the NEPSI Agreement on the basis of its objectives and monitoring system in place.

The first step requires raising awareness of the risks of RCS, followed by raising awareness of the importance of – and providing tools for - risk assessment. Once risk assessments are carried out, employers can be more aware of the potential hazards to their workers from exposure to RCS. On this basis, workplace changes can be implemented, including dust monitoring, health surveillance procedures, implementation of the Good Practices and training. This will then lead to an increased knowledge of the risk and control methods through a better assessment of the presence of the risk, better knowledge of the effect of exposure to RCS, improved knowledge of specific preventive measures and risk control. The ultimate outcome is increased protection of worker's health by minimising exposure to RCS, overall improvement of risk management strategies and improved workplace health and safety conditions.

Figure 8.1 Theoretical framework of changes expected by the implementation of the NEPSI Agreement



Source: ICF

Evaluating the impact of the Agreement requires a clear understanding of how the Agreement is intended to drive change in terms of expected outputs and outcomes (short-intermediate and long-term outcomes). Immediate changes such as organisational changes in workplaces and training, as well as short-term outcomes such as increased awareness and improved safety culture are key factors to drive long-term outcomes such as improved health of workers and reduced work-related illnesses.

In workplace programmes aimed at improving health and safety conditions, some tangible outputs and changes are essential to ultimately achieve the goal of safer workplaces and workers' health. These are:

- **Knowledge and assessment of the risk** i.e. whether organisations and workers are aware of the possible risks and whether these are properly assessed,
- **Implementation of a safety management** strategy,
- **Workplace safety culture and behaviour of people in workplaces** i.e. the way organisations and workers approach health and safety issues,
- Implementation of **changes to workplace procedures** to improve safety and health conditions, and
- **Promotion of knowledge and awareness raising activities** in workplaces.

In the context of the evaluation of the NEPSI Agreement it is critical to bear in mind that the Agreement is not a legislative measure and is not intended to lead to changes in national legislation. Rather, it isan instrument designed and implemented by industry organisations and intended to promote changes directly in workplaces in accordance with existing national regulations and requirements. Therefore, this evaluation did not expect any impact of the Agreement on national legislation.

The NEPSI Agreement is an autonomous voluntary agreement and therefore not binding i.e. Member States do not have the obligation to enforce it. However, the principles of the Agreement are binding to its signatories, committed to implement the Agreement.

With this background in mind, the assessment of the impact of the NEPSI Agreement looks at expected changes in workplaces as well other potential outcomes taking into account the

national context and relevant parallel developments in technologies and legislation. The table below summarises the approach to the evaluation.

Table 8.1 Summary of potential changes expected from the implementation of the Agreement

Level of impact	Expected direct impact of the Agreement in accordance with the objectives of the Agreement	Potential indirect impact of the Agreement
Workers	■ Increased knowledge of NEPSI Good Practice ■ Implementation of and compliance with different work processes/equipment to meet good practice standards	■ Increased protection of health of employees ■ Reduced risk of ill health absence ■ Reduced cost of health care/rehabilitation (where this is borne by individuals) ■ Reduced cost of retraining ■ Improved quality of life as a result of improved long-term health prospects
Workplace	■ Improved methods for measuring exposure ■ Reduced exposure to RCS ■ Improved working conditions, health and safety at the workplace	■ Reduced work-related illnesses resulting from exposure to RCS ■ Reduced sickness absence due to work-related illnesses resulting from exposure to respirable crystalline silica ■ Reduced cost resulting from work related absences and potential legal action ■ Reduced costs of occupational health insurance systems ■ Reduced costs of retraining or replacing staff
National context	■ Increased compliance with national legislation and/or guidance	■ Creation of other tools aimed at protecting from exposure to crystalline silica (identify, prevent or manage problems related to exposure) such as good practice guidance; measures to reduce exposure, personal protective equipment; training etc ■ Changes in case law in relation to exposure to crystalline silica ■ Changes in compensation schemes for recognised diseases linked to exposure to crystalline silica ■ Changes in enforcement priorities ■ Changes in enforcement procedures and exposure measurement regimes ■ Improved compliance procedures (e.g. inspections, fines) ■ Recognition of occupational diseases linked to exposure to crystalline silica ■ Reduced cost for health, care and benefit system which result from ill health, workplace absence, disability or unemployment

Source: ICF

The following sections provide information on the impact of the Agreement gathered via interviews with national stakeholders i.e. NEPSI members (national organisations and

companies), Labour Inspectorates and experts; an online survey carried out across sites of companies that are part of the NEPSI network; data from the NEPSI monitoring system.

Relevant findings by industrial sector are presented taking into account two key methodological factors: the confidentially of the source with reference to the interviews with NEPSI members (national associations and companies) and the precision of the outcome. A number of factors impact on the outcomes of different sectors. Sectors are significantly different across countries, for example the mining sector differs in each country in relation to the size and type of companies, the size of the industry and the nature of extractive industry, the industrial relations setting in which companies operate, the national legislative framework and other country specific settings. Other factors possibly driving the outcomes by sector include the commitment and stability of the NEPSI member organisations at national level. For example, in some cases the person in charge of the NEPSI network in the national association has been involved in the Agreement since early stages, including the design of the Good Practice guidance and the translation. In these cases, therefore, there is a high level of commitment and knowledge in supporting the implementation of the Agreement.

Additionally, when looking at the trends across years from NEPSI data it is important to bear in mind that the network has evolved since 2007. Therefore, changes in trends could be driven by dynamics such as national associations entering or leaving the network (e.g. some associations left the network because companies in the industry did not deal with silica or the risk of exposure was assessed as non-existent), and different level of accuracy[137] in the reporting across years also impact on results by sectors. Therefore, presenting a comparative assessment by sector or countries would be misleading and inaccurate.

The study included an online survey of employer and employee representatives to gauge the effects of the Agreement at company and site level. The online survey investigated whether the Agreement has had an impact at site level on the protection of workers exposed to RCS; minimising exposure to RCS at the workplace by applying the Good Practices to prevent, eliminate or reduce occupational health risk related to RCS; knowledge of potential health effects of RCS; and, the extent to which the Agreement has contributed to improve the health and safety conditions at the workplace. Interviewees were asked to disseminate the survey to their members (where the NEPSI member was a national association) or to their sites (where the NEPSI member was a company with multiple sites). Employers and managers were asked to forward the online survey to employee health and safety representatives or trade union representatives, however the majority of responses were provided by representatives of the employer side, only 1% of respondents coming from health and safety representatives in trade union organisations. The respondents indicated that they represent companies located in 15 Member States, with two-thirds of responses coming from companies located in five countries: the UK (18%), Spain (15%), France (13%), Italy (11%), and Germany (10%).

8.2 Impact on workplaces' health and safety management

The awareness and knowledge of and accurate assessment of risk is the first step towards a safer workplace. Likewise, making changes to the physical environment, to work procedures and management strategies as well as monitoring strategies are key factors to ensure a sustainable and consistent protection of workers.

Therefore, the evaluation looked at the workplace changes that the NEPSI Agreement envisages in its strategy and the extent to which workplace changes have been implemented in companies. These changes include:

[137] For example diverse interpretation of indicators, the reporting of sites with/without risk of exposure, the reporting employees potentially exposed etc…

- Risk assessment procedures
- Dust monitoring and changes in methods to control workplace exposure to RCS
- Health surveillance
- Implementation of Good Practices
- Implementation of different work procedures/management processes/equipment (including collective and personal protective equipment) to meet the good practice standards
- Training and awareness raising activities

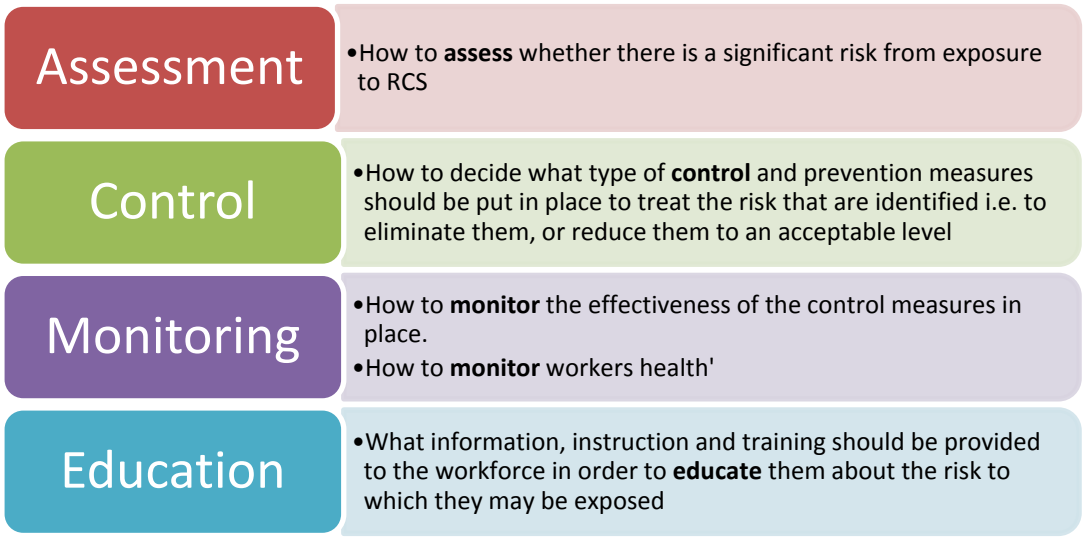
8.2.1 Risk management strategy, risk assessment and dust monitoring

The NEPSI Good Practice Guidance begins with a section on risk management and risk assessment to guide employers towards a better assessment of the presence of risk of exposure in their workplace and its overall management. The Good Practice document specifies that it provides guidance on assessment, control, monitoring and education.

8.2.1.1 Overview of risk management strategy

The figure below visualises the risk management process as it is presented in the guidance document. The risk management process recommended by the Agreement follows the general principles of international and national risk management approaches to control workplace risks, tailored to the risk of exposure to RCS. The first stage of implementing a risk management strategy requires identifying the hazards; in this specific case the Agreement provides practical guidance to assess the risk of exposure to RCS i.e. whether there is a risk of exposure and the level of risk. The control stage relates to the assessment of the steps that need to be taken to control the risk identified (i.e. develop safe working procedures, engineering controls, provision of personal protective equipment, etc.) which measures are already in place and gaps. Keeping a record of the results of the risk assessment and the measures taken is a key factor in risk management procedures that allow employers to monitor the effectiveness of the measures in place and the impact on workers. Therefore, monitoring the exposure to RCS allows employers to assess whether the measures are effective and the risk is consistently under control. Implementing health surveillance procedures is also crucial to monitoring workers' health. Education of managers and workers on the risks of exposure to RCS as well as measures needed to control the risk is a central element of the risk management strategy of the NPESI Agreement.

Figure 8.2 Risk management process of assessment, control, monitoring and education



Source: NEPSI Good Practice Guide

The NEPSI risk management strategy (Figure 8.3) summaries steps and responsibilities of both employers and employees, to ensure a comprehensive approach to risk control of exposure to RCS. Employers have the duty to perform risk assessment, measure exposure, provide the right equipment to control the risk, provide information and training and health surveillance. However, employees are also responsible to cooperate with the employer, to contribute to the risk assessment, to follow safe working procedures, attend training, wear the protective equipment as well as communicate problems to the employer.

Noticeably, the risk management strategy highlights for employers the importance of ensuring a good involvement of employee representatives and the responsibility of taking into account all types of employees (i.e. contractors, temporary, fix term contracts, agency, students on work experience, young people and new employees).

Figure 8.3 Summary of NEPSI risk management strategy

Source: NEPSI Good Practice Guide

Interviews with NEPSI members, both with employer organisations at national and European level and companies, confirmed that the **NEPSI Agreement has helped employers to**

implement a more coherent risk management strategy to control the risks of exposure to RCS. Companies interviewed reported that NEPSI protocols have been integrated into existing company procedures. Most companies already had control measures in place; however, the NEPSI Agreement triggered the implementation of additional steps (e.g. regular monitoring, specific training, managers' attitudes) needed to implement and improve their overall health and safety management strategy.

8.2.1.2 Exposure risk

A risk management strategy requires first and foremost knowledge of the potential risk and assessment of the level of the risk in the workplace. The risk management strategy in the Good Practice Guide starts with an initial assessment to determine whether there is a significant risk of exposure to RCS in the workplace. The NEPSI website and documents of the Agreement specify that *"the risk assessment procedure is a requirement of the NEPSI Agreement which must be performed regularly so as to help determine which measures or good practices to apply if needed and to ensure continuous improvements*".

Through the process pictured in the flow chart below (Figure 8.4) employers are asked to estimate the number of employees working on the site and potentially exposed to RCS.

Figure 8.4 Flow chart to carry out initial assessment to determine significant risk of exposure to RCS

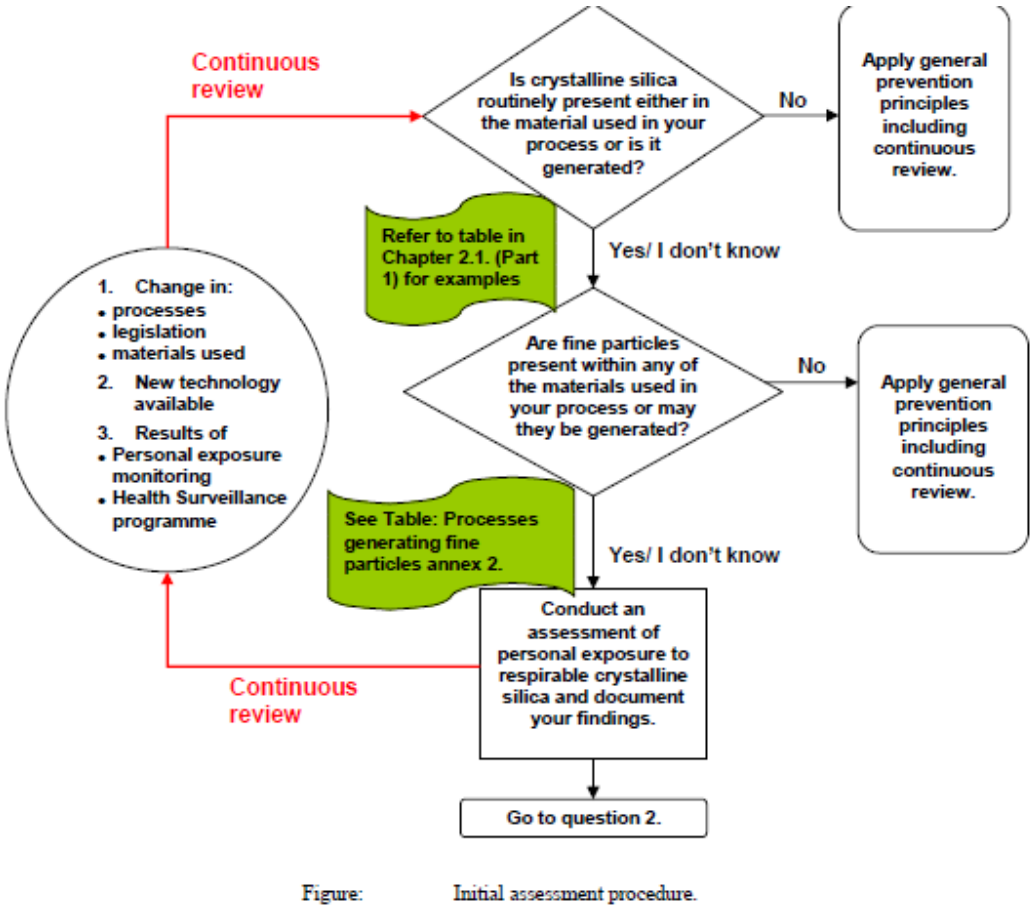


Figure: Initial assessment procedure.

Source: NEPSI Good Practice Guide

Following the flow chart presented above, employers estimate the number of employees potentially exposed to RCS. NEPSI data show that over the years there has been an overall

increase of the number of employees potentially exposed to RCS (Figure 8.5). **This increasing trend, together with the increasing number of sites reporting to the system, demonstrate that over time, a greater number of companies could be encouraged to join the NEPSI reporting system**, **therefore covering a greater number of employees potentially exposed.**

From interviews with companies and employer organisations it appears that companies implementing the NEPSI risk assessment procedure reported improvements in their ability to assess the risk of exposure and monitor the number of employees exposed to RCS. This was because the NEPSI Agreement provides guidance to conduct risk assessment specifically to assess the risk of exposure to RCS, whereas national legislations include broad provisions to conduct generic risk assessments in workplaces.

Additionally, the NEPSI Agreement to some extent also captures companies that would not follow national regulations on RCS and carry out a specific risk assessment for exposure to RCS, due to a lack of assessment of the risk. For example, a company reported that following the risk assessment as indicated in national legislation the risk of exposure to RCS had not been identified in some sites/work processes since the national legislations contained generic provisions on risk assessment. This is true mainly for those companies that do not have a high risk profile in relation to exposure to RCS and in countries where there is no legal obligation to carry out dust monitoring and/or monitoring of RCS. In all countries there is a legal requirement to carry out workplace risk assessment which arises from the European health and safety framework, but specific risk assessment on exposure to RCS is not carried out systematically across sectors and companies, specifically in companies where handling of silica is not part of the core business. Other companies, where the use of silica is part of the core business but where work-processes are performed in a closed environment – and as a result it appears that no workers are exposed - have spotted gaps in their risk assessment thanks to the implementation of the NEPSI risk assessment. For example, one company interviewed in the Netherlands explained that the presence of workers potentially exposed to RCS (i.e. cleaners and maintenance workers) has been identified in storage places only after the specific risk assessment of the NEPSI Good practice guidance was carried out. Another company in the UK reported that, although they intended to take action on managing exposure to dust, prior to the NEPSI Agreement the dust was seen as dust, now it is recognised as toxic and personal exposure monitoring is undertaken. The company acknowledged they were not aware of the national legislation and it was the Agreement which brought the risk associated to silica to their attention.

Also in Spain it was reported by NEPSI members that the Agreement has played a crucial role in helping companies detect problems at site levels, including risk of exposure as well as faults in the management system.

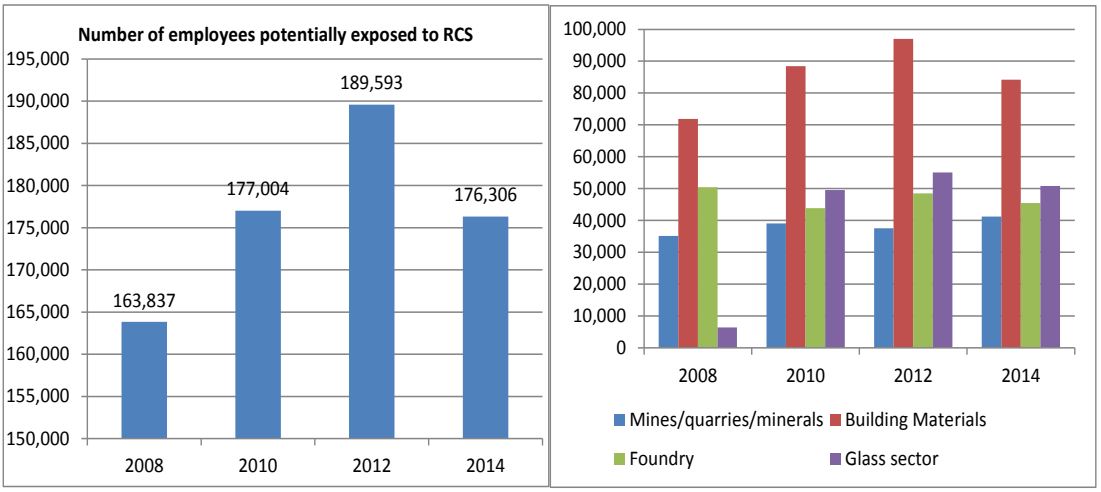
Notably, companies with a high risk profile of exposure to RCS already implement specific risk assessment as per national regulations and in many countries exposure monitoring is carried out regularly in accordance with national regulations and/or for insurance reasons. Furthermore, around 30 members of associations affiliated to IMA-Europe implement a dust monitoring protocol, which provides precise data on number of employees exposed. Therefore, it is not possible to provide estimates on the share of companies that have implemented new risk assessment procedures specifically to assess the number of employees potentially exposure to RCS. Nevertheless, **companies interviewed reported the implementation of more consistent industrial hygiene monitoring programmes by following the principles of the NEPSI Agreement.**

Overall, the NEPSI system has identified that in 2014 more than 176,000 workers are potentially exposed to RCS. The initially increasing numbers (between 2008 and 2012) can be explained through the addition of new members and companies to the system and/or better assessment. However, it is not straightforward to explain the decline experienced

between 2012 and 2014. This could be related to the exit of companies from the NEPSI network, for example, the building materials sector has been particularly affected by the economic crisis and many companies have closed or are no longer affiliated to the national organisation. However, as will be shown below, the survey of companies carried out as part of this study also indicates a decline in numbers of workers exposed (see section 8.2.1.4).

Problems of inconsistency in the interpretation of the indicator on the number of employees potentially exposed have been identified. The guidance on reporting explains that potentially exposed employees could include, for example, maintenance workers, transport workers, employees in internal laboratories, receptionists, health and safety managers, office employees at site level etc. In practice, some companies include only workers directly exposed to RCS, other companies also include administrative workers at the site. In some cases, only employees of the site are included in others also sub-contractors that work at the site, etc.

Figure 8.5 Number of employees potentially exposed to RCS



Source: NEPSI reports (data do not include voluntary reporting)

8.2.1.3 *Risk assessment, dust monitoring and exposure control measures*

The second step required by the NEPSI Agreement to identify and assess risk is the risk assessment and dust monitoring process. The NEPSI Agreement contains a Dust Monitoring Protocol (Annex 2) which "*is intended to be used by any company that wishes to carry out occupational exposure assessment in order to measure dust exposure levels at the workplace. … The requirements are more applicable for companies with no representative data on dust exposure levels. For the other companies (for example with valid database or implementing a similar dust monitoring protocol for a long time) a lighter version of this protocol (with no need to comply fully with all the requirements) can be applied".* The chart below (Figure 8.6) is the scheme provided in the NEPSI Good Practice guidance to support employers in the assessment of personal exposure to RCS. The chart also mentions that if employers already carry out dust monitoring then they are expected "*to make detailed notes of the dust control measures already in place in the workplace".* In this respect it is important to reiterate that the NEPSI Agreement is intended to be implemented in accordance with national regulations. The NEPSI Agreement requires carrying out personal exposure monitoring and recommends as guidance the EU standards EN 689 and EN 1232[138]. The

[138] EN 689: Workplace atmospheres-Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, 1995, CEN.

flow chart of risk assessment and dust monitoring requires comparing the results of the dust monitoring to the relevant exposure limits, thus highlighting the importance of complying with national regulations and maintaining low levels of exposure.

In accordance with the recommendations of the Agreement, employers should review their exposure values every two years in line with the two-year cycle of reporting. **The regular review of the dust monitoring data and the two-year reporting cycle has been reported by NEPSI members as a fundamental part of the Agreement, which allows employers to check their progress, find gaps and regularly address this topic with managers and employees. Also Labour Inspectorates and experts agree that the regular cycle of reporting is a key factor in keeping the focus on the topic of the risks of exposure to RCS.**

EN 1232: Workplace atmospheres-Pumps for personal sampling of chemical agents-Requirements and test methods, 1997.

Figure 8.6 Flow chart to assess personal exposure levels to RCS (risk assessment and dust monitoring)

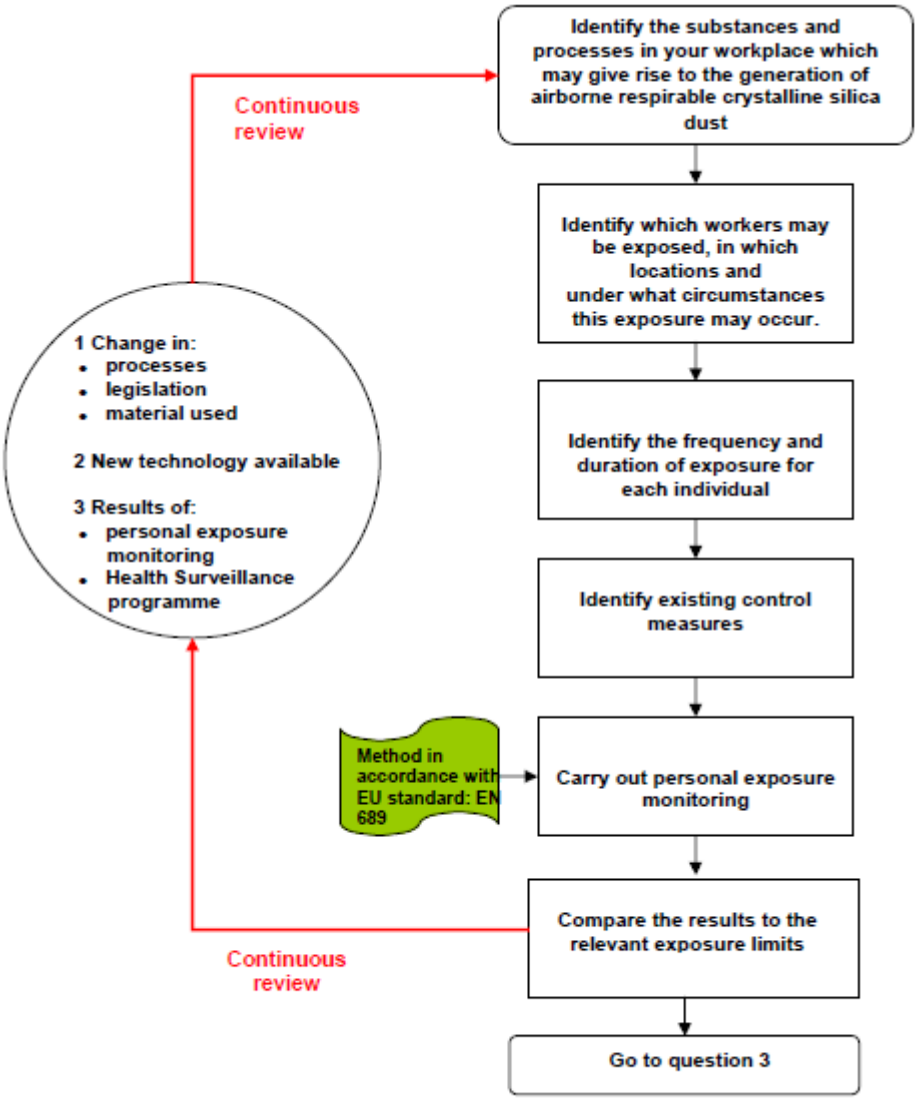


Figure: Assessment of personal exposure levels to respirable crystalline silica.

Source: NEPSI Good Practice Guide

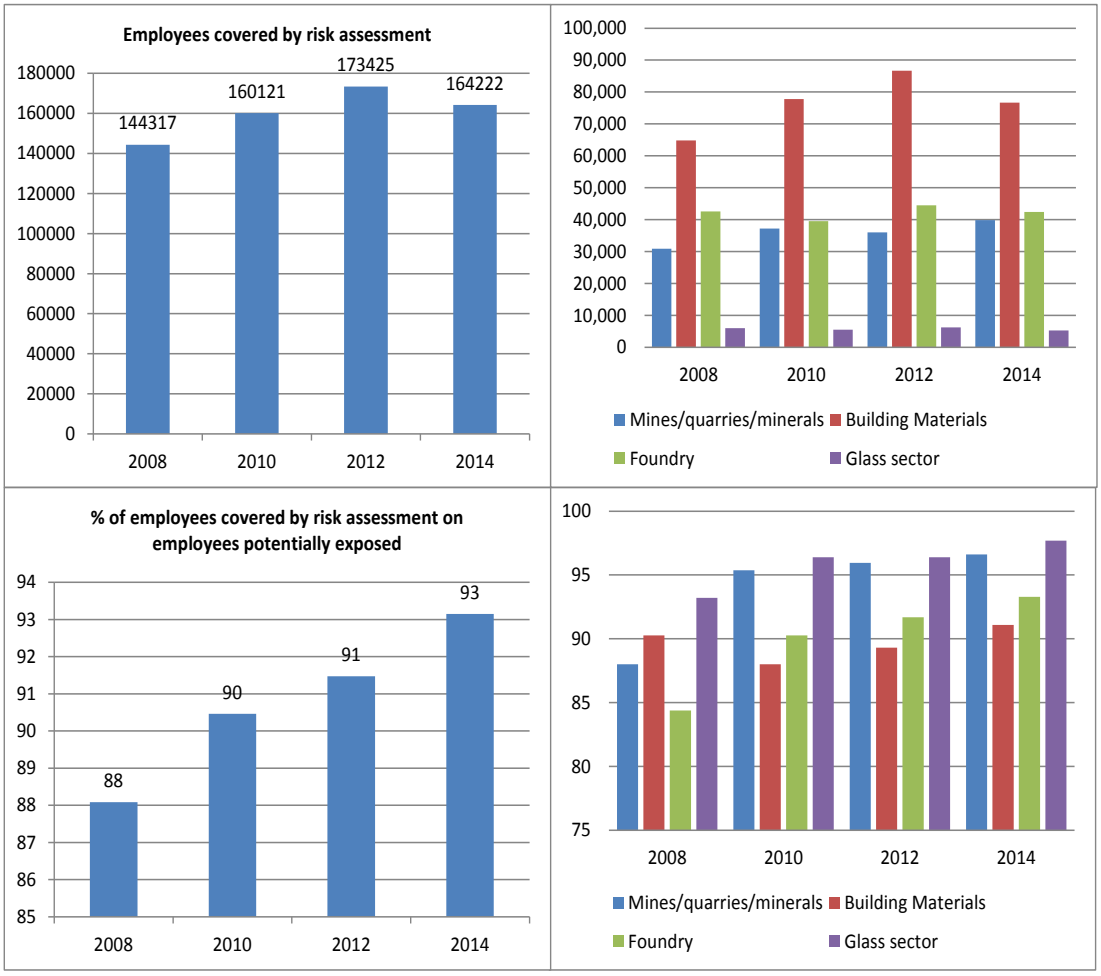
Results of the assessment of personal exposure level are recorded in the NEPSI reporting system under the indicators 'number of employees covered by risk assessment' and 'number of employees covered by exposure monitoring', these indicators are measured in relation to the number of employees potentially exposed to RCS.

The figures below (Figure 8.7) show that, among the number of employees potentially exposed to RCS, an **increasing number of workers has been covered by risk assessment of personal exposure levels**. Although this overall trend is also visible across sectors, a certain degree of fluctuation exists. The reasons for this variation are not easy to disentangle. They can be related to the exit of companies from the NEPSI network (including the reduction of number of companies due to the economic crisis), to the fact that some companies with no risk of exposure implemented this process in the early years of the Agreement but they now no longer report, or inconsistent interpretation of this indicator

throughout the years (i.e. different people reporting from the same company in different years interpreted the indicator differently).

Despite inconsistencies in reporting for the above-mentioned reasons, **there is a clear and consistent trend in the proportion of employees potentially exposed to RCS and covered by the risk assessment. Overall, the proportion of employees covered by risk assessment increased from 88% in 2008 to 93% in 2014. In the glass sector, 98% of employees are covered, in the mines/quarries and minerals 97%.** The sector building materials has the lowest percentage of coverage (91%). According to the NEPSI guidance on reporting, ideally the number of employees covered by risk assessment should be equal to the number of employees potentially exposed to RCS.

Figure 8.7 Number of employees covered by risk assessment and percentage of employees covered by risk assessment on employees potentially expose to RCS



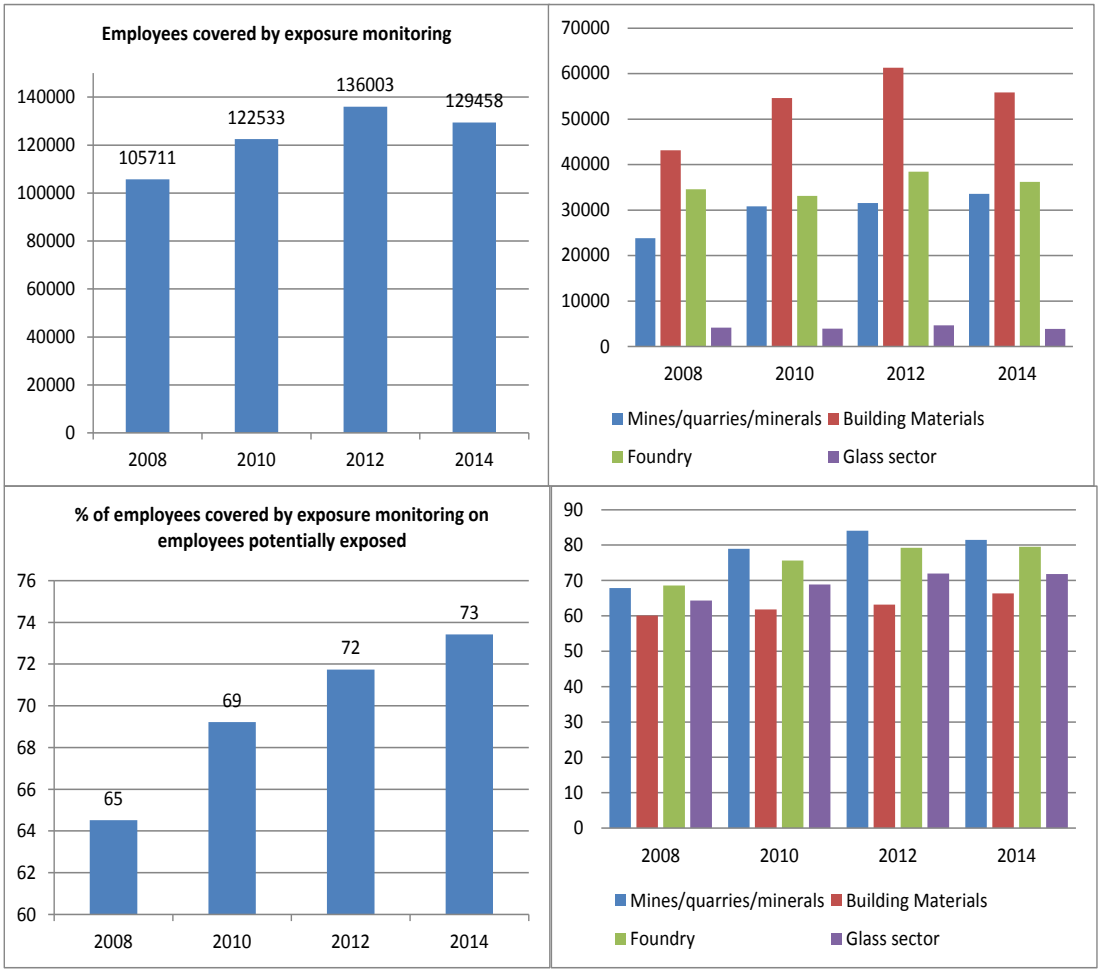
Source: NEPSI reports (data do not include voluntary reporting)

The second outcome of the assessment of the personal exposure levels should be a clear identification of the number of employees covered by exposure monitoring. According to the NEPSI guidance on reporting, employers are required to report '*the number of employees for whom the dust exposure monitoring data is available*', the guidance also states that '*if a representative sample of employees within a job function is monitored, then you can state that all employees with that job function are covered (it is not necessary for every individual employee to have worn the sampling apparatus. Where exposure monitoring campaigns are conducted periodically (e.g. every two years) then, as long as the monitoring programme is*

not overdue, you can state that employees are covered even if no monitoring has been conducted during the reporting period'.

In 2014, more than 129,000 were covered by dust exposure monitoring procedure. This represented 73% of employees potentially exposed to RCS; across sectors the coverage ranges from 66% in building materials to 81% in mines/quarries and minerals. Over the years, an increasing proportion of employees potentially exposed to RCS had been covered by monitoring assessment, from 65% in 2008 to 73% in 2014; increasing trends have occurred across all sectors.

Figure 8.8 Number of employees covered by exposure monitoring and percentage of employees covered by exposure monitoring on employees potentially expose to RCS



Source: NEPSI reports (data do not include voluntary reporting)

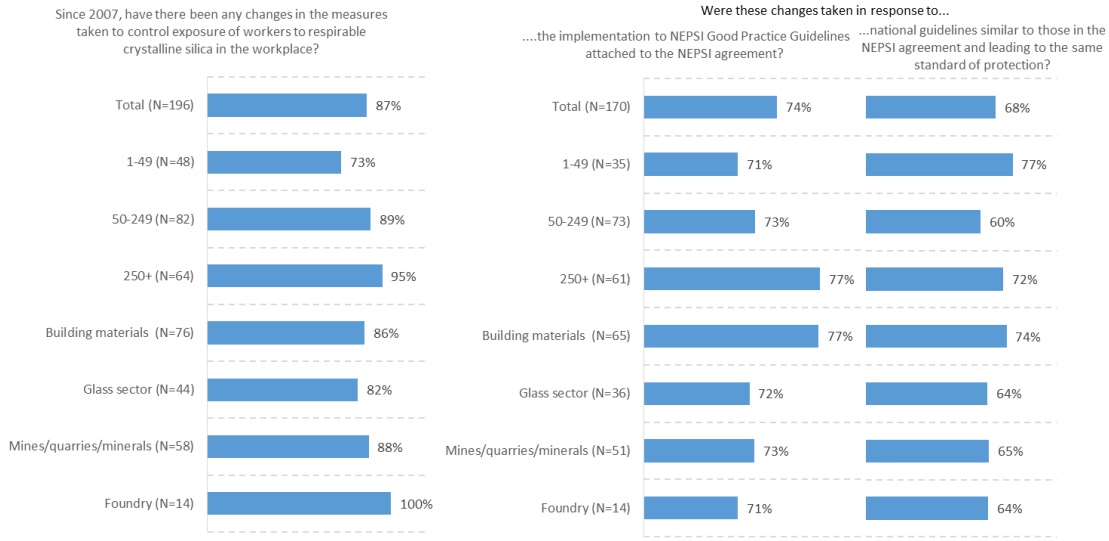
Again, it should be noted that in many countries companies carry out exposure monitoring irrespective of the NEPSI Agreement i.e. to comply with national legislation and/or for insurance reasons. From interviews with NEPSI members, labour inspectors and experts it **emerged that this is an area where the NEPSI Agreement has prompted employers to do it more consistently and has provided an harmonised method of sampling where national indications were not available.**

The online survey carried out among companies confirms these findings. Since 2007, the majority of companies **(87%) introduced changes to the measures taken to control the exposure of workers to respirable crystalline silica in the workplace** (Figure 8.9). **The majority of companies (74%) attributed these changes to the implementation to NEPSI Good Practice Guidelines attached to the NEPSI Agreement.** However, 68% of

companies also reported that these measures were taken as a result of national guidelines similar to those in the NEPSI Agreement and leading to the same standard of protection. **This confirms that the NEPSI Agreement has been operating in synergy with the national settings.**

Medium and large companies were more likely to have made changes in measures to control exposure of workers (respectively 89% and 95%), companies with more than 250 employees were also more likely to have introduced these changes in response to the implementation of the NEPSI Agreement (77%). In contrast a higher percentage of small companies, with fewer than 50 employees, more often indicated that measures were taken as a result of national guidelines (77%). From interviews with NEPSI members (at European and national level) it emerged that micro and small companies are hard to reach and difficult to commit; small companies are also more likely to implement the minimum standards required by the regulations, rather than 'going the extra mile'. Additionally, it appears that there is a lower level of awareness among small enterprises on whether some changes have been implemented because of national legislation or in compliance with the NEPSI Agreement.

Figure 8.9 Changes in the measures taken to control exposure of workers to respirable crystalline silica in the workplace

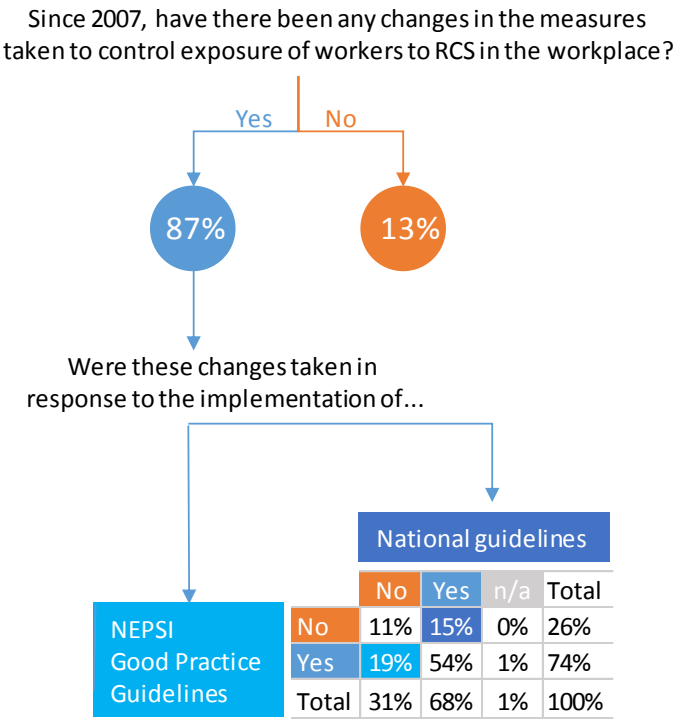


Source: ICF survey

Detailed analysis of survey results shows that **19% of employers (32 out of 170) introduced exposure control measures as a result of the implementation of the NEPSI Agreement.** These employers were more likely to work for companies employing between 50 and 250 employees, more likely to come from the foundry sector and in the mines/quarries/minerals; and more likely to be operating in Belgium, Poland and the Netherlands.

In contrast, 15% of respondents reported that changes were made due to national guidelines only similar to those in the NEPSI Agreement and leading to the same standard of protection (Figure 8.10).

Figure 8.10 Changes in the measures taken to control exposure of workers to respirable crystalline silica in the workplace



Source: ICF survey with health and safety representatives of companies in the sectors covered by the Agreement n=170

8.2.1.4 Changes in levels of exposure to RCS

The ultimate goal of the dust monitoring is to reduce levels of exposure and the number of employees exposed. Unless a statistical analysis of exposure data is carried out, it is not possible to gather statistical evidence on trends of levels of exposure. The NEPSI network does not store companies' data on exposure to RCS in a central database; therefore this evaluation is not in a position to provide statistical evidence on whether there has been a change in the exposure to RCS following the implementation of the NEPSI Agreement. Additionally, other factors are likely to contribute to the reduction of exposure levels e.g. the introduction or reduction of OEL in national legislation or new technologies.

Nevertheless, this evaluation gathered evidence that following the NEPSI Agreement, there have been improvements in restricting the level of exposure to RCS.

An independent Finnish study[139] looked into the impact of the Agreement on the exposure of workers to RCS in Finnish workplaces. The introduction of the NEPSI Agreement coincided with a new OEL value and study concluded that '***the decline in exposure cannot for the most part be explained by a decline in exposed workers or industrial activities. New technologies may contribute to the decline in exposure. However, due to time-dependency of the reported decline and the signing of the NEPSI treaty, it seems***

[139] Tuoni, T., Linnainmaa, M., Vaananen, V., and Reijula, K. Application of good practices as Described by NEPSI Agreement coincides with a Strong Decline in the Exposure to Respiratory Crystalline Silica in Finnish Workplaces

Ann Occup Hyg (2014) 58 (7) 806-817

http://annhyg.oxfordjournals.org/content/58/7/806.full

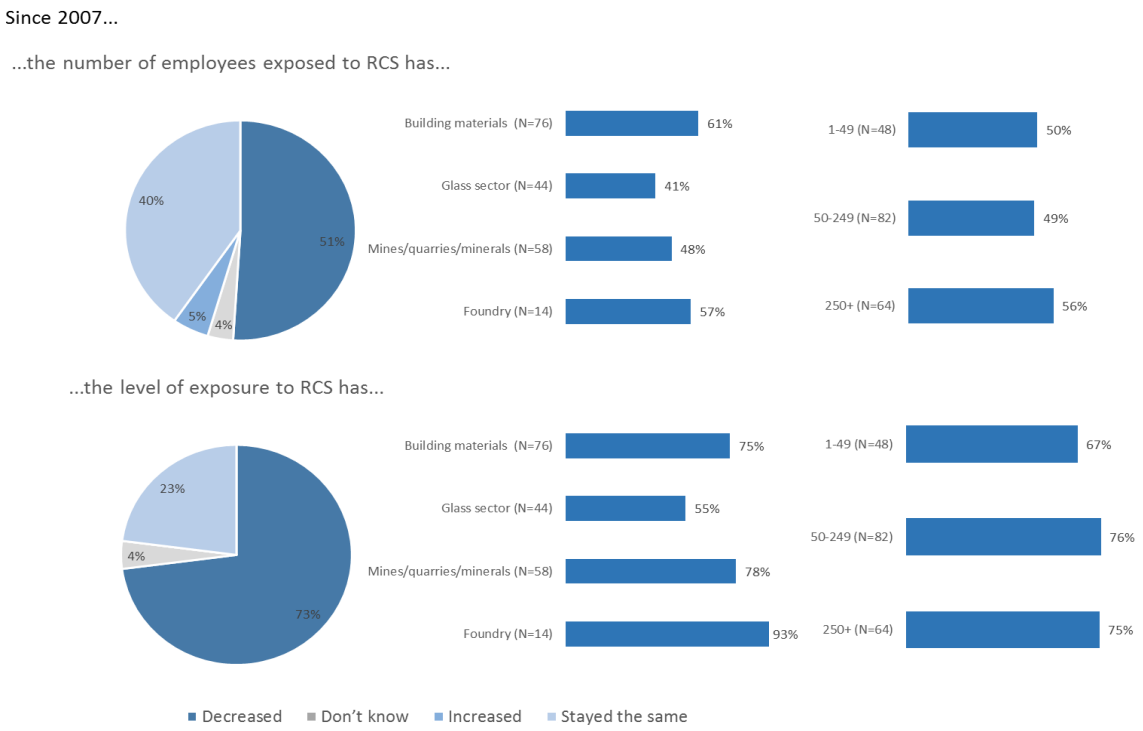
apparent that the implementation of the treaty [the Agreement] and the concomitant stipulation of a lower OEL to RCS both contributed to the decline in exposure'. The study examined exposure data gathered between 1994 and 2013, the dataset comprised 2,529 personal and static samples (taken mainly indoors), used to estimate workers' eight-hour time weighted average exposure. The samples were collected from a number of different sectors including construction, mining and quarrying, and a mixture of manufacturing activities. Embedded within the study was an additional project between 2008/09, which investigated the application of the NEPSI Good Practices in the concrete industry. The sampling results strongly supported the use of the advice in the Good Practice guidance which forms Annex 1 of the Agreement. In one plant, exposure was reduced by more than 50%, thanks to the concomitant lower OEL and implementation of the NEPSI Good Practices. The investigation revealed that samples taken between 1994 and 2003 were high, but stable. The mean was 0.11-0.42 mg/m3 and the median 0.05-0.19 mg/m3. Between 2004 and 2006, the concentrations remained high. From 2007 onwards (the NEPSI Agreement being signed in 2006), the average and median fall significantly. This also coincides with the introduction of a new lower Occupational Exposure Limit (OEL) of 0.05 mg/m3 for silica. By 2013, the average exposure was <0.05mg/m3 and the percentage of measurements, which exceeded the OEL was small, even though the new exposure level much more stringent that the previous level of 0.2 mg/m3. The expert view is that **the application of the NEPSI Good Practice guidance supported compliance with the new standards and that the two factors together, the Agreement and the lowering of the OEL were accountable for reducing exposure.**

The online survey included a question on the changes that have occurred in the level of exposure since the implementation of the Agreement. Although, this study cannot assess whether responses are always based on hard evidence i.e. whether employers based their response on real monitoring of exposure data or on the basis of subjective self-assessment; it is nevertheless a good source of information on the impact on the ground of the application of Agreement on exposure. The survey revealed that **almost three-quarters (73%) of companies participating to the online survey stated that the level of exposure to respirable crystalline silica has decreased since 2007, and 51% reckoned that there has been a decrease in the number of employees exposed to RCS**. These positive changes occurred more often in large companies with more than 250 employees.

It is worth noting that 40% of respondents did not know whether the number of employees exposed to RCS has changed over time and 23% could not provide an answer in relation to the level of exposure. This is likely to reflect a number of issues, from the difficulties in carrying out proper assessments of exposure to the fact that some companies still do not have procedures in place to measure exposure. Another factor to be taken into account is that external consultants perform the measurements therefore companies do not monitor the data as long as these are below the required OELs.

When reading these results is also important to consider that those companies responding to the online survey are likely to be the 'best performers' and more committed to the NEPSI Agreement.

Figure 8.11 Change in RCS exposure



Source: ICF survey

Interviews with NEPSI members confirmed the difficulties in gathering information on exposure trends, national organisations not storing companies' data and issues of confidentiality having to be considered in relation to exposure data at company level. However, **all interviewed stakeholders (including NEPSI members and experts) indicated that the level of exposure has decreased thanks to a number of concurrent factors, which include the implementation of NEPSI Good Practices and developments in technologies leading to cleaner working environments.**

Interviews with companies and members of IMA-Europe have reported a reduction in exposure backed up by evidence collected through the dust monitoring system implemented by these members. For example, in Germany, a reduction in exposure of around 5-7% per year was reported. IMA companies have been implementing various measures to reduce respirable dust and quarts, a pilot study commissioned by IMA-Europe in 2015[140] reports that '*the result of the IMA Dust Monitoring Programme, which has been in place since 2002 in IMA-Europe, show that this measures have resulted in an overall reduction of the exposure to respirable dust and quartz of 6-8% annually*'.

A company operating in the glass sector provided data on exposure levels from 2012 across three sites in France and Italy (Table 8.2) as hard evidence of the impact of the application of the Agreement at site level. The company argued that although high health hand safety standards were already in place before the Agreement, the implementation of Good Practices and the dust monitoring process led to a reduction in exposure levels.

[140] Report from IMA-Europe Pilot Study: Evaluation of the effectiveness of NEPSI control measures, University of Utrecht, Institute for Risk Assessment Science, 2015

Table 8.2 Company data on exposure to RCS provided by one company

Site	Local Exposure Limit value (OEL)		Year	Year	Year	Year
			2012	**2013**	**2014**	**2015**
Site 1	TLV: 0,025 mg/m3 (8h)	Ambient air batch house	0,014	0,022	0,021	
		8 hours operator monitoring	0,009	0,002	0,001	0,007
			2006	**2008**	**2014**	**2015**
Site 2	TLV: 0.05 mg/m3 (8h)	Ambient air batch house	No measures	< 0.01	No measures	Results not yet available
		8 hours operator monitoring	< 0.001	< 0.01	< 0,002	Results not yet available
			2007	**2013**	**2014**	**2015**
Site 3	TLV: 0.05 mg/m3 (8h)	Ambient air batch house	No measures	No measures	No measures	Results not yet available
		8 hours operator monitoring	0,013	0,05	0,004	Results not yet available

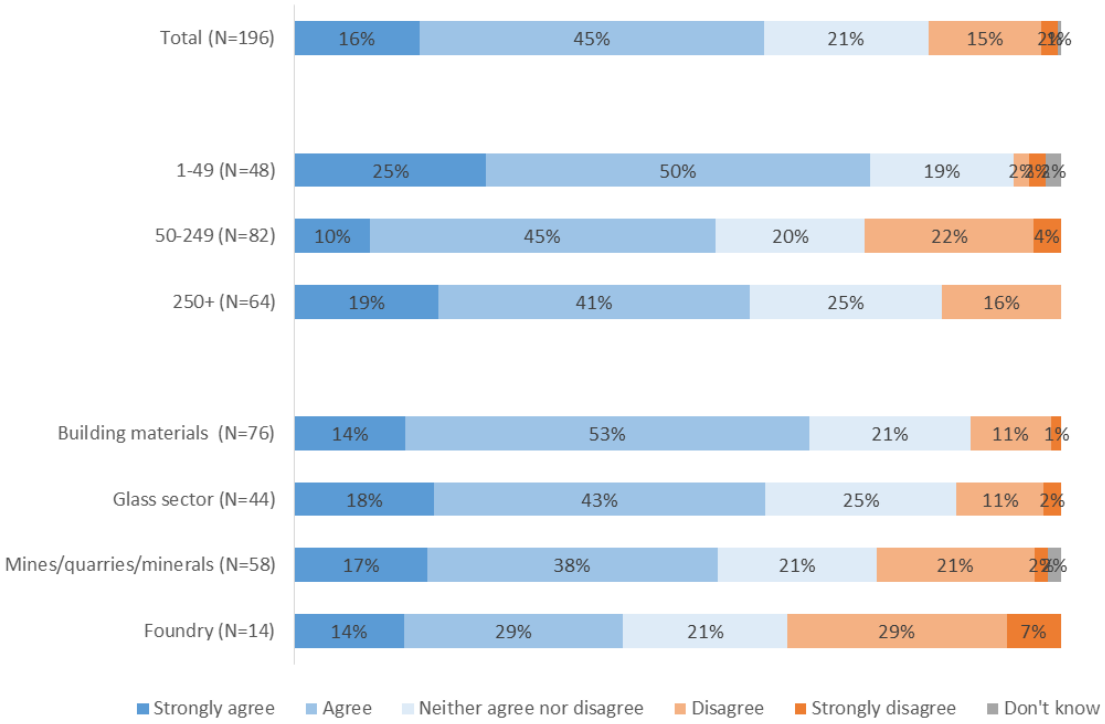
Source: data provided by company part of the NEPSI network

More than half (61%) of the companies surveyed believed that the level of exposure to respirable crystalline silica was not a problem in their workplaces. Small companies with less than 50 employees and companies in the building materials sector were more likely to state that the level of exposure was not a problem. From interviews with European and national NEPSI members, it emerged that organisations did not consider exposure to RCS as a problem. This was mainly for two reasons, either because the work processes of the industry did not involve handling of RCS, therefore the industry had a very low risk profile; or because, in those companies with high risk profile, sophisticated control measures and monitoring of exposure levels had been in place for a long time. This confirms that the NEPSI Agreement (and the survey) it is likely to capture those companies which are already committed to high health and safety standards in the workplace. This has also been confirmed by interviews with Labour Inspectorates and experts. Although it is worth mentioning that subjective views on this context may diverge; for example, another reason for not considering exposure a problem could relate to low levels of awareness of the issue (e.g. in the case of small companies) or the opposite e.g. high levels of awareness lead managers to consider the risk to be a problem even though it is under control.

Companies in the mines/quarries/minerals and foundry sector were more likely to believe that exposure was a problem. In this respect it is interesting to note that from interviews with NEPSI members in these two sectors, it emerged that in some cases the NEPSI Good Practices were not considered tailored to the foundry sector; while the small size of companies operating in the mines/quarries and minerals was considered by national

organisations to be an obstacle to reaching them and properly implementing the NEPSI Good Practices.

Figure 8.12 In this company the level of exposure to respirable crystalline silica is not a problem



Source: ICF survey

8.2.2 Health surveillance

The health surveillance of workers exposed to RCS is a crucial element of the risk management strategy. The NEPSI management strategy envisages the collection of information on: a) number of employees with risk assessment requiring health surveillance for silicosis; b) number of employees covered by generic health surveillance protocol; c) number of employees covered by health surveillance protocol for silicosis. Figure 8.13 presents an overview of the indicators related to health surveillance.

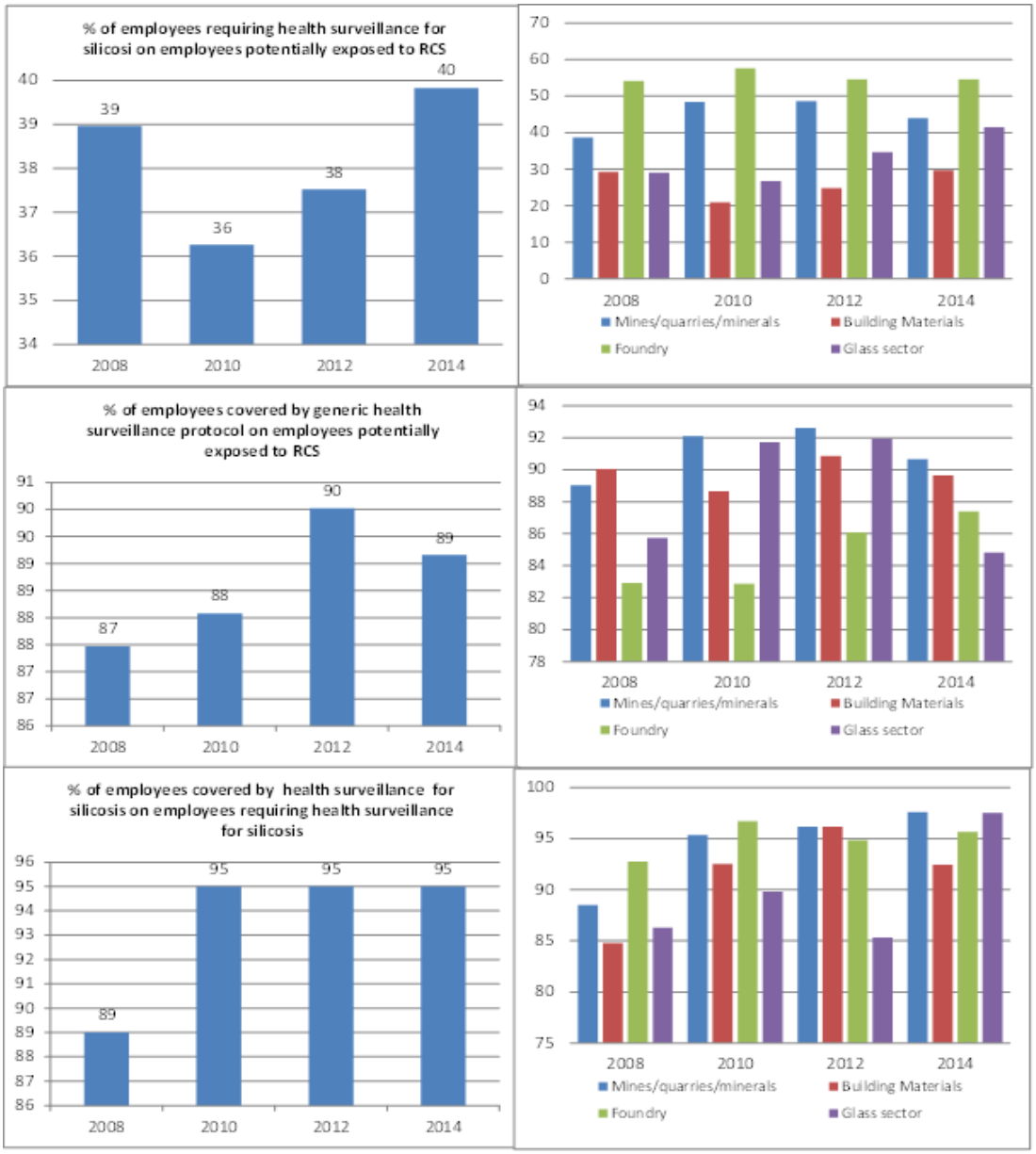
In most countries, health surveillance is required by national legislation, both generic health surveillance for all employees and specific health surveillance in case of exposure to RCS. The NEPSI reporting format for the indicator on generic health surveillance protocols also clarifies that '*target value is depending on company commitments or national laws*'.

In-depth interviews with several stakeholders have revealed that the content information collected on health surveillance is one of the most problematic to disentangle, and that whether health surveillance procedures are present in workplaces, it is likely to be unrelated to the implementation of the NEPSI Agreement. **Nevertheless, interviews with companies revealed that the Agreement has helped them to improve their health surveillance processes by implementing a more structured and planned approach. This is also in line with the objective of the NEPSI Agreement with reference to health surveillance; in the original intent of the Agreement these indicators provide an indication of the commitment of companies towards generic health monitoring or compliance with national law.**

In 2014, 40% of employees potentially exposed to RCS required health surveillance for silicosis. According to the NEPSI guidance on reporting, employers should indicate the number of employees for whom the result of a risk assessment indicated that they should be made subject to the specific health surveillance protocol for silicosis (as provided in the Annex 8 of the Agreement). However, it is not possible to disentangle whether this indicator is really the result of the risk assessment as indicated by the agreement of whether the need for health surveillance is identified according to national regulations. For example, it could be that companies with a risk of exposure are by law obliged to perform health surveillance on all their employees. The reasons for the fluctuation over time are also not clear; it could be related to different interpretation of the indicator over time. Similarly, the indicator on generic health surveillance, although the increasing trend of employees covered by generic health surveillance may indicate a better knowledge and awareness of health surveillance procedures.

Crucially, 95% of workers requiring health surveillance for silicosis were covered by the health surveillance protocol for silicosis. The improvement from 2008 (89%) is likely to indicate more awareness among employers on the surveillance procedures and/or better compliance with national legislation. This was also confirmed by interviews with NEPSI members and experts.

Figure 8.13 Indicators for health surveillance



Source: NEPSI reports (data do not include voluntary reporting)

As already discussed, all countries have national regulations on health surveillance and the Agreement main objective was to improve compliance to the health surveillance protocol existing in Member Stated. For example, in the UK, HSE has recently issued guidance on health surveillance protocols for workers exposed to RCS. Health surveillance is a legal requirement in the UK for workers where it is reasonably likely that they may develop silicosis. The guidance contains advice for medical practitioners and suitable examination record pro forma. In Italy, the NIS has published specific guidance on health surveillance in case of exposure to silica.

8.3 Management, workplace procedures and technical measures

In addition to changes to the risk assessment procedures and exposure risk management, the implementation of the Agreement generated a variety of organisational changes at

company and site level. Other critical changes to work procedures and technical equipment were made to reduce exposure.

For example, in France, one representative of the NEPSI organisation reported that new measures introduced in companies thanks to the implementation of the Good Practice Guide included the use of control cabins, new ventilation systems and sweepers. In some cases, it was also reported the substitution of silica with other materials whenever possible. Another example relates to a large company reporting that despite having already internal procedures in place, the NEPSI Good Practices made them think about new gaps in the area of cleaning. This led the company to rethink the cleaning of areas that used not to be covered by cleaning protocols, such as pallets where dust accumulates.

In Spain, organisational changes were made by establishing clearer responsibilities and tasks for each job profile. This led to a cascade of positive changes allowing companies to implement a more efficient risk assessment, identify the job profiles with a high risk of exposure, adapt health and safety protocols and introduce rotating shifts to avoid that the same workers were continuously allocated to job positions with high risk of exposure. As a result of implementing the Good Practices Guidance, interviewees also reported substitution of materials, improvements to dust cleaning processes, use of central vacuum systems, safer transport methods of materials containing RCS, and practical changes in handling powder materials at site level (e.g. cement and aggregates).

In Poland, a company reported introducing changes to risk management according to the Good Practice guidance and mandatory spirometry tests for all workers exposed to RCS.

Interviews with companies also pointed to the introduction of new signs on Personal Protective Equipment (PPE), industrial hygiene measures as well as new closed systems, additional meetings across sites on industrial hygiene practices.

A multinational company with sites across Europe also reported a more coherent approach to Total Productive Management (TPM) on cleaning and leaks. The company reported that the TPM approach provides data on equipment failing or requiring maintenance pushing the company to look for new technical solutions, thus reducing the exposure levels. Other improvements reported referred to new solutions and better supervision when unloading raw material from trucks to silos.

8.4 Training, implementation of NEPSI Good Practices and impact on workers

The main objective of the NEPSI Agreement is to increase knowledge about the potential health effects of RCS and about the Good Practices. The expected direct impact on workers and managers is therefore increased knowledge of NEPSI Good Practices, improved awareness and knowledge of issues related to RCS, methods of controlling exposure, health and safety procedures to control exposure; and potential health effects of exposure. For this medium-term outcome to occur, training and awareness raising activities need to be implemented beforehand. The other objective specifically mentioned by the Agreement is the increased protection of the health of employees.

8.4.1 Training and information, knowledge and awareness

The NEPSI Agreement envisages the collection of information about training on general prevention principles and training on the specific Task Sheets on Good Practices.

The General Prevention Principles as presented in the Good Practice guide (Figure 8.14) refer to the prevention strategy described in the Council Directive 89/391/EEC and its transposition in the general laws. The guidance note highlights that the practical application of the prevention principles in handling RCS in the workplace involves **substitution, provision of engineering controls, good housekeeping practices, work pattern, personal protective equipment and education**.

Figure 8.14 The General prevention principles as reported in NEPSI Good Practice guidance

General prevention principles

In the development of this Good Practices guide, the authors respected the prevention strategy, which is described in Council Directive 89/391/EEC and in its transposition in the national laws.

Nine prevention principles are described and one must consider the following hierarchy in the preventive measures to be taken:

- avoiding risks
- evaluating the risks which cannot be avoided
- combating the risks at source
- adapting the work to the individual
- adapting to technical progress
- replacing the dangerous by the non dangerous or the less dangerous
- developing a coherent overall prevention policy (including the provision of health surveillance of workers)
- giving collective protective measures priority over individual protective measures
- giving appropriate information, instruction and training to the workers

In the context where crystalline silica is handled in the workplace, examples of practical applications of the above principles are:

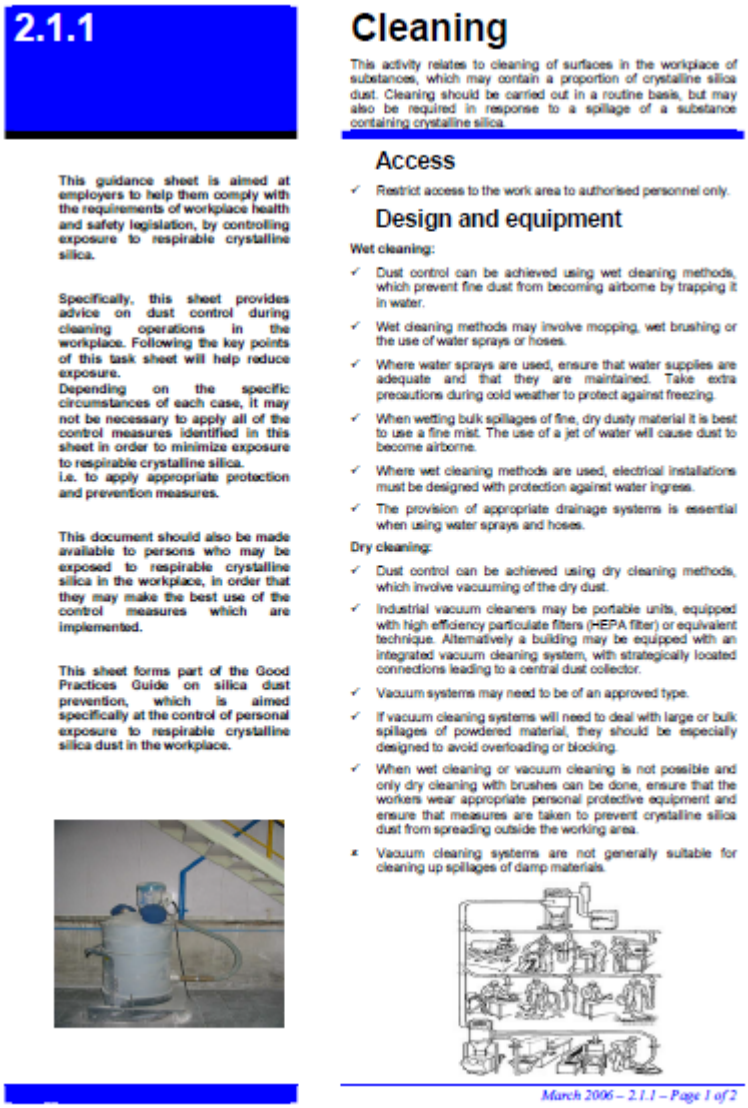
- **Substitution:** taking into account economic, technical and scientific criteria, replace a dust-generating process with a process generating less dust (e.g. use of a wet process instead of a dry process, or an automated process instead of a manual process).
- **Provision of engineering controls:** de-dusting systems (dust suppression[1], collection[2] and containment[3]) and isolation techniques[4].
- **Good housekeeping practices.**
- **Work pattern:** establish safe working procedures, job rotation.
- **Personal protective equipment:** provide protective clothing and respiratory protective equipment.
- **Education:** provide adequate health and safety training to the workers, information and instructions specific to their workstation or job.

Compliance with Member State Occupational Exposure Limits is just one part of the Risk Management process. You should additionally always ensure that you comply with the General Principles of Prevention, as defined in Council Directive 89/391/EEC.

Source: NEPSI Good Practice Guide

The Task Guidance Sheets provide detail explanation of activates to be implemented for each Good Practice. The figure below (Figure 8.15) provides an example of Task Guidance Sheet.

Figure 8.15 Example of Task Guidance Sheet in the NEPSI Good Practice guidance



2.1.1

This guidance sheet is aimed at employers to help them comply with the requirements of workplace health and safety legislation, by controlling exposure to respirable crystalline silica.

Specifically, this sheet provides advice on dust control during cleaning operations in the workplace. Following the key points of this task sheet will help reduce exposure.
Depending on the specific circumstances of each case, it may not be necessary to apply all of the control measures identified in this sheet in order to minimize exposure to respirable crystalline silica.
i.e. to apply appropriate protection and prevention measures.

This document should also be made available to persons who may be exposed to respirable crystalline silica in the workplace, in order that they may make the best use of the control measures which are implemented.

This sheet forms part of the Good Practices Guide on silica dust prevention, which is aimed specifically at the control of personal exposure to respirable crystalline silica dust in the workplace.

Cleaning

This activity relates to cleaning of surfaces in the workplace of substances, which may contain a proportion of crystalline silica dust. Cleaning should be carried out in a routine basis, but may also be required in response to a spillage of a substance containing crystalline silica.

Access

- ✓ Restrict access to the work area to authorised personnel only.

Design and equipment

Wet cleaning:

- ✓ Dust control can be achieved using wet cleaning methods, which prevent fine dust from becoming airborne by trapping it in water.
- ✓ Wet cleaning methods may involve mopping, wet brushing or the use of water sprays or hoses.
- ✓ Where water sprays are used, ensure that water supplies are adequate and that they are maintained. Take extra precautions during cold weather to protect against freezing.
- ✓ When wetting bulk spillages of fine, dry dusty material it is best to use a fine mist. The use of a jet of water will cause dust to become airborne.
- ✓ Where wet cleaning methods are used, electrical installations must be designed with protection against water ingress.
- ✓ The provision of appropriate drainage systems is essential when using water sprays and hoses.

Dry cleaning:

- ✓ Dust control can be achieved using dry cleaning methods, which involve vacuuming of the dry dust.
- ✓ Industrial vacuum cleaners may be portable units, equipped with high efficiency particulate filters (HEPA filter) or equivalent technique. Alternatively a building may be equipped with an integrated vacuum cleaning system, with strategically located connections leading to a central dust collector.
- ✓ Vacuum systems may need to be of an approved type.
- ✓ If vacuum cleaning systems will need to deal with large or bulk spillages of powdered material, they should be especially designed to avoid overloading or blocking.
- ✓ When wet cleaning or vacuum cleaning is not possible and only dry cleaning with brushes can be done, ensure that the workers wear appropriate personal protective equipment and ensure that measures are taken to prevent crystalline silica dust from spreading outside the working area.
- ✗ Vacuum cleaning systems are not generally suitable for cleaning up spillages of damp materials.

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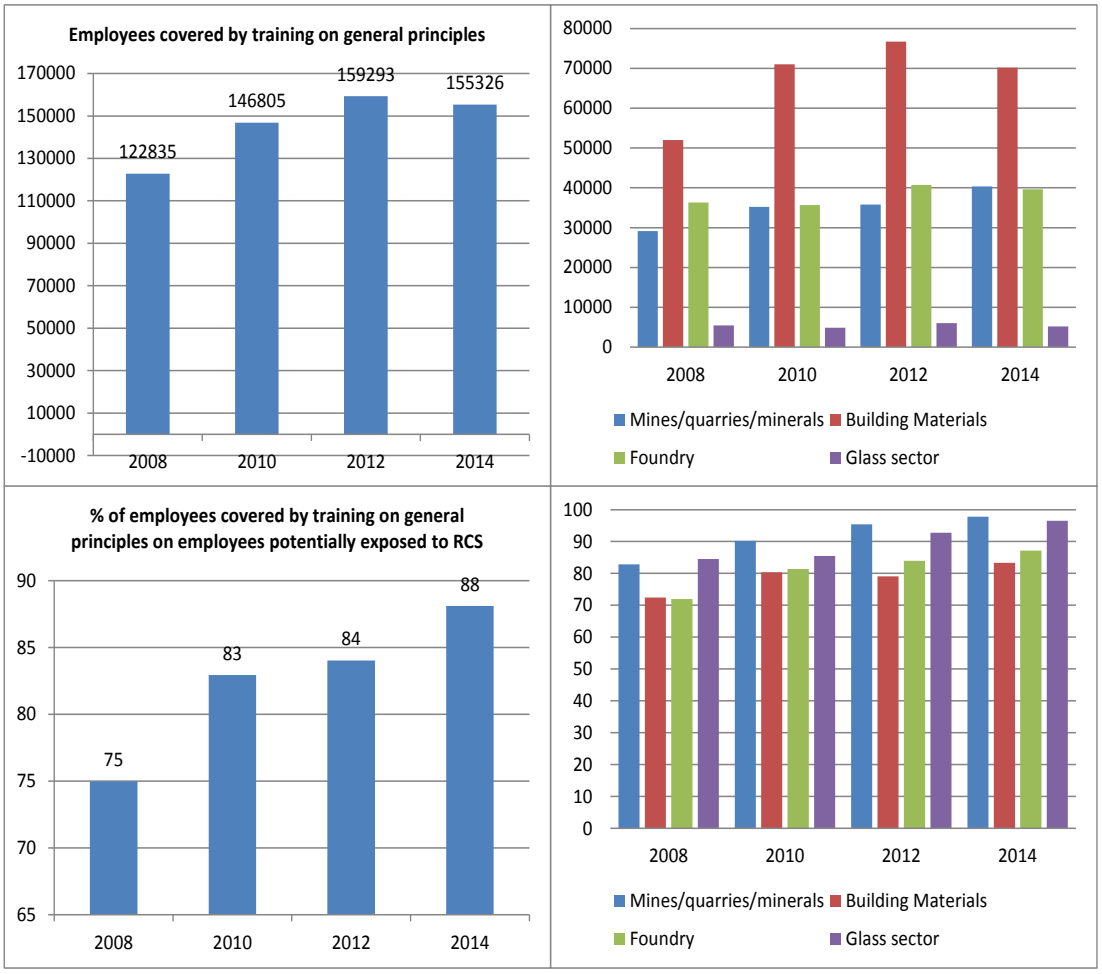
Source: NEPSI Good Practice Guide

The two indicators included in the NEPSI monitoring system are 'number of employees covered by information, instruction and training on General Principles' and 'number of employees covered by information, instruction and training on Task Sheets'. Training and information activities are deemed paramount to achieving the main object of improved knowledge and these are the activities that can be implemented and most influenced by the NEPSI network independent of national legislations and overall context. Therefore, these two indicators are vital to assessing the commitment of the NEPSI members and success of the Agreement.

By 2014, more than 155,000 employees were provided with information, instruction and training on the General principles included in the NEPSI Agreement. This constitutes more than 88% of all employees potentially exposed to RCS. The overall increasing trend from 2008, when 75% of employees received training, indicates the commitment of the NEPSI members to their main objective i.e. increasing the knowledge about potential health effects of RCS and about Good Practices. The

increasing trends by sectors show the equal commitment of NEPSI members across all industries.

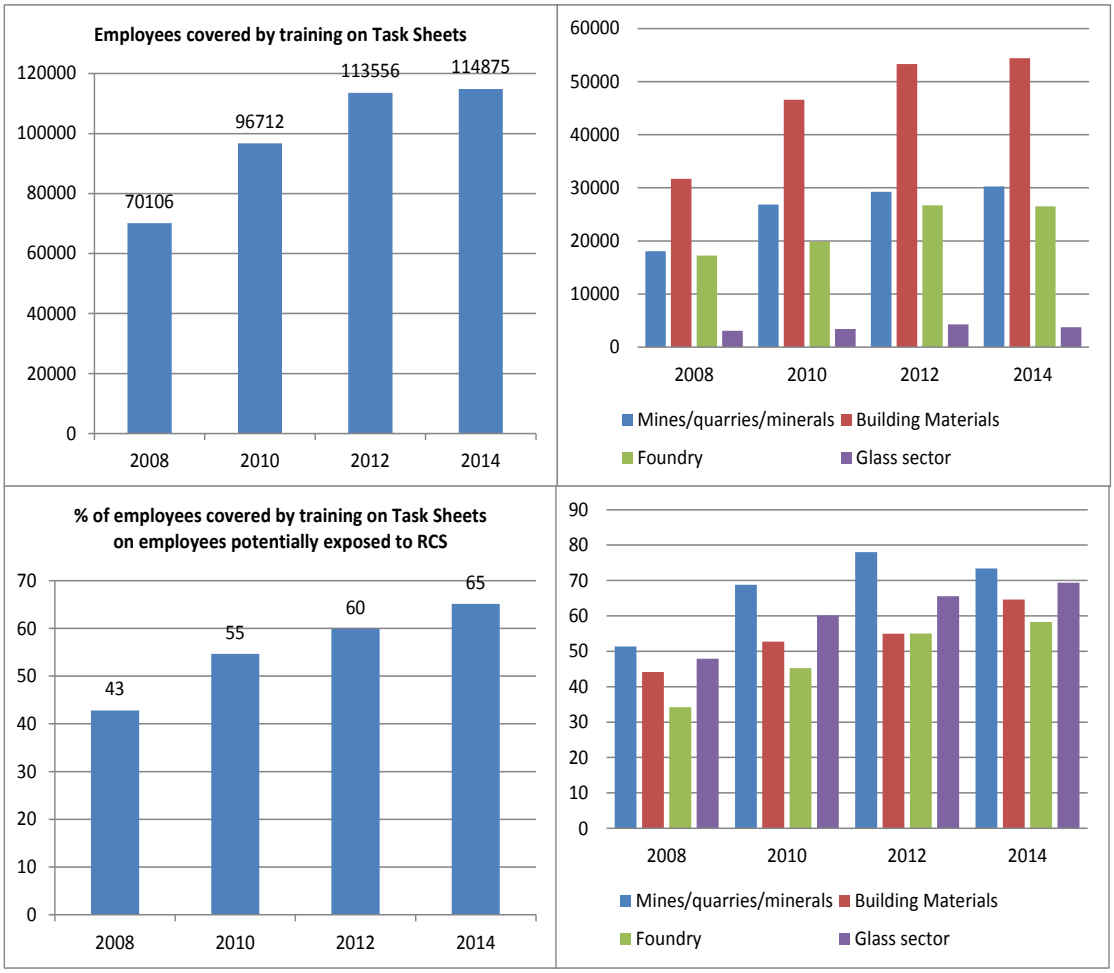
Figure 8.16 Employees covered by information, instruction and training on General Principles



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, almost 115,000 employees were covered by information, instruction and training on Task Sheets. This made up 65% of all employees potentially exposed to RCS. Consistently increasing trends showed an improvement in this indicator of more than 12 percentage points. Similarly, increasing trends are also found in all industry sectors.

Figure 8.17 Employees covered by information, instruction and training on Task Sheets



Source: NEPSI reports (data do not include voluntary reporting)

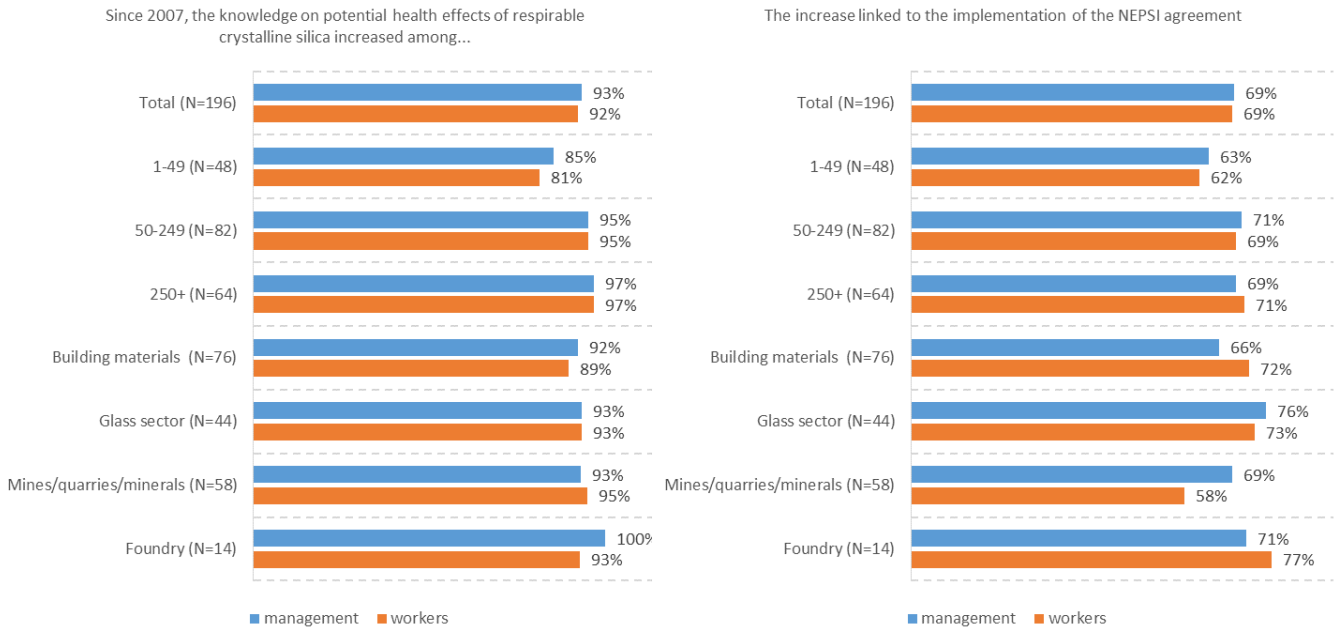
The online survey asked employers whether the knowledge of potential health effects among managers and workers had increased since 2007 and whether this was linked to the implementation of the RCS.

An overwhelming majority of respondents believed that knowledge of potential health effects of respirable crystalline silica had increased significantly among management (93%) and workers (92%) since 2007. Significantly, 69% of respondents attributed improved knowledge among workers and managers to the implementation of the NEPSI Agreement (Figure 8.18).

Large companies, with more than 50 employees, were **more likely** than small companies, with fewer than 50 employees, **to report an increase** in knowledge among managers and employees. Also, large and medium companies more frequently associated the increase to the implementation of the NEPSI Agreement in their company.

There are no remarkable differences between sectors in terms of improvements of level knowledge among workers and managers. There are however small differences in terms of linking these changes with the NEPSI Agreement. Companies in the glass sector were more likely than average to associate with the Agreement the improvement in the level of awareness among management. Respondents in the mines/quarries and minerals sector were less likely to link the change in workers' knowledge to NEPSI Agreement. This is in line with the fact that the glass sector is characterised by large companies while the mines/quarries and minerals is mainly made up of micro companies.

Figure 8.18 Increase of the knowledge on potential health effects of respirable crystalline silica



Source: ICF survey

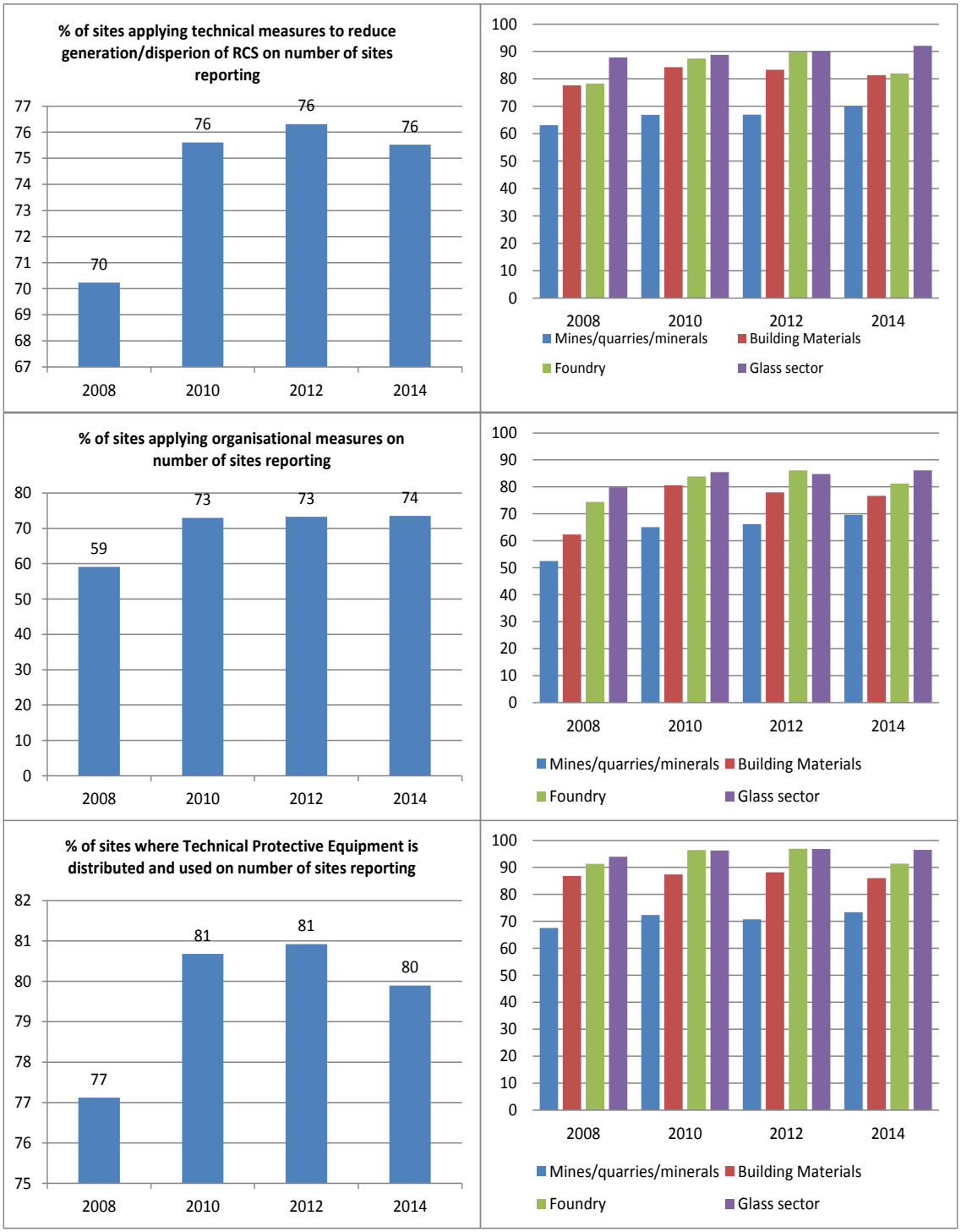
Training and information on good practices was reported by all NEPSI members interviewed, both national associations and companies. National associations run training and workshops to disseminate the NEPSI Agreement, provide training on the reporting system and in some cases workshops with expertise on RCS. For example, in the Netherlands it was reported that the launch of the Agreement was followed by a campaign on exposure measurement; as part of the campaign a workshop was organised with an expert in RCS and the national association supported companies wanting to carry out exposure measurements by liaising with relevant institutes. Similarly, in Belgium a measurement campaign was launched by one national organisation, cofounded by the organisation and companies. In France, in some companies exposure measurements were carried out by using the PIMEX movie technology (a software programme that provides the image of workers and graph of exposure, whereby an operational procedure is filmed by a video camera and simultaneously all exposures (such as dust, noise, thermal radiation, etc.). The films were also used for training and information to make workers aware of the risk. NEPSI members reported this as having a major impact on workers awareness of the issue.

8.4.2 Implementation of NEPSI Good practices

The implementation of the NEPSI Good Practices is a central part of the Agreement. The NEPSI reporting system comprises three indicators to assess whether employers have implemented the Good Practices in their workplaces. These include 'technical measures to reduce generation/dispersion of RCS', 'organisational measures' and 'distribution and use of personal protective equipment'.

In 2014, three-quarters of reporting sites had implemented Good Practices in the workplace, a consistently increasing trend since 2008. The application of technical measures to reduce the generation and dispersion of RCS increased from 70% in 2008 to 76%; in 2008, only 59% of sites applied organisational measures, while in 2014 this went up to 74%; finally, the percentage of sites distributing technical protective equipment increased from 77% to 80% in 2014. Increasing trends across all industry sectors demonstrate an overall commitment across NEPSI members in relation to the implementation of the NEPSI Good Practices (Figure 8.19).

Figure 8.19 Sites applying NEPSI Good Practices



Source: NEPSI reports (data do not include voluntary reporting)

The majority of NEPSI members interviewed reported the implementation of relevant good practices in workplaces. In some cases, the Good Practices were adapted beforehand by national organisations to meet the needs of the specific sectors, as reported in France, Italy, Spain, Belgium.

Good Practices were already implemented and used in large companies; however, interviewees reported that the Agreement triggered the revision of what was in place and helped in sustaining the Good Practices.

8.5 Workplace health and safety conditions

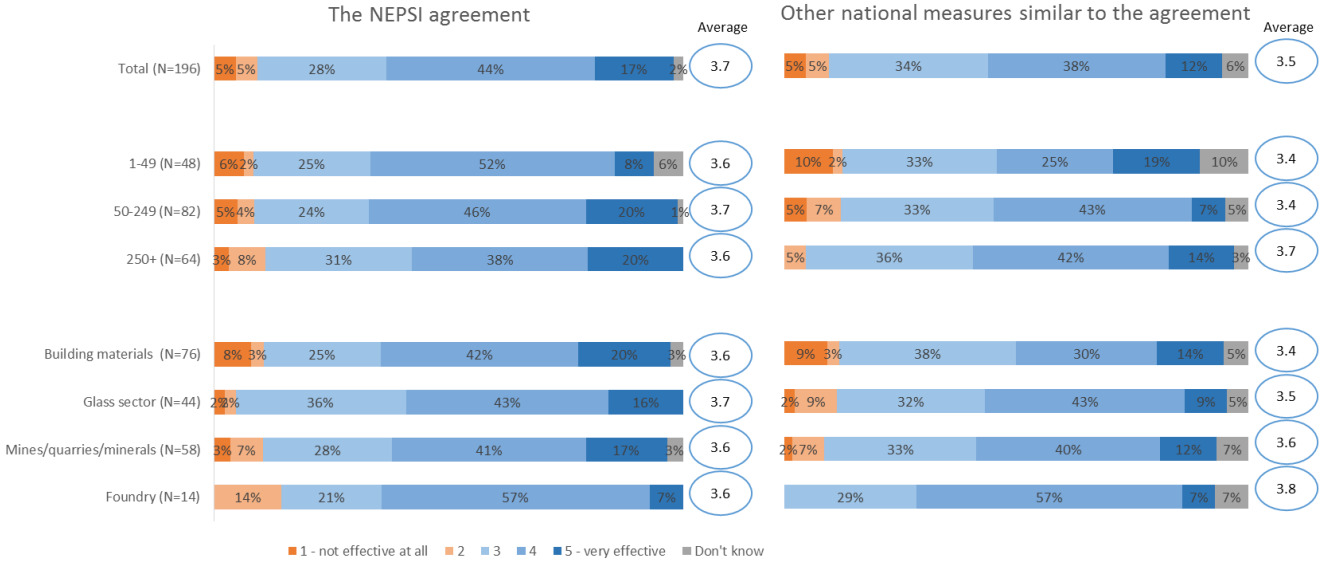
The implementation of the NEPSI Good Practices, dissemination and training activities should ultimately lead to an improvement in working conditions and overall health and safety conditions.

Figure 8.20 shows that a total of **17% of respondents to the online survey believed that the implementation of the NEPSI Agreement was very effective in improving working conditions, health and safety in the workplace, and 44% thought it was effective. Large and medium companies** with more than 50 employees were much more likely than small companies to respond that the NEPSI Agreement was very effective. However, interestingly, the **building materials and mining sectors**, which are characterised by small companies, were more likely than other sectors to state that the implementation of the Agreement was very effective in improving the overall working conditions.

The survey also asked whether other national measures to control exposure to RCS similar to the Agreement were considered effective in improving working conditions. Overall, 12% of employers believed that the national measures were very effective and 38% effective. The representatives of small companies, with up to 50 employees, more often consider national measures as very effective in improving working conditions, health and safety in workplace (19%).

Overall, on a scale from 1 to 5 where one is 'not effective at all' and 5 'very effective', the NEPSI Agreement was deemed as more effective in improving working conditions and health and safety conditions in the workplace, with an average score of 3.7 against 3.5 for national measures (bearing in mind that 99% of these answers were provided by management side representatives at company level). This was confirmed by interviews with some national stakeholders, who believed that the bottom-up approach and the active participation of employers in shaping the Good Practices were key factors in driving commitment to workplace changes truly focused on improving working conditions, rather than simply complying with minimum standards required by national legislation. This does not lead to the judgement that the NEPSI Agreement is more effective than national legislation or measures, but that it has contributed to enhancing awareness and knowledge and that its good practices have in many cases enhanced existing guidance.

Figure 8.20 The assessment of effectiveness of the NEPSI Agreement and other national measures in improving working conditions, health and safety in workplace



Source: ICF survey

NEPSI members in the UK rated the effectiveness of the Agreement in improving working conditions and health and safety as high. While changes linked to health benefits were not yet evident, there was anecdotal evidence to suggest that plants were cleaner, illustrated by awards for health and safety won by companies.

Companies and national organisations reported 'good housekeeping' as an overall result of the implementation of the Good Practice, including regular housekeeping audits following the Agreement.

8.6 Impact on work-related illnesses resulting from exposure to RCS

Changes to work-related illnesses and sickness absence are long-term outcomes; the NEPSI Agreement has now been in force for almost 10 years and therefore the impact of the Agreement on disease development should now be apparent for acute and accelerated silicosis. Both forms of the disease can develop in less than 10 years after initial exposure since they are characterised by exposure to high concentrations of silica and, in the case of acute silicosis, very high concentrations[141][142]. Chronic silicosis develops around 10 years after the initial exposure to relatively low concentrations of dust, and therefore cases are unlikely to have developed since the signing and implementation of the Agreement. Any reduction in exposure since the Agreement was signed is unlikely to have had any impact on cancers associated with exposure to RCS. Those workers developing lung cancer now will have been exposed many tens of years ago when dust control was less effective and exposure was higher.

A number of factors make it impossible to measure the impact of the Agreement on work-related illnesses. Hard outcomes on illnesses can be measured only years after changes in a workplace have occurred and data on work-related illnesses should be consistently

[141] Rice, F. Crystalline silica, quartz. Concise international Chemical Assessment Document 24, WHO, Geneva 2000 http://www.who.int/ipcs/publications/cicad/en/cicad24.pdf

[142] Silicosis http://silicosis.com/index.php

recorded. Additionally, in the context of exposure to RCS it is difficult, if not impossible, to identify the direct link between workplace exposure and illnesses such as lung cancer, mainly because the illnesses develop years after the exposure and the direct link between RCS and lung cancer is not recognised by national legislations. Therefore, only anecdotal evidence can be used to assess the likely impact of the Agreement on work-related illnesses.

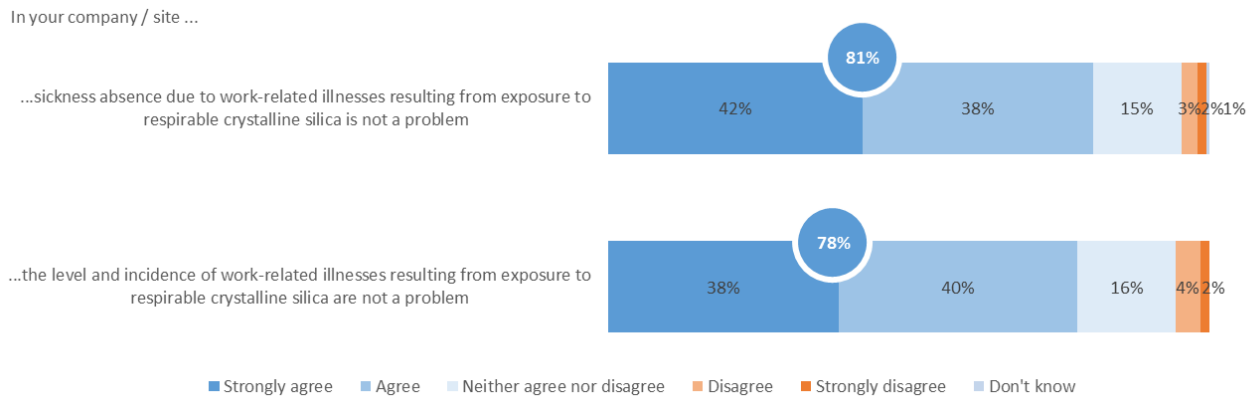
The online survey investigated changes on levels of incidence of work-related illnesses and sickness absence resulting from exposure to RCS. **In more than one in two sites surveyed the situation was deemed as steady**, in 55% of cases the level and incidence of work-related illnesses resulting from exposure to RCS has remained the same, likewise in 54% of cases the sickness absence due to illnesses resulting from exposure. One-in-six companies reported a reduction in the incidence (15%) and sickness absence (17%) of work-related illnesses resulting from exposure to RCS. The greatest improvements were made in large companies and in companies in the mines/quarries/minerals, and building materials sectors.

Figure 8.21 Work-related illnesses resulting from exposure to respirable crystalline silica

Source: ICF survey

In most cases, the level and incidence of work-related illnesses (78%) and the sickness absence (81%) from illnesses resulting from exposure to RCS were deemed as not being a problem for the company (Figure 8.22).

Figure 8.22 Whether exposure to RCS is considered a problem at site level



Source: ICF survey

8.7 Spillover effect of the Agreement

A spillover effect of the Agreement can be identified outside the NEPSI members, in sectors and companies not covered by the Agreement and countries outside the EEA area. Here, the spillover effect refers mainly to the implementation of Good Practices across sites outside the EEA area that are part of bigger groups. Interviewees also reported the NEPSI members were approached by companies and organisations outside the NESPI network to discuss the Good Practices.

For example, in Italy it was reported that national organisations and companies have been approached at local level by other companies and organisations to discuss the NEPSI approach to exposure control management and the Good Practices.

In France, the contraction sector was approached by NEPSI members and, in 2010, social partners in the construction sector launched an awareness raising campaign about the risk of exposure to RCS.

All multinational companies interviewed reported that they apply the NEPSI principles across all sites and report into the NEPSI reporting system. This include sites in the US, Asia, Turkey, South America, Russia, Norway, Switzerland and other countries outside the EU and not part of the NEPSI network. The table below (Table 8.3) shows that, since 2008, there has been a growing trend of sites voluntarily reporting to the NEPSI network, from 130 in 2008 to 317 in 2014 to covering almost 12,000 employees potentially exposed to RCS.

Table 8.3 NEPSI voluntary reporting

	2008	2010	2012	2014
General Information				
Number of Sites	135	296	335	327
Number of Reported Sites	130	263	320	317
Number of Reported Employees	16,966	24,102	25,592	24,627
Exposure Risk				
Number of Employees potentially exposed to RCS	9,991	13,736	12,658	11,903
Risk Assessment and Dust Monitoring				
Number of Employees covered by risk assessment	9,251	13,481	12,202	11,617
Number of Employees covered by exposure monitoring	1,743	5,045	4,993	5,226

	2008	2010	2012	2014
Number of Employees with risk assessment requiring Health Surveillance Protocol for Silicosis	977	1,753	2,465	2,064
Health Surveillance				
Number of Employees covered by generic health surveillance protocol	9,762	13,264	12,116	11,279
Number of Employees covered by Health Surveillance Protocol for Silicosis	909	1,707	2,280	1,991
Training				
Number of Employees covered by information, instruction and training on General Principles	6,791	12,520	11,671	11,136
Number of Employees covered by information, instruction and training on Task Sheets	6,108	11,897	9,830	9,915
Good Practices				
Technical measures to reduce generation/dispersion of fine particles at source	102	204	237	245
Organizational measures	71	203	223	240
Distribution and use of Personal Protective Equipment	112	227	271	265

Source: NEPSI reports (data include only voluntary reporting)

8.8 Assessment by sectors on NEPSI indicators

As discussed at the beginning of this chapter, a comparative assessment of trends in the NEPSI data over the years and by sectors would be misleading because the NEPSI network has evolved over the years and changes may be driven by other factors such as associations leaving or entering the network, different interpretations of NEPSI indicators over time, etc.

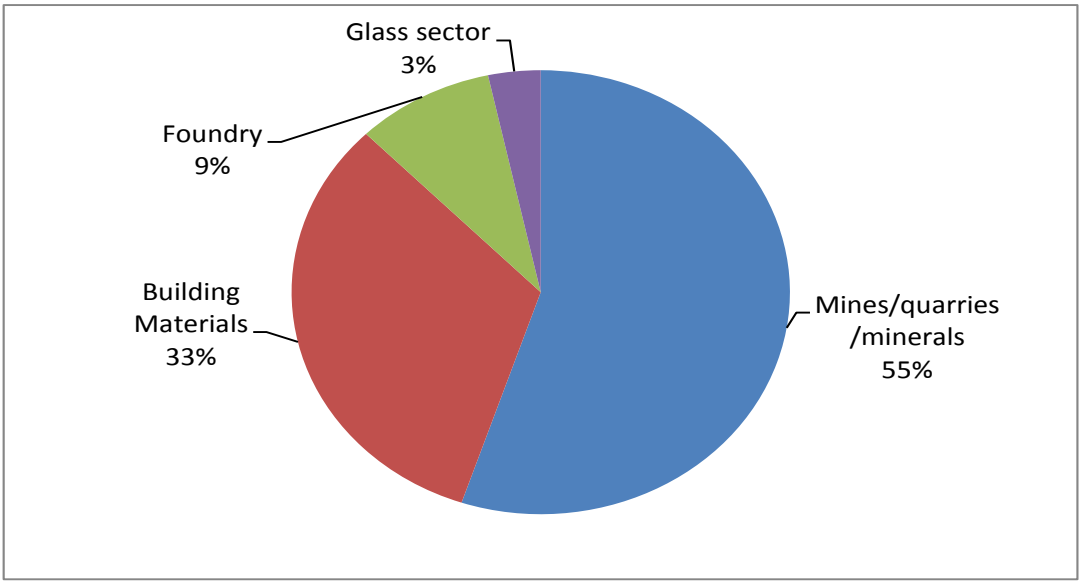
Similarly, a comparative assessment between sectors for a given year needs to take into account some critical factors. NEPSI sectors are characterised by remarkable differences including the size of companies, the risk profile in relation to exposure to RCS, the history and nature of industries they operate in etc.

Finally, the methodological coverage of NEPSI members (organisations and companies) across sectors and countries (in relation to interviews and the online survey) was uneven and dependent entirely on voluntary participation. This led to sectors with a higher participation rate to this study than others and self-selection bias needs to be considered when reading the results, e.g. all participants regardless the sector are likely to be the 'best performers'.

For all these reasons, this study did not find significant differences across sectors in terms of implementation and/or impact. However, in some cases it is possible to present an overall view by sectors.

Overall, 5,944 sites report to the NEPSI network (excluding voluntary reporting), the mines/quarries/mineral sectors constituting the majority (55%), followed by building materials (33%) and foundry (9%), with lastly the glass sector covering 3% of the sites reporting. The number of sites reporting to the NEPSI network is likely to be driven primarily by the size of companies operating in the sectors and the nature of the sectors. For example, the glass sector is characterised by large companies thatcover most of the European market, whereas small and medium-size companies operate in the main/quarries and minerals sectors (Figure 8.23).

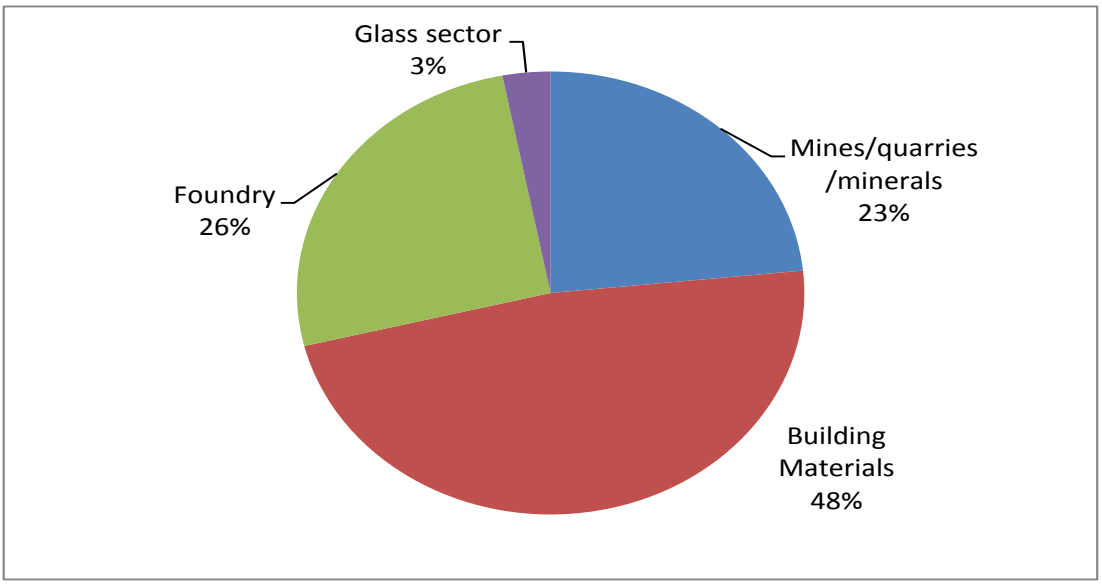
Figure 8.23 Number of reported sites by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

Overall, 176,306 employees were assessed as potentially exposed to RCS among the sites reporting to the NEPSI network. The majority of employees potentially exposed operate in the building materials sector (48%) followed by mines/quarries/mineral (23%) foundry and glass sector (Figure 8.24). Interestingly, respondents to the online survey in the building materials sector were more likely than average to report that the number of employees potentially exposed to RCS has decreased since 2007.

Figure 8.24 Number of employees potentially exposed to RCS by NEPSI sectors (2014)

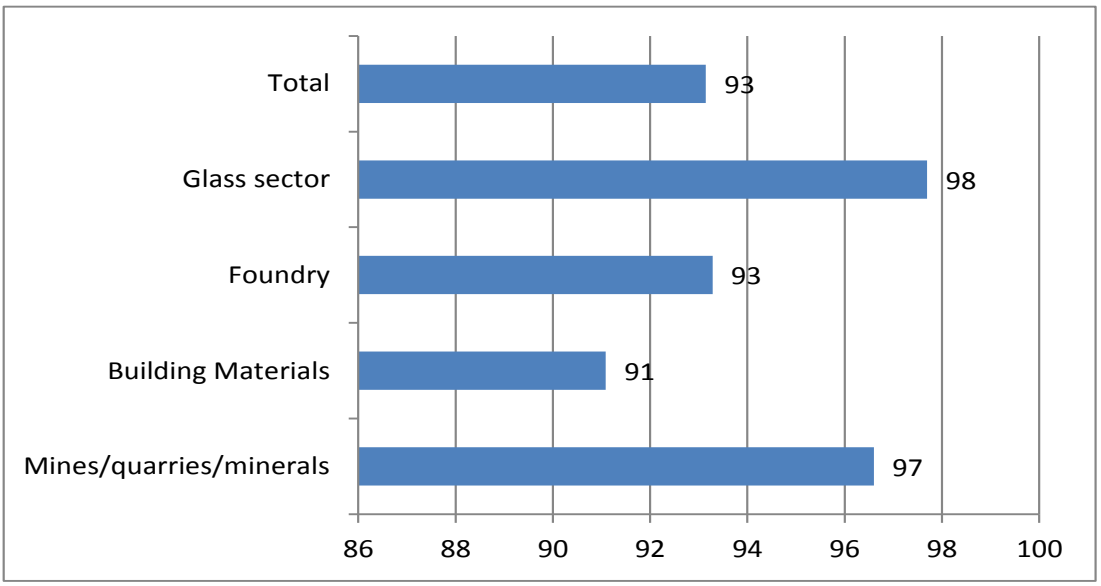


Source: NEPSI reports (data do not include voluntary reporting)

A total of 164,222 employees were covered by risk assessment in 2014, which equalled 93% of the total employees potentially exposed to RCS. High percentage of coverage is found in all sectors, however the glass sector and mines/quarries/minerals show respectively 98% and 97% of coverage of employees potentially exposed, while lower percentages are found in the foundry sector (93%) and building materials (91%). According to the NEPSI guidance,

all employees potentially exposed to RCS should be covered by the risk assessment. Therefore, in some sectors there is still room for improvement in the coverage of this indicator (Figure 8.25).

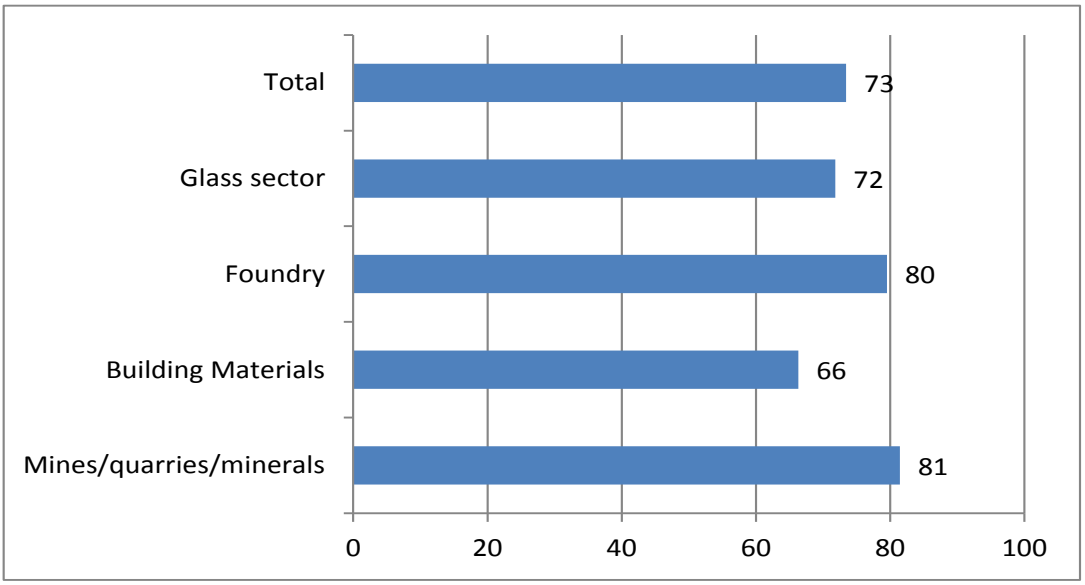
Figure 8.25 Percentage of employees covered by risk assessment on employees potentially exposed by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, 129,458 employees were covered by dust exposure monitoring procedures, representing 73% of all employees potentially exposed to RCS (Figure 8.26). The highest proportion of employees covered was found in the mines/quarries/minerals sector (81%) followed by foundry (80%) and glass (72%). Building materials have the lowest proportion of coverage (66%); however, respondents from this sector in the online survey were more likely than average to state that the level of exposure to RCS has decreased since 2007.

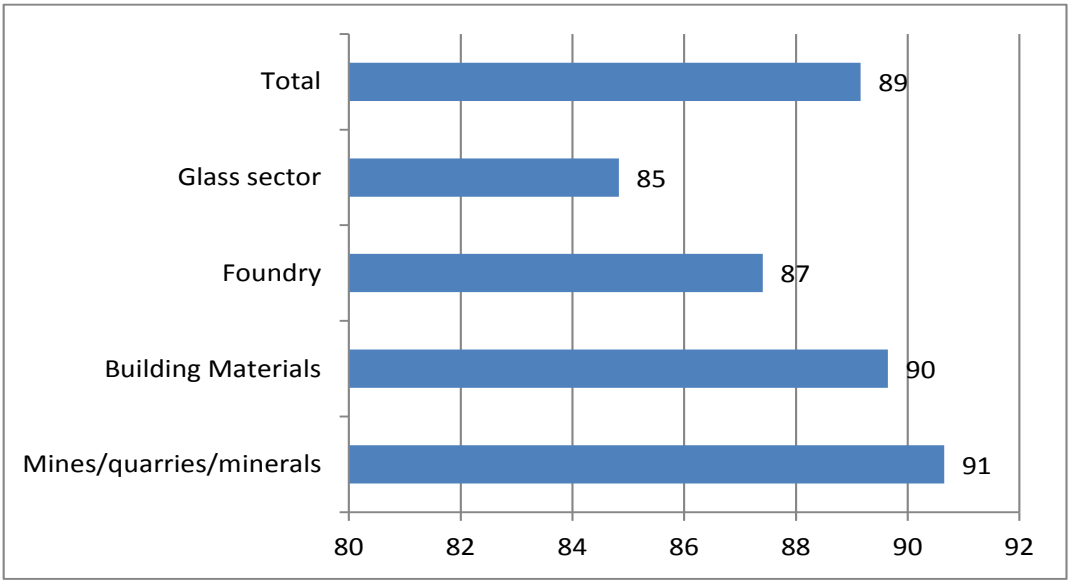
Figure 8.26 Percentage of employees covered by exposure monitoring on employees potentially exposed by NEPSI Members (2014)



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, a total of 157,189 employees were covered by generic health surveillance protocols (Figure 8.27), covering 89% of employees potentially exposed to RCS. The sectors mines/quarries/minerals and building materials presented the highest percentage of coverage, 91% and 90% respectively, followed by foundry (87%) and glass (85%).

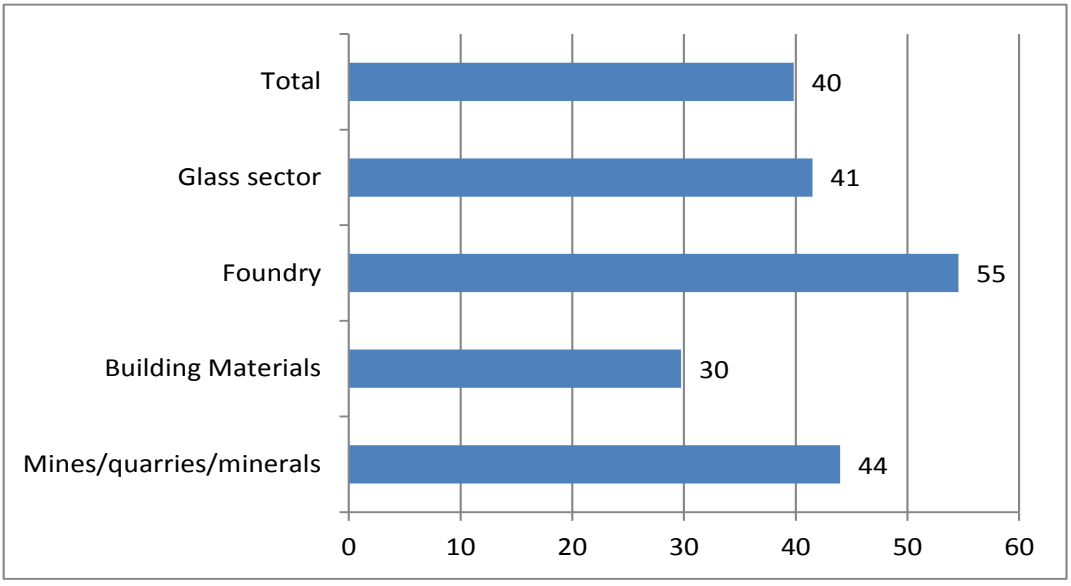
Figure 8.27 Percentage of employees covered by generic health surveillance protocols on employees potentially exposed to RCS by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, 70,225 employees required health surveillance protocols for silicosis; this corresponded to 40% of employees potentially exposed to RCS. The foundry sector had the highest proportion of employees covered (55%) followed by mines/quarries/minerals (44%) and the glass sector (41%). In the building materials sector only 30% of employees were covered (Figure 8.28).

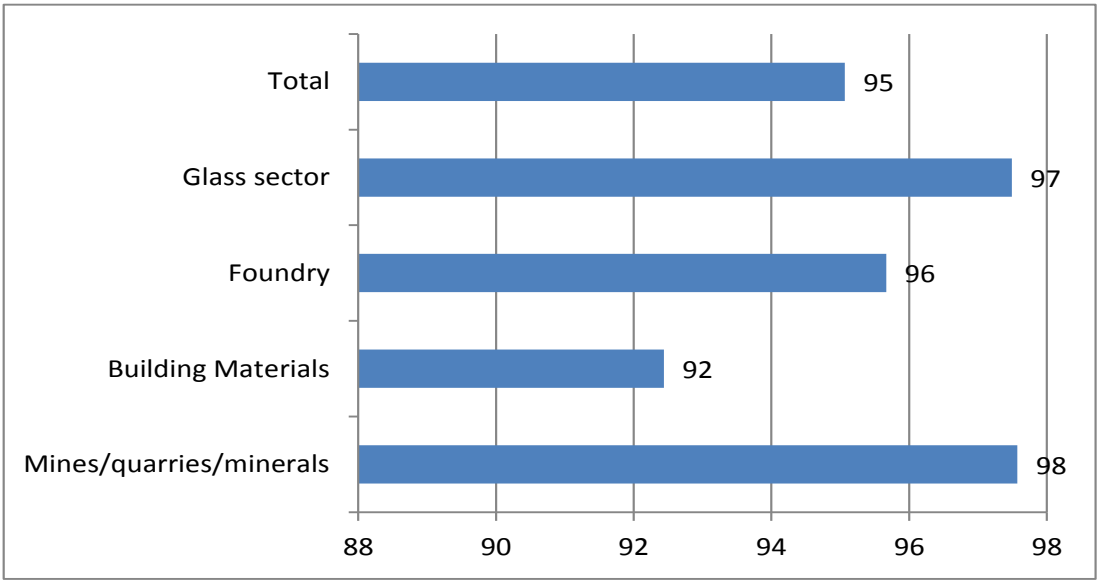
Figure 8.28 Percentage of employees requiring health surveillance protocols for silicosis on employees potentially exposed to RCS by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, 70,225 employees required health surveillance protocols for silicosis and 66,761 employees were covered by generic health surveillance protocols for silicosis, a total of 95%. The highest proportions were found in the mines/quarries/minerals sector (98%) and in the glass sector (97%), followed by foundry (96%) and building materials (92%) (Figure 8.29).

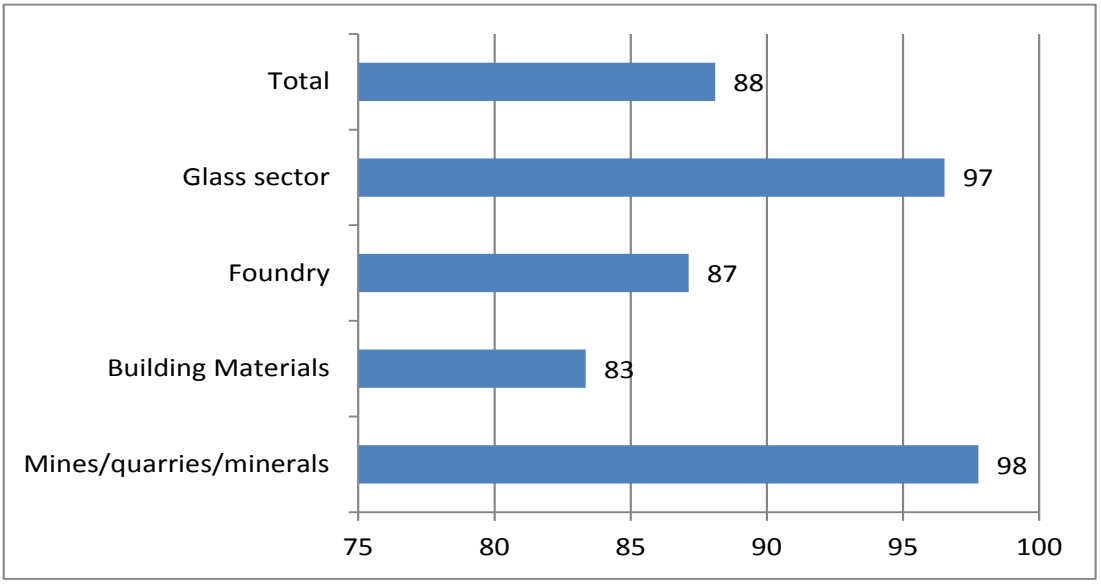
Figure 8.29 Percentage of employees covered by health surveillance for silicosis on employees requiring health surveillance for silicosis by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, 155,326 employees were covered by training on general principles, a total of 88% of employees potentially exposed. The mines/quarries/minerals and glass sectors had the highest proportions of trained employees, 98% and 97% respectively. In the foundry sector 87% of employees were covered by general training and in the building materials 83% (Figure 8.30).

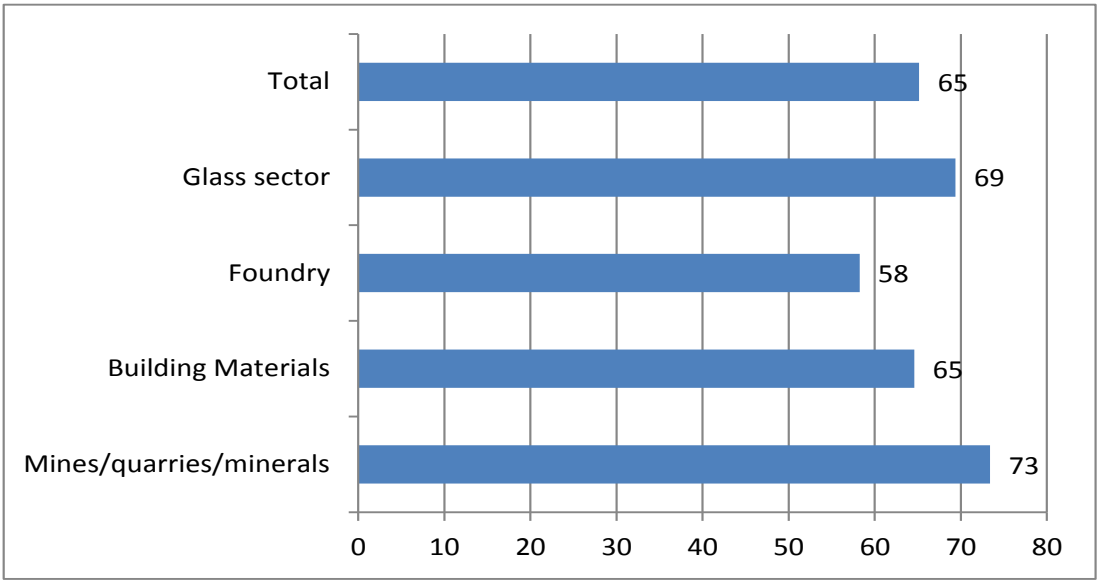
Figure 8.30 Percentage of employees covered by training on general principles on employees potentially exposed to RCS by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

In 2014, 114,875 employees were covered by specific training on Task Sheets, 65% of employees potentially exposed to RCS. The highest coverage was found in mines/quarries/minerals (73%) followed by the glass sector (69%) and building materials (65%). In the foundry sector only 58% of employees potentially exposed were covered by specific training (Figure 8.31).

Figure 8.31 Percentage of employees covered by training on Task Sheets on employees potentially exposed to RCS by NEPSI sectors (2014)



Source: NEPSI reports (data do not include voluntary reporting)

9 Conclusions and Recommendations

9.1 Introduction

The goal of this study was to provide the Commission with an assessment of the implementation of the NEPSI Agreement and its impact and to assess its contribution towards achieving the Community's objectives.

To achieve these goals, the Terms of reference called for:

- a description and comparison of actions by the European level signatories of the agreement and their national affiliate members, companies, sites and public authorities for the implementation of the agreement;
- an assessment of compliance, level of coverage and the binding character of national instruments with the provisions of the Agreement;
- a description and comparison of other national instruments in the Member States regulating exposure to crystalline silica and an analysis of the effectiveness of those national instruments in providing employers and workers with a framework to identify and prevent or manage problems related to exposure to crystalline silica (including control measures in place and a comparison of their effectiveness and state of the art in technology);
- an assessment of the evolution (incidence) of work-related illness resulting from exposure to crystalline silica; and,
- an assessment of the effectiveness of this Agreement in the frame of European Social Dialogue in achieving the objectives it was designed.

This section presents the overall conclusions and recommendations arising from this study.

9.2 Existing legislation aimed at minimising the health risks of workplace exposure to RCS at EU and national level

At EU level, the European Framework Directive 89/391/EEC sets out the general framework for health and safety at work. It is supplemented by other individual Directives such as Directive 98/24/EC on the risks related to chemical agents at work[143] or Directive 2004/37EC on exposure to carcinogens or mutagens at work[144]. While all Member States have implemented the EU acquis, there are some differences, particularly in relation to the setting of OELs and whether RCS is officially classified as a carcinogen and thus whether illnesses linked to exposure to RCS are recognised as occupational illnesses.

Three Member States from the 12[145] assessed in more detail for the purposes of this study recognise RCS as a carcinogenic agent, Slovakia, the Netherlands and Belgium, however in Belgium it is recognised as carcinogenic only for sandblasting activities.

With the absence of an occupational limit value (OEL) at EU level, there is no harmonisation either on the national OEL in the countries studied and variations can be observed. Twelve countries out of 24 (BE, DK, EE, FI, FR, EL, IT, LT, NL, NO, PT, RO, ES, SE) for which information was available had a limit of 0.05 mg/m3 for Cristobalite and Tridymite. The majority of Member States are above the SCOEL recommendation for Quartz and only

[143] Directive 98/24/EC of 7 April 1998 on the risks related to chemical agents at work

[144] Directive 2004/37EC (repealing Directive 90/394/EEC) on exposure to carcinogens or mutagens at work

[145] 12 countries were selected for in-depth research plus, further research was carried out in Austria, Finland, Cyprus and Ireland

Finland, the Netherlands and Portugal set the value below or equal to 0.05 mg/m3 as illustrated in the table below.

Few estimates are available on compliance with relevant health and safety regulations[146] and none are specific to RCS. It is generally estimated that compliance rates are in the region between 30-40%.

In terms of the effectiveness of existing legislation, it can therefore be considered that compliance remains an issue and can be affected by a number of things such as:

- Awareness raising
- Clarity of guidance on the existence and implementation of legislation
- Frequency of inspections and level of sanctions

The dearth of good comparable data on exposure to RCS and occupational illnesses linked to RCS, as well as the absence of impact assessment studies showing impact over time of any legislative changes linked to the control of exposure of workers to RCS make it challenging to conduct a meaningful assessment of the impact of different national regulations on health outcomes (and therefore their effectiveness). Similarly, existing data does not make it possible to assess, for instance, whether countries with more restrictive OEL show a lower incidence rate of work related illnesses linked to exposure to RCS.

The only judgement possible on the basis of existing research is that improvements in awareness raising and the delivery of clear guidance and practice tools can have an impact on company practice. The implementation of better control mechanisms and work organisation/production design is key in improving health outcomes.

For policy makers at EU and national level it is a concern that existing exposure and health impact data (see also below) is insufficient to enable a meaningful assessment of the impact of legislation and policy in this area.

9.3 Coverage of the NEPSI Agreement

The study sought to address the question how many workers exposed to RCS in the EU are covered by the NEPSI Agreement and whether there are any sectors with significant exposure risk not covered by the Agreement. This is important when looking at the assessment of the impact of the Agreement as, in principle, the same benefits are then not shared by organisations and companies and workers not in membership of the relevant NEPSI signatories or indeed in sectors not currently signed up to the Agreement.

However, as assessment of the coverage of the NEPSI Agreement in terms of employees and sectors across Europe and Member States and an assessment of how far this protects a significant share of workers exposed to RCS is challenging. A precise assessment would require good data on a) the number of workers (potentially and actually) exposed to RCS in the workplace; b) the number of individuals employed in relevant sectors; the share of such employees covered by national members of the signatories to the NEPSI Agreement. However, a number of methodological issues do not allow a clear mapping of employment and exposed workers across Europe and by sectors. The first methodological issue relates to different definitions of industry sectors for data on employment, exposure and the NEPSI sectors i.e. the NEPSI sectors cannot be mapped against comparable EU-LFS data on employment and the limited available data on exposure.

[146] For instance a study in the UK on compliance with health and safety regulations among SMEs found compliance rates between 19 – 61%; http://www.hse.gov.uk/research/rrpdf/rr366.pdf

The risk of exposure is patchy across sectors and companies because exposure to RCS occurs only in some work processes and only some workers are at risk of exposure. Therefore, the number of workers in a given sector cannot be taken as a proxy for workers exposed or potentially exposed. The EU-LFS is the only source of comparable data across Europe. However, because of the lack of methodological comparability for industry sectors and issues on reliability, it is not possible to provide a clear assessment of the number of workers active in the sectors potentially covered by the NEPSI Agreement.

Signatories of the NEPSI Agreement are employer confederations and IndustriAll, NEPSI members active in the implementation of the Agreement include national employer and trade union organisations and companies; therefore, the presence of the NEPSI members across Member States depends on the structure of national economies as well as the structure of industrial relations and how far social partner organisations and companies have elected to be in membership of the relevant European level organisations. As a result, NEPSI Members cover primarily Western European and Nordic countries, whereas the presence in Eastern European countries is sporadic, only Poland, the Czech Republic and Hungary appear to have high number of reporting sites. Fewer members were found in Bulgaria, Cyprus, Croatia, Lithuania, Latvia, Slovenia, Iceland and it was not possible to assess the number of reporting sites in these countries. No presence of NEPSI members was found in Malta and Lichtenstein. Additionally, it was not possible to provide a precise assessment of the coverage of the industries by national employer organisations, trade unions and direct company members. Based on the information available, this study assessed that the NEPSI members present a good coverage of their sectors either in terms of employment or in terms of turnover i.e. those associated to the NEPSI network are the main players at European and national level.

It appears that SMEs are hard-to-reach by national organisations and the coverage of national associations is likely to be patchy in sectors characterised by micro and small companies. Similarly, the self-employed are very unlikely to be affiliated to any national organisations, although the level of self-employment in the sectors covered by the Agreement is likely to be very low or nil.

This study could not clearly assess the number of workers exposed to RCS across Europe and in Member States. Data on exposure to RCS is scarce, out-of-date and not comparable across Member States. The only comparable database at European level, the CAREX database, shows that the construction sector is the sector with the highest risk of exposure comprising 67.7% of all workers exposed[147]. Interviews with national experts and Labour Inspectorates have confirmed that construction is the sector with the highest risk of exposure that is not covered by the Agreement. Therefore, the NEPSI network includes the majority of sectors at high risk across Europe. However, the exclusion of the construction sector is a concern in terms of coverage of risk sectors. This sector is also characterised by high incidence of self-employment and micro businesses which are also at risk of low compliance with health and safety regulations.

[147] It should be noted that it is not meaningful to compare CAREX with NEPSI data, for a number of reasons. CAREX and SHECan are based on estimates derived from 2 countries and assume a strong link between activity in a given sector and exposure to RCS, which is not necessarily the case. NEPSI data, on the other hand relies on reporting from sites/companies affiliated to or being directly members of NEPSI signatories. Although the general picture is that NEPSI members/companies at national level provide a high coverage of the respective sectors, it is not possible to clearly map their coverage rate. The two sources should therefore not be directly compared as sources of data on levels of exposure to RCS in the EU. Generally speaking, having assessed the methodologies behind the collection of both sets of data it appears likely that CAREX and SHECan over-estimate the number of workers exposed whereas NEPSI reporting provides a limited view of overall exposure levels (e.g. limited to the coverage of their members and reporting rates).

FIEC (employers' confederation in the construction sector) believes that the NEPSI reporting is inappropriate for the activity of the construction sector because this would require a stable workplace. FIEC's position was also that companies in the construction sector in Europe already comply with the legislation and that the NEPSI reporting system would place additional burden on companies. EFBWW, the trade union confederation in the construction sector, is in favour of crystalline silica to be recognised as a carcinogen in Directive 2004/37/EC, and in favour of an European threshold value for respirable dust. The mobile nature of the work, high levels of self-employment and the widespread use of subcontracting was also mentioned by trade unions as factors which would hinder a correct implementation of the Agreement in this sector.

9.4 Implementation

The implementation of the NEPSI Agreement required a number of actions to be taken at European and national level by European and national organisations, as well as companies. At European level this included setting up the NEPSI Council, translation and dissemination of the agreement, regular review of good practice guidance and steering and analysis of the regular reporting cycle.

At national level, national organisations took four types of implementation measures:

- Dissemination activities: Dissemination of the NEPSI Agreement through newsletters, emails and organisations' websites, etc.
- Training activities: Face-to-face and online training sessions with companies
- Awareness-raising initiatives: Workshops and conferences to raise awareness on exposure to RCS and associated health risks

Other activities at national level include measurement campaigns in the Netherlands and setting-up a 'Silica Round table' in Germany.

At company level, implementation of the Agreement required changes to workplace procedures and management. This consisted mainly of introducing new training modules into the company to raise awareness among managers and employees or adding symbols on Personal Protective Equipment (PPE). For some companies and particularly large multinationals, no specific action was taken to implement the NEPSI Agreement as they already had internal procedures in place that they judged compliant with the NEPSI Agreement.

9.4.1 Reporting

The reporting of data collected at site level to the NEPSI Council is a key feature of the NEPSI Agreement and is unique in its kind for autonomous social dialogue agreements. NEPSI national members are required to report every two years via the NEPSI online reporting system. Key indicators they need to report on amongst others: the exposure risk, the risk assessment and dust monitoring, training and the implementation of NEPSI Good Practices.

Interviews with national associations revealed that, overall, a high proportion of members with an exposure risk actually report to the NEPSI system. Similarly, companies interviewed stated that all sites with a risk of exposure to RCS report. In addition, the NEPSI data shows that the percentage of sites reporting is relatively high across all Member States and sectors. Sectors with lowest percentages are usually those characterised by small companies. However, the coverage of the NEPSI reporting (i.e. how many members of national associations report to the NEPSI system) could not be assessed precisely for the same methodological reasons highlighted above. Furthermore, there is no evidence of processes being put in place to spot check the information being provided by sites (which is not

required in the agreement, but leads to strong reliance on the data generated by self-reporting).

Most of the national members interviewed considered the online reporting system as user-friendly, clear and efficient, even though some SMEs can find the system complex.

However, some areas for improvement have been identified by this study:

- The NEPSI reporting is based on a self-assessment process and there is no assessment and/or monitoring of how far companies apply the principles of the Agreement on the ground and/or what is actually implemented, for example which Good Practices are used, which equipment is used etc. NEPSI members reported an interest in sharing this information either through the NEPSI reports or workshops with companies at national and/or sectoral level;
- The way results are presented in the NEPSI consolidated reports does not allow for a clear assessment of results by countries, sectors and years; therefore, a different approach could be discussed taking into account confidentiality issues;
- The qualitative information presented in the NEPSI report is little use in the way it is currently presented and there is little common understanding of the information required. However, NEPSI members consider the open text as an invaluable tool that could be effectively used to present examples of Good Practices, context information etc;
- Inconsistent interpretation of NEPSI indicators has been identified in this study. Despite a NEPSI guidance on which information needs to be included under each indicator, there is still a margin of error. The NEPSI council should look into ways of better dissemination of the NEPSI guidance and clearer explanations of the indicators; and,
- There is no requirement to report exposure data that would contribute the effective measurement of the impact of the implementation of the Agreement and its good practices.

9.5 Work-related illnesses resulting from exposure to RCS

Exposure to RCS can cause a number of permanent respiratory diseases including silicosis and lung cancer. The level of risk depends on the duration of exposure, the intensity of exposure and the concentration of crystalline silica in the dust. There is usually a delay of more than 10 years between the exposure to dust and the first symptoms of pneumoconiosis (i.e. lung diseases). However, in cases of high concentration and long exposure, symptoms may occur quickly such as in cases of acute silicosis.

Due to the long latency period, statistics on health outcomes mainly reflect past working conditions. In Europe, there are no harmonised statistics on silicosis and work-related cancers because of differences in occupational diseases recognition criteria and compensation schemes. At national level, the collection of such data also proved challenging as data gathering techniques and the presentation of such information is not comparable.

Bearing in mind these limitations, overall, declining trends in cases of silicosis and other pulmonary diseases recognised as being linked to the exposure of RCS have been found in all countries studied. But interestingly, new cases of silicosis have been diagnosed among active workers in new sectors such as the manufacturing of kitchen countertops or new work processes (e.g. sanding of jeans).

The overall reduction of silicosis cases could be seen to be at least partly linked to the decline in some industries where workers are likely to be at risk of exposure to RCS, as well as improvements in technology linked to control mechanisms. Given the overall process of ongoing economic restructuring, it is difficult to disentangle the impact of such changes from various legislative, implementation or enforcement regimes when looking at trend data in occupational illnesses linked to exposure to RCS.

The lack of clear impact (before and after) assessments, either in relation to the implementation of CAD, national guidance or indeed the Agreement, is a further barrier.. In this study, an assessment of the impact of the Agreement on improvements in workplace procedures and technologies used was therefore limited to evidence drawn from a survey of companies and employee health and safety representatives, as well as interviews with social partner, labour inspectorates and health and safety experts carried out for this study. Despite a predominance of employer side respondents in all aspects of the method, it is important to note that no significant differences of opinion emerged between the two sides.

9.6 Impact of the Agreement

The impact of the Agreement needs to be assessed against the background of the original intention and its intended goals, which are:

- Protection of health of employees from exposure to RCS
- Minimising occupational exposure to RCS by applying the Good Practices
- Increasing knowledge about potential health effects of RCS and about Good Practices

The theory of changes of the NEPSI Agreement is based on four main steps:

Awareness raising of the risk of RCS, encouraging the performance of tailored risk assessment and the introduction (where relevant) of new risk management protocols and processes, including the implementation of good practices and training. This should ultimately lead to better protection of health of workers (i.e. minimising exposure to RCS, overall improvement of risk management strategies, improved workplace health and safety conditions).

The NEPSI Good Practice Guidance provides detailed guidance on risk assessment regarding exposure to RCS and relevant risk management. NEPSI members **interviewed reported that the NEPSI Agreement helped employers to implement a more coherent risk management strategy to control the risk of exposure to RCS**, by either introducing new procedures or improving already existing health and safety procedures.

Companies implementing the NEPSI risk assessment procedure reported **improvements in employers' ability to assess the risk of exposure and monitor the number of employees exposed to RCS**. This added value of the Agreement relates to the fact that national legislation includes provisions on generic risk assessment, whereas the NEPSI Agreement provides a very specific practical guidance on steps to follow to assess the risk of exposure to RCS.

NEPSI data show that over the years, a greater number of companies could be encouraged to join the NEPSI reporting system, therefore covering a greater number of employees potentially exposed.

NEPSI data show that an increasing number of workers has been covered by risk assessment. Overall the proportion of employees covered by risk assessment increased from 88% in 2008 to 93% in 2014. In 2014, more than 129,000 were covered by dust exposure monitoring procedure. This represented 73% of employees potentially exposed to RCS. Over the years, an increasing proportion of employees potentially exposed to RCS had been covered by exposure monitoring, from 65% in 2008 to 73% in 2014; trends have increased across all sectors.

Stakeholders interviewed including NEPSI members, experts and Labour Inspectorate, agreed that exposure monitoring is an area where the NEPSI Agreement has prompted employers to do it more consistently and has provided some harmonised guidance on sampling methods, valuable in national situations where no clear indication is provided.

The online survey of companies and employee health and safety representatives shows that, since 2007, 87% of companies introduced changes to the measures taken to control exposure to RCS. Changes in workplaces can be made in response to national legal provisions and/or to implement the NEPSI Agreement, 74% of employers made changes in response to the implementation of the NEPSI Good Practice Guidance and 68% in response to national guidelines. Notably, 19% of employers made changes exclusively in response to the implementation of the NEPSI Agreement, while 15% exclusively in response to national guidelines.

Ultimately, the implementation of better management strategies should lead to a reduction of exposure to RCS. **There is evidence of reduced workplace exposure following the implementation of the Agreement**. An independent Finnish study looking into exposure of workers in Finnish workplaces concluded that the concomitant implementation of the NPESI Agreement and the lowering of the national OEL resulted in lower levels of exposure to RCS. The NEPSI Agreement supported employers by providing tailored tools to implement relevant workplace changes to comply with the new OEL levels. A study commissioned by IMA-Europe and carried out by the University of Utrecht concluded that the implementation of the IMA Dust Monitoring Programme, which has been in place since 2002, show that the measures resulted in an overall reduction of the exposure to quartz and dust of 6-8% annually. Almost three-quarters (73%) of employers participating to the online survey reported that the level of exposure in their workplaces has decreased since 2007, and 51% believed that there has been a decrease also in the numbers of employees exposed. Stakeholders interviewed (NEPSI members and experts) agreed that **the level of exposures have decreased thanks to a number of concurrent factors, including the implementation of the NEPSI Good Practices but also developments in technologies and work processes and enforcement mechanisms of existing legislation**.

The NEPSI Agreement requires employers to report information on the implementation of the Agreement every two years including a review of the exposure values. **The regular review of the dust monitoring data and the two-year reporting cycle is deemed by NEPSI members as a fundamental part of the Agreement, allowing employers to check their progress, find gaps and regularly address the topic of exposure to RCS with managers and employees**. Also Labour Inspectorates and experts agree that the regular cycle of reporting is key to maintaining focus on the topic of the risks of exposure to RCS. Such regularity encourages a culture of continuous improvement.

A main objective of the Agreement is to increase knowledge of the risk of exposure to RCS and control methods, therefore training on general principles and NEPSI Good Practices is crucial to achieve this objective.

NEPSI data report that in 2014, 155,000 employees, 88% of all employees potentially exposed to RCS, received training on general principles included the NEPSI Agreement. From 2008, there has been an overall increasing trend, when 75% of employees received training. The increasing trends by sectors show the equal commitment of NEPSI members across all industries. In 2014, almost 115,000 employees were covered by information, instruction and training on Task Sheets, this made up 65% of all employees potentially exposed to RCS. Consistently increasing trends showed an improvement in this indicator of more than 12 percentage points. Similarly, increasing trends are also found in all industry sectors.

An overwhelming majority of respondents to the online survey believed that knowledge of potential health effects of respirable crystalline silica had increased significantly among managers (93%) and workers (92%) since 2007. Significantly, 69% of respondents attributed improved knowledge among workers and managers to the implementation of the NEPSI Agreement.

Increased knowledge and awareness was the area where all stakeholders perceived the NEPSI Agreement had the greatest impact, including NEPSI members and experts.

Trade unions also believe that increased awareness of employers on health risks of exposure to RCS was the main result of the NEPSI Agreement together with putting an emphasis on preventive measures to protect workers from RCS.

The implementation of NEPSI Good Practices is a central part of the Agreement. The NEPSI reporting system monitors the implementation of Good Practices by asking employers whether the following measures were implemented 'technical measures to reduce generation/dispersion of RCS', 'organisational measures' and 'distribution and use of personal protective equipment'. **NEPSI data shows that since 2008 employers have increasingly applied a range of Good Practices.**

Finally, the NEPSI Agreement should lead to overall improvements in workplace health and safety conditions. Overall, 61% of respondents to the online survey believed that the NEPSI Agreement was effective or very effective in improving working conditions, while 50% stated that other national measures where effective or very effective in improving working conditions. The fact that measures implemented through the NEPSI Agreement were deemed somehow more effective that other national measures in improving workplace health and safety conditions was also confirmed by interviews with NEPSI members. **The bottom-up approach of the Agreement ensured commitment from employers encouraging them to go beyond legislative requirements. While the tailored tools (i.e. the Good Practice Guidance) provided practical guidance in implementing effective workplace changes and improve compliance with national legislation, which contains generic principles.**

9.7 Overall assessment and recommendation

For the reasons outlined above, the available data do not make it possible to provide a measurement of the net impact of the Agreement i.e. how far changes are due to the NEPSI Agreement and/or to other external factors such as national regulations, existing management processes and workplace procedures, technological developments etc. To allow for such assessments to take place in future, more comparable data on the following needs to be available:

- Clear mapping of NEPSI sectors again existing NACE codes and alignment of such codes with exposure measurement data;
- Updated, comparable and comprehensive collection of RCS exposure data; and
- Regular, comparable collection of data on work-related illnesses linked to exposure to RCS.

However, according to information gathered for this study, the Agreement has accelerated processes and investments anticipated by employers either in response to new national provisions and/or for businesses purposes. In some cases, the Agreement has also helped employers to improve compliance to national regulations by providing tailored guidance on risk assessment and risk control strategies.

Overall impact of the Agreement

Overall, it seems that the Agreement and its implementation mechanisms can be deemed suitable to meet its objectives: a) Protection of health of employees and other individuals occupationally exposed at the workplace to RCS from materials/products/raw materials containing crystalline silica; b) Minimising exposure to RCS at the workplace by applying the Good Practices stipulated to prevent, eliminate or reduce occupational health risks related to RCS; c) Increasing knowledge of potential health effects of RCS and about Good Practices.

From information gathered using different sources including interviews with NEPSI members but also trade unions and experts, assessment of NEPSI data and independent studies:

- The Agreement is improving the protection of health of employees occupationally exposed at the workplace to RCS. This objective is being achieved in a number of ways including better knowledge and awareness of the risk and relevant control measures, improved managerial processes, and improved behaviour of managers and employees and implementation/improvement of relevant control measures.
- There is evidence that efforts to minimise exposure to RCS in the workplace has occurred following the implementation of the Agreement. The evidence suggests that the reduction in exposure is a concomitant result of the implementation of the NEPSI Agreement, technological developments in control measures, and changes to legal framework e.g. the reduction of OELs. Due to the absence of relevant impact assessment studies at national level, it is not possible to disentangle the effects of different measures. This is also due to the relative lack of relevant exposure and occupational illness data. It is, therefore, not possible, for example, to contrast the various impact of the implementation of CAD and the application of different OELs on exposure data and the risk of occupational illness. With regard to the Agreement, what can clearly be stated is that stakeholders are in agreement that the Agreement and the Good Practices contained therein provide useful guidance to companies about the steps needed to effectively apply existing legislation and best practices with regard to risk assessment and the implementation of control measures. The survey results (albeit bias towards employer side responses) show that a significant number of companies have taken actions to implement new approaches in response to the guidance in the Agreement.
- Increased knowledge about potential health effects of RCS and about Good Practices has therefore been reported as the main positive result of the Agreement by all stakeholders interviewed, including experts and trade unions. NEPSI data also provide evidence that training on general principles and Good Practices has been provided to most employees. Although training on health and safety was provided at company level before the implementation of the Agreement, NEPSI members reported that in many cases, following the implementation of the Agreement, specific modules on RCS have been added to the training.

Available data does not make it possible to provide a measurement of the net impact of the Agreement i.e. how far the changes are due to the NEPSI Agreement and/or to other external factors such as national regulations, existing management processes and workplace procedures, technological developments etc. However, it seems that the Agreement has accelerated processes and investments anticipated by employers either in response to new national provisions and/or for businesses purposes. In some cases, the Agreement has also helped employers to improve compliance to national regulations by providing tailored guidance on risk assessment and risk control strategies.

Therefore, it seems that **overall the Agreement and its implementation mechanisms are suitable to achieve its objective and better protect workers**. However, it is important to bear in mind that the Agreement was implemented across businesses that operate in complex national and sectors within existing regulatory frameworks and businesses with organisation procedures already in place.

Finally, the NEPSI Agreement provides guidance on monitoring of exposure but does not require reporting of exposure measured. Currently, there is no standardised way to measure and monitor exposure and data are not comparable, leading to difficulties in assessing whether improvements have been made on hard outcomes such as level of exposure. Therefore, the **NEPSI Agreement has the potential of initiating a database of exposure monitoring, which despite all the methodological limitations linked to measurement issues, could lead in the long-term to a certain level of comparability across Europe**.

Annex 1 National data on work-related illnesses and exposure data

A1.1 Work-related illnesses in selected European countries

In **Austria**, since 2008, there have been around 30 to 50 cases of silicosis and silico-tuberculosis.

In **Belgium**, in 2014, in the private sector, 111 first claims for incapacity to work linked to silicosis were filed to the *Fonds des Maladies Professionnelles* (FMP), 73 cases were rejected and 38 were recognised as cases of permanent disability (no cases of curative or temporary disability were recognised)[148]. In the past 20 years, the number of recognised cases of silicosis leading to permanent incapacity has decreased by 89%: from 347 in 199, to 90 in 2004 and 38 in 2014. This can mainly be explained by the disappearance of the mining sector in the country, the last mine was closed in 1992. Since the beginning of the activity of the FMP in 1964, 5,768 permanent incapacity claims linked to silicosis were recognised by the Fund[149]. Additionally, in 2013, 1,431 claims were brought by beneficiaries (*ayant-droit*) following death linked to a work related illness of which 479 cases were recognised by the FMP as deaths linked to recognised work related illness. 851 claims related to silicosis (59% of the total claims), of these 191 were accepted by the FMP i.e. silicosis was recognised as the cause of death[150]. Since the establishment of the FMP, 7,176 people were recognised by the Fund as having died because of silicosis (7,168 men and 8 women)[151].

In **France**, in 2013, 204 cases of pneumoconiosis/silicosis were officially recognised and received a first payment in 2013. Of these, 200 cases were recognised as permanent disabilities[152]. The worst affected sectors were the "wood, furniture, paper and cardboard, textiles, clothing, hides and skins and stones and lights ashore industries", with 40 cases of pneumoconiosis/silica and 35 cases of permanent disability; followed by the metal industry with 21 cases of pneumoconiosis/silica and 18 cases of permanent disability; and, the building and construction industries with 14 cases of pneumoconiosis/silica and 17 cases of permanent disability[153].

In **Germany**, it was reported by the relevant employers' liability insurance associations in all sectors with exposure to RCS that in the past 50 years, the number of individuals who develop silicosis has significantly declined[154]. Whereas in 1950, 21,005 suspected cases of silicosis were reported (associated with 6,618 new occupational pensions approved), by 2002, there were 1,726 reported cases with 375 occupational pensions approved; meaning that reported cases dropped by 92% and new pension approvals by 94% during this period.

[148] Statistical annual report FMP, 2014

[149] Statistical annual report FMP, 2014

[150] Annual report FMP, 2013.

[151] Statistical annual report FMP, 2014

[152] The number of recognised diseases for which a first payment has been issued in 2013. This only represents the number of diseases which have been compensated for the first time that year and do not provide a full picture of the number of recognised diseases.

[153] Statistiques de sinistralité des maladies d'origine professionnelle dans le cadre du Régime général pour l'année 2013.http://www.risquesprofessionnels.ameli.fr/fileadmin/user_upload/document_PDF_a_telecharger/etudes_statistiques/MP_2013/MP2013-%20tous%20CTN%20et%20par%20CTN%20(n-2014-247).pdf

[154] Ortleb, H (2003), Crystalline silica dust – a ubiquitous material in the focus of science and legislation; http://six4.bauverlag.de/sixcms_4/sixcms_upload/media/1232/ortleb_1103.pdf.

In **Italy,** the annual report from INAIL (National Insurance Institute for Employment Injuries) provides information on work-related illnesses; however, data are all aggregated under the generic group of pulmonary diseases which declined from 1,426 cases in 2010 to 1,264 in 2014. The report provides information on the cases of deaths linked to silicosis/asbestosis, which decreased from 820 cases in 2010 to 490 in 2015, almost entirely involved people over the age of 65[155].

Lithuania has data on the instances of new cases of occupational diseases by key groups of diseases (e.g. diseases of the respiratory system, diseases of the skin and subcutaneous tissue, etc.) but not by causes and not specifically providing information on diseases resulting from exposure to RCS[156]. The State Labour Inspectorate collects data on the number of occupational diseases by causes at a broad level. In 2014, 3% of diseases were caused by exposure to chemicals and 1% by exposure to biological agents (the majority 65% were caused by physical reasons). The information received from the State Labour Inspectorate showed that on average there is 1 silicosis case per year in Lithuania in all sectors combined.

In the **Netherlands**, in 2014, 8,513 occupational diseases were reported by the Labour Inspectorate, 13 of which were cases of silicosis, whereas in 2010, 11 cases of silicosis had been identified. Cases of lung and respiratory illnesses in 2014 numbered 22, up from 19 in 2012[157].In **Poland,** there were 298 confirmed cases of silicosis between 2007 and 2009[158].Around 100 identified silicosis cases per annum also appears in other sources[159]. At the same time, 1,350 confirmed cases of pneumoconiosis were also recognised. In 2000, there were 155[160] recognised cases of silicosis. This had declined to 83 cases[161] in 2013. Data on silicosis has been collected since the 70s and since 1999 these data have been held in a central register[162]; however, data are not publicly available.

In **Romania,** the labour inspectorate reported 235 cases of silicosis in 2014, distributed as follows across different industrial sectors: manufacture of other non-metallic mineral products (72), steel industry (59), mining and quarrying (34), manufacture of electrical equipment (20), manufacture of parts and accessories for motor vehicles (16), manufacture of machinery and equipment (11), manufacture of other transport equipment (9), manufacture of fabricated metal products (8), manufacture of motor vehicles and trailers (6)

In **Slovakia** the following diseases are recognised as linked to exposure to RCS dusting of lungs caused by dust containing silicon oxide (silicosis, silico-tuberculosis) including (coal worker) pneumoconiosis. Overall, 24 cases of illness were recognised as linked to exposure to RCS in 2014 – down from 74 in 2001. Workers affected are mainly men over the age of 65, in the mining and quarrying sector, followed by manufacturing of basic metals. Lung cancer as an occupational disease is recognised only in relation to radioactive substances and exposure to asbestos dust.

In **Spain**, there are two main sources of information for cases of silicosis: the National Institute for Silicosis (INS) and the Observatory of Occupational Diseases. The INS database

[155] INAIL (2015) Annual report INAIL on work place accidents and work-related illnesses

[156] http://osp.stat.gov.lt/en/statistiniu-rodikliu-analize?id=1527&status=A

[157] http://www.beroepsziekten.nl/sites/default/files/documents/ncvb_kerncijfers2015.pdf

[158] INDEMA (2011), Przeciwdziałanie pylicy w środowisku pracy (Prevention of pneumoconiosis in workplace), Report for ZUS http://www.zus.pl/files/dpir/Broszura_Przeciwdziałanie_pylicy_w_%20srodowisku_pracy.pdf

[159] Maciejewska A (2014), Crystalline silica: quartz and cristobalite – respirable fraction. Documentation of proposed values of an occupational exposure limit (OEL), Podstawy i Metody Oceny Środowiska Pracy, no 4(82), pp. 67–128. http://archiwum.ciop.pl/zasoby/5.krzemionka.pdf

[160] http://cybra.p.lodz.pl/Content/7837/Medycyna_Pracy_2002_T_53_nr_1_(23-28).pdf p. 2

[161] http://medpr.imp.lodz.pl/Choroby-zawodowe-w-polsce-w-2013-r-i-ich-czynniki-przyczynowe,549,0,2.html

[162] http://www.imp.lodz.pl/home_pl/o_instytucie/reg_and_databases/work_dissises1/o_rejestrze/

was established in 2007 as an exhaustive register of occupational diseases, while the Observatory monitors silicosis based on voluntary reporting. Underreporting of cases of silicosis in both databases is acknowledged in the literature[163]. For instance, in the last report the Balearic Islands, Cantabria, La Rioja, Madrid and the Navarra regions did not provide data[164].

According to INS statistics, the number of cases of silicosis decreased from 375 in 2003 to 115 in 2007; however, since then, the number of reported cases of silicosis steadily increased to 256 in 2011[165]. Similarly, the Observatory of Occupational Diseases reported an increase from 95 to 295 cases in the same period[166]. Thus, overall, Spain seems to have experienced an increase in the incidence of silicosis[167]. A relevant change in the trends of silicosis was detected in different industry sectors[168]. In 2011, the number of silicosis cases among coal mining workers was lower than in other occupations, an indication of changes taking place in different industrial sectors. According to Observatory's database, workers in the manufacturing industry accounted for 78% of cases[169]. In 2009, for example, there was an emergence of several cases of silicosis among active workers related to the manufacture of kitchen countertops in southern Spain[170]. New cases of silicosis have been related to the manipulation of building materials. These materials contain silica dust and may have contributed to the appearance of new cases of silicosis in workplaces not previously considered at risk. Some studies also underlined a high prevalence of silicosis in industries such as the granite industry[171] or the sandblasting of denim fabrics with silica sand that could also explain increasing trends in recent years. Of the 166 cases detected in 2012, 95 were among active workers and 71 among retired workers[172]. The identification of young and active workers among recent cases of silicosis and related lung diseases confirms the active risk, and some cases were recognised as acute silicosis.

In **Sweden**, according to statistics from the Swedish Work Environment Authority's information systems regarding occupational injuries (ISA), there have been 40 work-related

[163] Rego G, Pichel A, Quero A, Dubois A, Martínez C, Isidro I, et al. A high prevalence and advanced silicosis in active granite workers: a dose-response analysis including FEV1. J Occup Environ Med. 2008; 50: 827-33.

[164] Instituto Nacional de Silicosis. Nuevos casos de Silicosis registrados en el INS durante el año 2011. Oviedo: INSS; 2012. http://www.ins.es/documents/10307/10507/fichero12_1.pdf

[165] Instituto Nacional de Silicosis. Nuevos casos de Silicosis registrados en el INS durante el año 2011. Oviedo: INSS; 2012 [cited 2012 Oct 10]. Available from: http://www.ins.es/documents/10307/10507/fichero12_1.pdf.

[166] Cases reported to the Observatory and to the INS could be the same ones, therefore it is not possible to add them to find a more accurate data. Observatorio de enfermedades profesionales. Ministerio de Empleo y Seguridad Social. Available from: http://www.seg-social.es/Internet_1/Estadistica/Est/Observatorio_de_las_Enfermedades_Profesionales/index.htm.

[167] Aránzazu Pérez-Alonso; Juan Antonio Córdoba-Doña; José Luis Millares-Lorenzo; Estrella Figueroa-Murillo; Cristina García-Vadillo; and José Romero-Morillo. Outbreak of silicosis in Spanish quartz conglomerate workers. International Journal of Occupational and Environmental Health, 2014. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137811/

[168] Martínez C, Prieto A, García L, Quero A, González S, Casan P. Silicosis: a disease with an active present. Arch Bronconeumol. 2010;46:97–100.[PubMed] http://www.archbronconeumol.org/en/silicosis-disease-with-an-active/articulo/13148670/

[169] Observatorio de enfermedades profesionales. Ministerio de Empleo y Seguridad Social [cited 2012 Nov 4]. Available from: http://www.seg-social.es/Internet_1/Estadistica/Est/Observatorio_de_las_Enfermedades_Profesionales/index.htm.

[170] García Vadillo C, Gómez JS, Morillo JR. Silicosis in quartz conglomerate workers. Arch Bronconeumol. 2011;47:53.[PubMed]

[171] Rego G, Pichel A, Quero A, Dubois A, Martínez C, Isidro I, et al. A high prevalence and advanced silicosis in active granite workers: a dose-response analysis including FEV1. J Occup Environ Med. 2008; 50: 827-33.

[172] Martínez C, Prieto A, García L, Quero A, González S, Casan P. Silicosis: a disease with an active present. Arch Bronconeumol. 2010;46:97–100.

illnesses related to silica exposure between 2007 and 2011. Almost half (19 cases) of the reported cases relate to breathing difficulties. The diagnosis of silicosis is no longer registered in connection with work injury reports, but is part of a larger group of respiratory diseases. As such, silicosis can no longer be distinguished from other respiratory diseases. Following a review of reported work injury reports, around 1-2 silicosis cases annually are estimated by the Swedish Work Environment Authority.. According to the National Board of Health and Welfare's (*Socialstyrelsen*) mortality registers, most newly reported cases of silicosis relate to construction workers[173].

In the **UK**, the health and safety executive (HSE) collates information on cases of non-asbestos related pneumoconiosis; the most recent statistics were published in 2014[174]. The data are collected through physician reporting schemes and from Industrial Injury Benefits Schemes. There was a decrease of 60% in the number of deaths due to non-asbestos related pneumoconiosis between 1993 and 2012 (from 28 cases in 1993 to 11 cases in 2012) and the number of new cases of non-asbestos and coal workers pneumoconiosis (mainly silicosis) assessed for benefit between 2003 and 2013 declined by almost half (from 80 cases in 2003 to 45 in 2013).

A1.2 Exposure data in selected European countries

The collection of exposure data from national sources proved to be particularly difficult either because of the absence of national databases[175] and/or because data were not publicly available or made available to researchers. This section provides information gathered by this study on the national sources on workplace exposure.

In **France**, three national databases contain information on risk exposure to RCS (COLCHIC, SCOLA and SUMER), however only data from SUMER survey are publicly accessible. The SUMER survey[176] was launched by the Ministry of Labour[177] in 1994, with two subsequent waves in 2003 and 2010. The survey contains information on employees under health surveillance as a result of being identified at being at risk of exposure through the risk assessment; therefore, it collects medical surveillance data on workers' exposure. This cross-sectional survey allows the mapping of occupational exposures of employees, the duration and intensity of exposure and the protective equipment (collective or individual) eventually made available by employers. In 2010, 2,400 occupational health physicians were able to interrogate 47,983 employees. When comparing the three SUMER surveys covering 16 years, it can be noted that the number of salaried workers exposed to RCS increased from 97,000 in 1994 (representing 0.8% of all employees in France), to 269,000 and 294,900 respectively in 2003 and 2010 (representing 1.5% and 1.4% of all employees from the private sector). Data from the 2010 SUMER wave show that 53% of workers exposed to RCS worked in the construction sector; followed by the rubber and plastic products and other non-metallic mineral products manufacturing (6%), the metallurgy industry (6%) and other manufacturing industries (4%). Interestingly, data from 2003 showed that 39% of employees exposed to RCS were not provided with collective protective equipment and this percentage went up to 46% in 2010, indicating a likely deterioration of the situation. According to

[173] Arbetsmiljöverket (2014), Konsekvensutredning för Arbetsmiljöverkets förslag till reviderade föreskri2fter om kvarts

[174] Pneumoconiosis in Great Britain 2014 HSE V1 2014
http://www.hse.gov.uk/statistics/causdis/pneumoconiosis/pneumoconiosis-and-silicosis.pdf

[175] Belgium, Sweden, Lithuania, Spain, Romania, Slovakia, Austria and the Netherlands

[176] Surveillance médicale des expositions aux risques professionnels. http://travail-emploi.gouv.fr/etudes-recherches-statistiques-de,76/statistiques,78/conditions-de-travail-et-sante,80/les-enquetes-surveillance-medicale,1999/l-enquete-sumer-2010,15981.html

[177] Direction Générale du Travail-Inspection médicale du travail et la Direction de l'animation de la recherche, des études et des statistiques (DARES)

SUMER data 36% of workers exposed were employed in micro companies between one and nine employees[178].

From interviews with national experts, the SUMER data may underestimate the level of employees exposed to RCS with a degree of variation across sectors. For example, estimates for small sectors, such as the dental laboratory market, are likely to be more precise than estimates for large sectors such as construction, where there is also a large proportion of workers who are self-employed and/or without regular contracts, therefore it makes it more difficult to monitor these workers. Experts also highlighted that SUMER does not contain data on self-employed or freelance workers; similarly, SMEs may not be well represented.

In **Germany**, three national databases contain information on exposure of RCS: a) the so called 'Quartz Report' (2006) from BGIA (*Bundesgenossenschaftliches Institut für Arbeitsschutz* – Institute for Occupational Safety and Health of the German Social Accident Insurance) gives an overview of different sectors and is based on a measuring campaign in 2006 to take stock of exposure. There have been discussions about a revision in line with the preparation of the report on dust exposure by the BGIA (*Staubreport*). It records data from 1972 to 2004. The measurements were carried out in around 8,900 companies and contain 104,000 measurements. b) A database (MEGA exposure database) of the Institute for Occupational Safety of the German Social Accident Insurance. c) Exposure database on the basis of Technical Rules for Hazardous Substances (*Technische Regeln für Gefahrstoffe* - TRGS) TRGS 410, which is currently in preparation. The TRGS 559 contains a list of exposure measurements across sectors which are intended to be used by employers as a yardstick to implement protection measures. Data is based on exposure measurements and literature reviews. The assessment of exposure levels for individual tasks in different sectors is based on exposure measurements and expert opinions. Data comes from the measuring campaign for the Quarz Report in 2006 or from the database of the Institute for Occupational Safety of the German Social Accident Insurance analysed (estimated 2009 data) and the expert opinion is based on a the TRGS 559 working group that was active until 2009. The TRGS contains data on 12 different sectors with 73 overarching task where RCS occurs which are often split into specific subtasks. It lists the 10% value (10% of all measured values are below this value), the 90% value (90% of all measured values are below this value) and the arithmetic average (MW) of exposure to RCS.

None of these databases provide information on total numbers of workers exposed to RCS. In the late 1990s, in the extractive industries sector alone, 13,300 people were exposed to RCS at work. In the extractive sector, this number has been declining steadily as a result of the overall economic decline and reduced share of employment in this sector. Since the 1970s, the share of individuals exposed to levels of RCS above the occupational exposure limit (in force at the time) of 0.15 mg/m3 has steadily declined and in the late-1990s stood at around 10% of exposed workers. However, in assessing such figures, it must be borne in mind that measurements are only carried out regularly in establishments considered to be 'high risk'[179].

In **Italy**, a national database has existed since 1996 to collect information from employers on exposure to carcinogenic substances, entitled the Italian information system for recording occupational exposures to carcinogens (SIREP)[180]. Between 1996 and 2005, the professional exposure history of approximately 36,547 employees from 2,778 companies was recorded. In 2005, more than 100,000 exposure histories were collected, accounting for

[178] Surveillance médicale des expositions aux risques professionnels. http://travail-emploi.gouv.fr/etudes-recherches-statistiques-de,76/statistiques,78/conditions-de-travail-et-sante,80/les-enquetes-surveillance-medicale,1999/l-enquete-sumer-2010,15981.html

[179] http://www.steine-und-erden.net/se100/quarz.htm

[180] Legislative Decree 626/94 (art.70)

0.2% of the Italian workforce[181]. Employers are compelled to register on SIREP all those workers identified by the risk assessment at risk of exposure to carcinogenic substances and are therefore subject to risk surveillance. The information registered includes: job tasks, the carcinogenic substance and the exposure value (when known)[182].

Employers are responsible for keeping records of exposure data while INAIL (National Insurance Institute for Employment Injuries) and ASLs (Azienda Sanitaria Locale – the local health authorities) are responsible for managing the information flow from companies. The carcinogenic substances subject to compulsory reporting include those identified by the European CLP regulation. At the end of 2012, 14,264 companies were reporting into this system and the number of workers exposed to carcinogenic substances was 158,778 (88% men). For 77% of workers the exposure value is also included. In total the registry contains 342,111 work exposure histories and 370,010 exposure measurements. The sectors with the greatest numbers of workers exposed to carcinogenic substances include manufacturing (30,772), wood industry (29,678), production of metals and manufacturing (13,217). Regions with the highest concentration of companies and workers exposed include Lombardy, Veneto, Emilia-Romagna, Tuscany and Lazio. Since 2008, there has been a significant increase in the number of companies reporting to the system, due to the implementation of the Ministerial Decree 155/2007 which implemented the Legislative Decree 626/94 (art.70) on the SIREP[183][184]. Form the literature review it seems that data on exposure to RCS are registered together with exposure to asbestos.

In **Poland**, data available on workplace exposure relate to fibrosis inducing industrial dusts, a broader category than RCS. This is regularly monitored by the central statistical office through annual reporting mandatory for all companies with at least 10 employees (in most sectors of the economy). The most recent data are available for 2014[185]. The incidence of workplace exposure to fibrosis inducing industrial dusts is estimated at around 0.8% of all workers employed in the enterprises subject to reporting or 43,000 workers. This compares to around 60,600 in 2006 and 49,000 in 2010. A gradual reduction of exposure was identified, for example, during 2014, in 8,425 cases exposure was eliminated or limited to levels below relevant norms. In 7,608 cases exposure was limited but not below the norms. During the same year 9,574 new cases of exposure were identified. According to these data, sectors where exposure is most common include mining, in particular hard coal mining, where more than a quarter of all employees are exposed. Construction is another sector with relatively high levels of exposure. Such a high concentration of all incidence cases on mining implies a strong regional dimension to the problem with 70% of all cases located in just one voivodship (region): śląskie.

In **Slovakia,** the information system used by the Public Health Authority to register hazardous work (on the basis of an automatized system of risk classification) monitors only two categories of silicates 'amorphous silica' and 'other silicates' i.e. not specifically

[181] Scarselli A1, Montaruli C, Marinaccio A., (2007) The Italian information system on occupational exposure to carcinogens (SIREP): structure, contents and future perspectives. Ann Occup Hyg. 2007 Jul;51(5):471-8. Epub 2007 Jun 25.

[182] Inail (2012) Esposizione ad agenti cancerogeni nei luoghi di lavoro, Dipartimento di Medicina del lavoro http://www.inail.it/internet_web/wcm/idc/groups/salastampa/documents/document/ucm_portstg_109033.pdf

[183] INAIL (2014) Il registro INAIL di esposizione a cancerogeni professionali http://sicurezzasullavoro.inail.it/PortalePrevenzioneWeb/wcm/idc/groups/prevenzione/documents/document/ucm_161716.pdf

[184] Ministerial Decree 155/2007 Regolamento attuativo dell'articolo 70, comma 9, del decreto legislativo 19 Settembre 1994, n. 626. Registri e cartelle sanitarie dei lavoratori esposti durante il lavoro ad agenti cancerogeni http://old.unipr.it/arpa/spp/Norme/Decreto%20155-2007%20e%20allegati.pdf

[185] GUS (2015), Warunki pracy w 2014 r. (Working conditions in 2014), http://stat.gov.pl/obszary-tematyczne/rynek-pracy/warunki-pracy-wypadki-przy-pracy/warunki-pracy-w-2014-r-,1,9.html Ministry of Economy (2015), Information on the functioning of hard coal mining in June 2015 and in January-June 2015 period, http://www.mg.gov.pl/files/upload/8155/Jedynka%20tekst%20czerwcowy.pdf

RCS.Also, since 2001 a new system of risk categorisation is being used in which all chemical substances are classified as 'chemical agents' and carcinogens/mutagens and dust are registered as subgroups to chemical agents. Therefore, data on workers' exposure from the central registry of hazardous work are available for these two subgroups; in 2003, 30,472 workers were estimated to be exposed to dust and in 2014 this number went down to 16,404; while the number of workers exposed to carcinogens/mutagens decreased from 4,617 in 2003 to 5,557 in 2014[186].

In **Spain**, the data found on exposure relate to a recent study[187] aimed at creating a job-exposure matrix for the Spanish working population for the period 1996-2005 to allow automatic allocation of the probability and intensity of exposure to occupational risks in different jobs. The study identified 39 occupations (out of 482) where workers face a high risk of exposure to RCS. The study also estimated that in 11 of these occupations there is a high probability of the exposure is exceeding legal limits. Moreover, in six of these 11 occupations, exposure is affecting more than 70% of workers. The analysis estimated the level of intensity of the exposure and the percentage of workers exposed. Using both indicators, eight occupations show the highest results and also account for a high level of confidence in the results. The occupations are: concrete placers, concrete finishers, benders and similar; personal cleaning building facades and chimney sweeps; parquet manufacturers, tilers and similar; moulders and core makers; glass-makers, cutters, grinders and finishers; glass etching; operators in mining facilities; operators of machinery to manufacture products of non-metallic minerals.

In **Sweden**, limited data exist on exposure and few measurements are reported back to the Work Environment Authority, around 200 per year (including some of the large mining companies). The impact assessment published in 2014 and carried out for the new RCS regulation[188] estimated that around 100,000 employees work in sectors[189] where the exposure to RCS is most common, a large majority of these employees work in the construction sector (approx. 79,000). The impact assessment also estimated that around 150,000 employees may be exposed to RCS. Again, most of these are active in the construction sector. The study also highlights that there are very few service providers/ consultancies that conduct exposure measurements and this, together with measurement of exposure levels not considered satisfactory, is an important reason for the new regulation further emphasising the possibility of using reference measurements (although these should not be more than five years old).

In **the UK**, HSE estimates that at least 100,000 workers are regularly exposed to dusts containing RCS in a variety of industry sectors. These include mines and quarries, iron and steel foundries, the heavy clay industry (including brick manufacture), potteries, construction, stonemasons and the industrial sand industry[190]. Other estimates have suggested a figure

[186] Central registry of hazardous works, Public Health Authority of Slovak Republic

[187] MA thesis of BRICEÑO F, Occupational Safety and Environmental Hygiene Engineer, Centro de Investigación en Salud Laboral. Universitat Pompeu Fabra. https://www.upf.edu/cisal/_pdf/TFM_Freddy_Bricexo.pdf The study is based on the MatEmESp project which aims at building "a job-exposure matrix for Spain's working population, tapping into available information and drawing on the experience and knowledge of researchers and experts in the field of occupational risk prevention in Spain".

[188] Arbetsmiljöverket (2014), Konsekvensutredning för Arbetsmiljöverkets förslag till reviderade föreskri2fter om kvarts

[189] The NACE sectors covered are as follows: 45: Construction; 26: Manufacture of other non-metallic mineral products; 13: Mining of metal ores; 27: Manufacture of basic metals; 28: Manufacture of fabricated metal products, except machinery and equipment; 29: Manufacture of machinery and equipment n.e.c.; 14: Other mining and quarrying; 60: Land transport; transport via pipelines; 90: Sewage and refuse disposal, sanitation and similar activities

[190] Control of Substances hazardous to Health Regulations 2002 (as amended 2005) Proposal for a Workplace Exposure Limit for Respirable Crystalline Silica CD 203 C10 HSC 11/05 www.hse.gov.uk/consult/condocs/cd203.pdf

exposed in Britain of 564,787, 80% of which work in construction[191]. Trends in occupational exposure to RCS are falling. The UK National Exposure Database (NEDB) was set up in 1986, it was initially populated with measurements of workplace exposure to chemicals taken by specialist HSE inspectors during their investigations and inspections. The database would be used to display standardised information[192]. The database contains some 80,000 measurements taken between 1986 and 2001, most of the data came from HSE, some came from HSE sponsored industry wide surveys, from exposure measurement development surveys, and industrial sources. The NEDB contains >6000 measurements of quartz, although the number of all samples collected has reduced dramatically recently. However, there are quality issues with the data related to the purpose for which it had been collected, and therefore may not be representative. The number of datasets has declined significantly in the 2000s. However, exposure to carcinogens is declining, both in terms of numbers exposed and level of exposure. Reduced exposure is attributed to reduced number of emission sources and the use of engineering controls. Other studies suggested improved technology in production processes, availability of improved equipment and responses to legislation have reduced exposure. Since the early 1990s the exposure in British workplaces has reduced by approximately 30% assuming a reduction of 6% per year.

Extrapolating to 2025 with a continued reduction at this rate, exposure could be around 2% of that in the 1990s[193].

Annex 2 Literature review

This stand-alone paper provides the results of the transnational literature review and provides an overview of health risks associated to exposure to respirable crystalline silica (RCS), sector and activities at risk of exposure, protective measures to reduce exposure and evidence of impact of reducing exposure.

A2.1 Health risks associated with exposure to Respirable Crystalline Silica

Silica is found in rocks and soil; it is comprised of the two most abundant chemicals found in the Earth's crust, silicon and oxygen. Silica is a generic term used to cover minerals of different crystalline structures such as quartz, tridymite and cristobalite. Crystalline forms of silica are more toxic than non-crystalline or amorphous forms. Though, amorphous silica is less common than the crystalline form[194]. RCS consists of very fine particles of crystalline silica, small enough to penetrate into the gaseous exchange part of the lung or alveoli[195][196]. Respirable particles are so small they are invisible to the naked eye, with a typical diameter

[191] Van Tongeren, M., Jimenez, A. S., Hutchings, S. J., MacCalman, L., Rushton, l., and Cherrie j., W. Occuaptional Cancer in Britain, Exposure Methodology British Journal of Cancer (2012) 107 518-526

http://www.ncbi.nlm.nih.gov/pubmed/22710674

192 Burns, D.K. and Beaumont, P.L. The National Exposure Database (NEDB) Annals Occ Hyg (1989) 33(1) 1-14

http://annhyg.oxfordjournals.org/content/33/1/1

[193] Cherrie, J.W., Van Tongeren, M., and Semple, S. Exposure to Occupational Carcinogens in Great Britain Annals of Occupational Hygiene Vol 51 No 8 pp 653-664 2007
http://annhyg.oxfordjournals.org/content/51/8/653.full.pdf+html

[194] What is silica? European Association of Industrial Silica Producers Website

http://www.eurosil.eu/what-silica

[195] ISO 7708:1995 Air quality: Particle size fraction definitions for health-related sampling International Standards Organisation

[196] BS EN 481:1993 Workplace atmospheres: Size fraction definitions for measurement of airborne particles British Standards Institution

of less than 5um. Workers can be unknowingly exposed to high concentrations of toxic silica dust. Exposure occurs in industrial sectors that extract and process rock and manufacture or use products that contain silica. These sectors are principally construction, brick and ceramic manufacture, foundries, glass making, and stone masonry.

The diseases associated with occupational exposure to RCS are silicosis[197], pulmonary cancer, and chronic Obstructive Pulmonary Disease (COPD)[198]. Exposure to silica began when man first created flint tools, since flint contains a very small proportion of silica[199]. The word silica is derived from the Greek work silex, which means flint. Both Pliny and Hippocrates mentioned the silicosis[200]. Some two thousand years later in 1700, the father of occupational medicine, Ramazzini, reported evidence of silicosis in stone workers[201]. It is clear that workers exposed to silica have been developing and suffering from a recognisable lung disease for many thousands of years.

Silicosis is divided into three categories, chronic, accelerated, and acute. The differences between the categories are attributed to the concentration and duration of exposure to RCS. Chronic silicosis is the most common and occurs 10 or more years after first exposure to typically low concentrations of RCS. Accelerated silicosis is associated with exposure to higher concentrations which would give rise to chronic silicosis and it develops five to 10 years after first exposure. Acute silicosis is the most aggressive form of silicosis; it develops very quickly and can be fatal within months after exposure to extremely high concentration of RCS, although the onset of symptoms may occur only weeks after exposure.

Silicosis is characterised by nodular fibrosis. Typically, with a nodular diameter of 2-5mm, and usually concentrated in the middle and upper zones of the lung. The nodules can merge together to form a Progressive Massive Fibrosis (PMF). Symptoms of silicosis include cough, shortness of breath, and unexplained weight loss. There is no cure and treatment is focused on alleviating symptoms. Diagnosis is made by establishing a history of exposure to RCS, assessing the time of first exposure and the development of symptoms, and chest radiographs, which exhibit the characteristics of a nodular fibrosis. Complications include lung cancer, respiratory failure and tuberculosis[202][203].

In 1997, IARC (International Agency for Research on Cancer) working party published its assessment of carcinogenic risk of silica to humans[204]. It concluded that silica was associated with lung cancer and assigned it a group 1 classification. This view was

[197] American Lung Association Website
http://www.lung.org/lung-disease/silicosis/understanding-silicosis.html

[198] Hnizdo, E., and Vallyathan, V. Chronic obstructive pulmonary disease due to occupational exposure to silica dust: A review of the epidemiological Pathological Evidence Occup Env Med 2003 ; 60 :237-243
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740506/pdf/v060p00237.pdf

[199] Kalin, J. Flint Knapping and silicosis
http://www.pugetsoundknappers.com/interesting_stuff/knapping_silicosis_article.html

[200] Sherson D. Silicosis in the twenty first century. Occup Environ Med. 2002 Nov. 59(11):721-2
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740242/pdf/v059p00721.pdf

[201] Regulations and requirements Centre for Construction Research and training Website
http://www.silica-safe.org/regulations-and-requirements/status-of-regulatory-efforts/history

[202] Jedynak, A. R. Imagining in silicosis and coal workers pneumoconiosis Medscape Updated 12 July 2013
http://emedicine.medscape.com/article/361778-overview

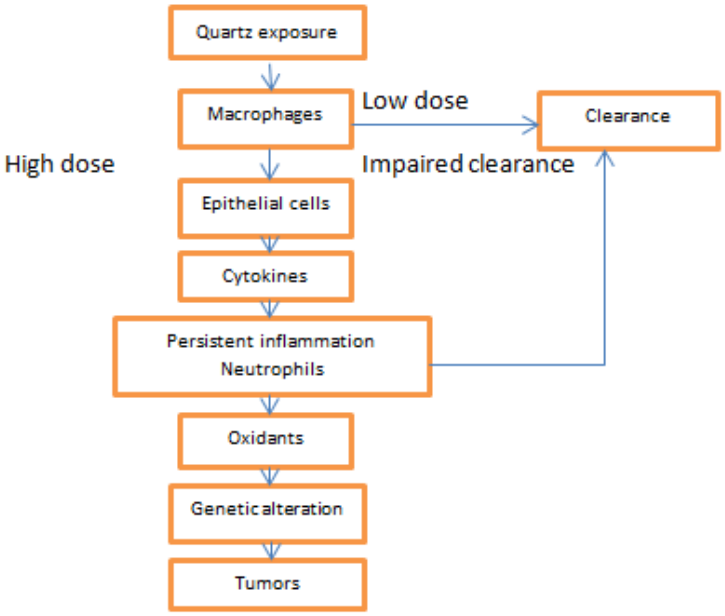
[203] Hadjiliadis, D. Silicosis Medline Plus Updated 20/5/2013
https://www.nlm.nih.gov/medlineplus/ency/article/000134.htm

[204] IARC Working Party on the Evaluation of Carcinogenic Risks in Humans; Silica, Some silicates, Coal dust and Para-Aramid fibrils. Lyon 15-22 October 1996 IARC Monog Eval Carcinog Risks Hum 1997; 68;1-475
http://monographs.iarc.fr/ENG/Monographs/vol68/mono68.pdf

reaffirmed in a further review published in 2012[205]. However, there remain unanswered questions relating to the mechanism that leads to the development of lung cancer. The issue of whether silicosis is a precursor to cancer has now been addressed, however, and found to be incorrect[206].

It is thought that the fibrotic and carcinogenic properties of RCS are associated with the strong inflammatory response, which exposure to silica evokes in the lung. Rat studies have demonstrated that phagocytes, which engulf silica particles, are themselves killed releasing their cell contents which contain oxidants and cytokines causing continued inflammation. This leads to cell proliferation as fibrosis[207]. A possible mechanism for the development of lung cancer after exposure to RCS is illustrated below[208].

Figure 9.1 Possible mechanism for the development of lung cancer after exposure to RCS



In terms of the relationship between COPD (Chronic Obstructive Pulmonary Diseases) and silica exposure, a review published in 2003 of epidemiological and pathological data has demonstrated that those exposed to RCS can develop COPD without radiological signs of silicosis[209]. COPD includes within the definition chronic bronchitis and emphysema, which

[205] IARC Working Party on the Evaluation of Cancer Risks in Humans; Arsenic, metals, fibres and dusts; A Review of Human carcinogens Vol 100C Lyon 17-24 March 2009 2012

http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C.pdf

[206] Steenland, K., and Ward, E. Silica: A lung Carcinogen CA Cancer J Clin 2014; 64;63-69

http://onlinelibrary.wiley.com/doi/10.3322/caac.21214/full

[207] Steenland, K., and Ward, E. Silica: A lung Carcinogen CA Cancer J Clin 2014; 64;63-69

http://onlinelibrary.wiley.com/doi/10.3322/caac.21214/full

[208] Rice, F. Crystalline silica, quartz. Concise international Chemical Assessment Document 24, WHO, Geneva 2000

http://www.who.int/ipcs/publications/cicad/en/cicad24.pdf

[209] Hnizdo, E., and Vallyathan, V. Chronic obstructive pulmonary disease due to occupational exposure to silica dust: A review of the epidemiological Pathological Evidence Occup Env Med 2003 ; 60 :237-243

both increase airway resistance, and reduce forced expiratory airflow. Fibrosis due to silicosis will also reduce flow. Again, it is suggested that the inflammatory response initiated in the lungs by inhalation of RCS is responsible for the development of COPD. The review looked at two groups, those with silicosis and those without silicosis. In the group with silicosis controlled for age, height and smoking, the average excess loss in 9.8ml of LEV1 per year. The presence of silicosis was not associated with any significant loss of FEV1 or FVC. A 12 year follow up survey of granite crushers without silicosis indicated a reduction in FEV1 of 150ml, when matched with a control group matched for age and smoking habits. In short, a dose response relationship exists for cumulative exposure to silica and reduced airflow in both smokers and non-smokers.

The review also examined studies that explored the relationship between smoking and silica and COPD and concluded that smoking potentiates the impact of silica, and therefore silica exposure should be reduced, and those exposed encouraged to quit smoking to prevent COPD. The review concluded that low level of silica exposure could result in emphysema and chronic bronchitis, which can result in airflow obstruction even in the absence of silicosis.

A2.2 Sectors/activities having the greatest risk of exposure to RCS and effective protective measures to protect from exposure to RCS

Workers in many industry sectors undertaking various activities are likely to be exposed to RCS. The sectors and activities will be principally those which use sand or rock and materials which contain sand or rock. Low level exposure to RCS will occur on beaches and from dust in ambient air, although there is no evidence that low levels of exposure cause health effects. The table below illustrates common sectors and activities where exposure to RCS can occur[210].

Table 9.1 Occupations and industries with silica exposure

Occupation	Industry
Sandblasting	Ship building, iron working, construction/painting (cleaning painted areas)
Miner	Mining underground
Miller	Silica flour mills
Ceramic worker	Pottery and ceramics
Glassmaker	Glass production
Granite quarry worker	Mining in quarries
Sand grinding	Industrial sand
Stone grinding	Granite industry (monuments)
Casting, shake out blasting	Foundry

Source: Steedland, K., and ward, E. Silica: A lung carcinogen CA; A cancer Journal for clinicians Vol 64 Issue Pages 63-69 Jan/Feb 2014

In terms of controlling exposure, the accepted principle is elimination of the risk or substitution of the toxic substance with an alternative, either non-toxic or less toxic. Exposure is controlled by a series of measures termed the General Principals of Prevention contained

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740506/pdf/v060p00237.pdf

[210] Steedland, K., and ward, E. Silica: A lung carcinogen CA; A cancer Journal for clinicians Vol 64 Issue Pages 63-69 Jan/Feb 2014

http://onlinelibrary.wiley.com/doi/10.3322/caac.21214/full

within Council Directive 89/391/EEC (as amended)[211] . In practice, the engineering controls for reducing exposure to RCS are local exhaust ventilation, wet suppression of dust, and the use of Respiratory Protection Equipment (RPE). However, the use of engineering controls must take precedence in any exposure control strategy. RPE may be used in combination with other controls if they cannot adequately control the risk alone.

The industry sector that employs the largest at risk group of workers in the EU 15 is construction[212]. Within the construction sector there are many activities and trades performed and exposure to RCS does vary significantly between trades. According to an exposure database constructed from a review of exposure data, plumbers have the lowest mean exposure of 0.01 mg/m3 with abrasive blasting having the highest of 1.59 mg/m3[213].

Many agencies offer advice on the control of RCS in construction. In the USA, the Occupational Safety and Health Administration (OSHA) has produced detailed guidance for the construction industry in many common activities that produce RCS. These include stone cutting saws (hand held and stationary), hand operated grinders, tuck pointing and jack hammers[214]. OSHA also produces an extensive range of Fact Sheets which recommend safety precautions to use in specific construction activities including precautions to reduce silica exposure[215].

The Health and Safety Executive (HSE) in the UK also provide information on measures to be taken to reduce exposure to dust in a number of construction processes[216]. Again, the principle method of control recommended is wet suppression or local exhaust ventilation. It also produces more general information on the control of silica which directs employers and employees to further sectoral information[217].

EU-OSHA focused their European Week of Safety 2004 campaign on construction activities, and the control of silica exposure from road surface milling was identified as a good practice case study[218].

Silica-safe is a website dedicated to the recognition and control of the risks associated with silica in construction. The site is operated by the Centre for Construction Research and Training (CPWR)[219]. Silica was identified as a priority by a working group established by

[211] Council Directive 12th June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work 89/391/EEC (OJ L183 29/6/89 P1)

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01989L0391-20081211&from=EN

[212] CAREX Industry Specific Estimates, Summary 26th March 1999

http://www.ttl.fi/en/chemical_safety/carex/Documents/5_exposures_by_agent_and_industry.pdf

[213] Beaudry, C, Lavoué, J., Sauvé, J., Bégin, D., Rhazi M. S., Perrault, G., Dion, C., & Gérin, M. Occupational Exposure to Silica in Construction Workers: A Literature-Based Exposure Database. Journal of Occupational and Environmental Hygiene Vol 10 Issue 2, 2013

http://www.tandfonline.com/doi/abs/10.1080/15459624.2012.747399

[214] Occupational Safety and Health Administration (OSHA). Controlling Silica Exposures in construction OSHA 3362-05 2009

https://www.osha.gov/Publications/3362silica-exposures.pdf

[215] OSHA fact Sheets index for activities giving rise to RCS.

https://www.osha.gov/pls/publications/publication.searchresults?pSearch=silica

[216] Construction dust Construction Information Sheet No 36 (Revision two) HSE 06/13

http://www.hse.gov.uk/pubns/cis36.pdf

[217] Control of exposure to silica, a guide for employees INDG 463 HSE 05/14

http://www.hse.gov.uk/pubns/indg463.pdf

[218] Building in safety, Prevention of Risks in Construction-in practice. European Agency for health and safety at Work 2004

https://osha.europa.eu/en/tools-and-publications/publications/reports/108

[219] Working safely with silica website, Centre for Construction Training and research 2012

OSHA, National Institute for Occupational Safety and Health (NIOSH) and CPWR. The website provides access to online tools to assist employers to develop a silica control plan[220].

Work Safe British Columbia has also produced guidance to assist employers in the construction industry to reduce exposure to silica by developing a silica control plan. The plan is a legal requirement and contains information on how to control exposure in common construction processes, and provides examples of the documentation necessary to support the plan[221].

A review of occupational health hazards in mining observed that "Axial water-fed rock drills, wet techniques, ventilation, enclosed cabins and respiratory protection have largely controlled silicosis in developed nations. However, silicosis remains a problem in developing nations…"[222]. Water sprays and ventilation both dilution and extract ventilation are used commonly in underground mining to reduce dust generated by the removal and transport of minerals[223][224].

RCS exposure in agriculture occurs during mechanical preparation of soil by ploughing and disking which can generate significant dust clouds. The highest exposures are experienced by those driving tractors with open cabs with total particle exposures of up to 100 mg/m3[225]. The use of tractor cabs with filtered ventilation systems, which maintain the cab under positive pressure, will reduce exposure to all dusts including RCS, with a reduction in average exposure from 2 mg/m3 to a range of 0.1 to 1mg/m3. Respirable quartz exposures as low as 0.05 mg/m3 have been reported in closed cabs[226]. Exposure to RCS is also an issue during harvesting as dust, which has settled on plants during the growing phase will be raised into the air during the harvesting process[227] and, again, well designed and maintained ventilated tractor and harvester cabs will reduce exposure to all dust[228].

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http://www.silica-safe.org/about/purpose

[220] Create a plan to control the dust

http://plan.silica-safe.org/

[221] Work Safe BC, Developing a silica exposure control plan

http://www2.worksafebc.com/Portals/Construction/HazardousMaterials.asp?ReportID=34096

[222] Donoghue, A. M. Occupational Health Hazards in Mining; an overview. Occupational Medicine. (2004) 54 (5) p 283-289

http://occmed.oxfordjournals.org/content/54/5/283.full.pdf+html

[223] Colinet, J.F., and Thimons, E.D. Dust control practices in underground coal mining NIOSH 2006

http://www.cdc.gov/niosh/mining/userfiles/works/pdfs/dcpfu.pdf

[224] Kessell, F.N., Handbook for dust control in mining Information circular 9465, NIOSH 2003

http://www.cdc.gov/niosh/nas/rdrp/appendices/chapter3/a3-23.pdf

[225] Bhargia, L.J., Non Occupational Exposure to Silica. Indian Journal of Occupational and Environmental Medicine 2012 Sept-Dec 16 (3): 95-100

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3683189/

[226] Schenker, M. B., (chair) Respiratory Health Hazards in Agriculture. Supplement American Thorasic Society American Journal of Respiratory and Critical Medicine November 1998 Volume 158 Number 5 Part 2

https://www.thoracic.org/statements/resources/archive/agriculture1-79.pdf

[227] Rom, W., and Larkowitz, S.B., ED Environmental and Occupational Medicine Fourth Edition, Lippincott, Williams and Wilkins 2007

https://books.google.co.uk/books?id=H4Sv9XY296oC&pg=PA572&dq=reducing+dust+exposure+by+using+ventilated+tractor+cabs&hl=en&sa=X&ved=0CDQQ6AEwAGoVChMIgefAjNqgxwIVCT0UCh2efwdZ#v=onepage&q=reducing%20dust%20exposure%20by%20using%20ventilated%20tractor%20cabs&f=false

[228] Harvesting Grain and Seed Crops AG1, COSHH Essentials for farmers, Control Approach 2 Engineering Control HSE 12/06

http://www.hse.gov.uk/pubns/guidance/ag1.pdf

NIOSH in the USA has outlined in detail the control measures, which can be adopted to reduce dust exposure in mineral mining and processing[229]. Dust controls covering activities including blasting and drilling, crushing, milling and screening, conveying and transport. Specific advice is given for dust control in control rooms, operator booths and enclosed cabs. In the UK the Health and Safety Executive have produced a series of guidance notes on the control of exposure to silica in various industries including quarrying[230]. Other industries covered by specific HSE guidance include brick and tile making, ceramics, construction, foundries, and manufacturing, slate and stone masons[231].

Recently, the Glass Alliance Europe published its position on exposure of workers in the sector to RCS[232]. The purpose of the statement was "to shed light on the handling of RCS in our (the glass) industry, the potential exposure of workers, and the risk prevention measures already in place". It concluded that "workers in the glass industry are well protected against health risks arising from exposure to respirable crystalline silica". In terms of those exposed to RCS, it is stated that only 10% of employees in the industry are at risk of exposure, and these are employed in handling, mixing and transportation of the raw materials to the furnace. The industry is confident that 90% of those potentially exposed are subject to risk assessment and 65% have their exposure monitored. It suggests that both technical (e.g. ventilation) and organisational (e.g. staff rotation) measures are in place, and form part of company's health and safety management systems. Though, it makes the point that risk assessment must drive controls on an individual site by site basis. It also comments that improvements have been made over the last decade, since the signing of the Social Partner agreement. In terms of control of exposure to RCS, the raw material for glass production is sand and RCS forms <15% by weight. Further, the moisture content of the sand is 3-4%, which reduces the generation of dust.

Foundry workers could also potentially be exposed to RCS in the preparation, and dismantling of moulds for metal castings. The American Foundry Society recognised some time ago the need to address the issue, and has produced guidance for the industry[233] . The guidance contains industry good practice case studies, demonstrated to reduce exposure in foundry activities such as grinding. Following the guidance will assist in delivering lower exposure through the application of an Exposure Control Programme Strategy.

Stone masons are another specific group at risk of exposure to RCS. This includes those working on the restoration of historic buildings, and others engaged on monumental masonry. Again, the risk is well known and HSE in the UK have produced guidance to assist mason to reduce their risk of exposure[234]. The effectiveness of commercially available

[229] Cecala, A.B., O'Brien, A.D., Schall, J., Colinet, J.F., Fox, W.R., Franta, R.J., Joy, J., Reed, W.R., Reeser, P.W., Rounds, J.R., Schultz, M.J. Dust Control Handbook for Industrial Minerals Mining and Processing, Report of Investigations 9689 NIOSH 2012-112

http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.392.8914&rep=rep1&type=pdf

[230] Control of Substances Hazardous to Health Essentials Guidance Publications Quarrying Series HSE

http://www.hse.gov.uk/pubns/guidance/qyseries.htm

[231] Control of Substances Hazardous to Health Essentials Guidance publication Index HSE

http://www.hse.gov.uk/pubns/guidance/index.htm

[232] Respirable crystalline silica in the Glass industries, Glass Alliance Europe, Jan 2014

http://www.glassallianceeurope.eu/images/cont/glass-alliance-europe-statement-on-respirable-crystalline-silica_file.pdf

[233] Scholz, R.C., Slavin, T.J., and Roundtree, K. Control of Silica Exposure in Foundries, American Foundry Society Nov 2007

http://www.afsinc.org/files/silica_book_no%20copyright.pdf

[234] Controlling exposure to stone masonry dust, Guidance for Employers. HSG201 HSE First Ed. 2001

http://www.hse.gov.uk/pubns/priced/hsg201.pdf

vacuum shrouds fitted to angle grinders used in stone masonry has been evaluated[235]. They performed significantly better in reducing exposure when compared with grinders with no shroud. Both dust and RCS concentrations were reduced by between 90 and 99%. Again, respiratory protection equipment would need to be deployed on ensure the American Conference of Governmental Industrial Hygienists Threshold Limit Value of 0.025 mg/m3 was achieved.

There is common acknowledgement that those industry sectors posing the highest risk of exposing their employees to RCS have recognised the problem, and that action is required to reduce exposure. The controls introduced are based on the application of ventilation both local exhaust and dilution/general ventilation, and wet dust suppression techniques. This is particularly evident in construction activities such as the use of cut off saws and concrete grinding, where these controls reduce dust emission significantly. There is some evidence that in a number of construction activities, such as those mentioned above and referred to elsewhere in this review that engineering controls may not be adequate to comply with exposure limits and appropriate RPE must also be used to further reduce exposure.

A2.3 Evidence of impact of reducing exposure

Occupational exposure to RCS increases the risk of developing lung disease, principally silicosis and pulmonary cancer[236]. Silicosis could be considered to be one of the oldest occupational disease, since it is associated with occupations and activities which produce dust containing RCS. Silicosis is a nodular fibrosis, characterised on X-rays by a profusion of small opacities.

A number of studies of exposed workers and examination of mounted lung tissue samples have shown that the higher the exposure of the individual, and therefore the greater RCS concentration in the lungs, the more severe the resulting silicosis. Clearly, the risk of developing silicosis increases with higher exposures and concentration of CRS in the lungs. A clear dose response relationship exists. One study looked at silicosis prevalence in 100 miners in Colorado. It was found that those exposed to concentrations of silica >0.1mg/m3 exhibited a silicosis prevalence rate of 48.6%, those exposed between >0.05mg/m3 and 0.1mg/m3 had a prevalence rate of 22.5% and those exposed <0.05mg/m3 had 10% prevalence of silicosis. A study of foundry workers also confirmed a dose response relationship. , Reducing exposure to RCS will clearly reduce the risk of developing silicosis[237].

Occupational exposure to RCS is associated with lung cancer as stated by International Agency for Research on Cancer. This was the conclusion of a review of the literature published in 1997[238] and resulted in the reclassification of silica to group one. Cancer risk appeared to be related to cumulative exposure to CRS, duration of exposure, peak intensity

[235] Healy, C.B., Coggins, M.A., Van Tongeren, M., MacCalman, L., McGowan P. An Evaluation of on-tool shrouds for controlling respirable crystalline silica in restoration stone work Annals of Occupational Hygiene 2014 Nov 58 (9) 1155-67

http://annhyg.oxfordjournals.org/content/58/9/1155.abstract

[236] Rice, F. Crystalline silica, quartz. Concise international Chemical Assessment Document 24, WHO, Geneva 2000

http://www.who.int/ipcs/publications/cicad/en/cicad24.pdf

[237] Rice. F., crystalline silica, Quartz concise international chemical assessment document 24, World health Organisation 2000

[238] IARC Working Party on the Evaluation of Carcinogenic Risks in Humans; Silica, Some silicates, Coal dust and Para-Aramid fibrils. Lyon 15-22 October 1996 IARC Monog Eval Carcinog Risks Hum 1997; 68;1-475

http://monographs.iarc.fr/ENG/Monographs/vol68/mono68.pdf

of exposure, the presence of silicosis, and length of the follow up time from the silicosis diagnosis. This view that silica is a carcinogen was reaffirmed in 2012[239].

Discussions have continued over the strength of the evidence to support the Group One status of RCS. There are also anomalies between sectors where exposure is high, but risk of lung cancer is low. The impact of confounding factors such as smoking and silicosis are also not fully understood, but smokers appear to be more likely to develop silicosis than non-smokers. It has been suggested that if exposure is maintained at a level that prevents silicosis, this will also reduce the risk of lung cancer. However, even at exposures of <0.5 mg/m3, there remains risk of developing chronic silicosis, over a lifetime. Therefore, the reduction of Occupation Exposure Limits (OEL) and compliance with lower limits may be justifiable. Silicosis deaths in Great Britain are declining, therefore suggesting that exposure is also declining. If silicosis is a necessary step resulting in lung cancer, then enforcement of current OELs would also protect workers against cancer. If a direct causal link between RCS and cancer is determined, then regulatory standards should be reviewed accordingly. But the most effective action to reduce the risk of cancer is to reduce exposures to prevent silicosis, and encourage workers exposed to RCS to quit smoking[240].

A recent review examined the outcomes of studies that address some of the points raised above[241]. This paper suggests that there is significant evidence to support the view of a positive exposure response relationship between cumulative silica exposure and lung cancer mortality. Further, a Chinese study reviewed in the same paper supported this view, and addressed the question of whether silicosis was a precursor to cancer. This study of excluded subjects with radiological evidence of silicosis and found that silicosis was not in fact a requirement for lung cancer. The same study also sheds light on the relationship between smoking and cancer in those who had been exposed to silica. It found that the relative risk to smokers and never smokers was about the same. However, because smoking has such a big risk factor for lung cancer, taken together with exposure to RCS the risk of lung cancer is therefore high, confirming the advice above to quit smoking, which will over time reduce the risk.

In the UK the Health and Safety Executive's (HSE) disease reduction programme sought to address the issue of occupational cancer as part of a comprehensive strategy to reduce illness caused by exposure to hazardous substances at work[242]. RCS was included with this programme, and it was suggested that it was a hypothetical possibility to reduce exposures and prevalence of exposure to known carcinogens to a level where by 2025 they would contribute less than 1% of all future cancers.

More recent studies on occupational cancer have also considered the likely future outcomes in terms of reduced incidence by the application of various hypothetical exposure and compliance scenarios for a number of occupational carcinogens including RCS[243][244]. The

[239] IARC Working Party on the Evaluation of Cancer Risks in Humans; Arsenic, metals, fibres and dusts; A Review of Human carcinogens Vol 100C Lyon 17-24 March 2009 2012

http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C.pdf

[240] Brown, T. Silica exposure, smoking, silicosis, and lung cancer-complex interactions Occupational Medicine 2009, 59, 80-93

http://occmed.oxfordjournals.org/content/59/2/89.full.pdf+html

[241] Steenland K. and Ward E Silica: A lung Carcinogen, CA A Cancer Journal for Clinicians Vol 64, Issue 1, pages 63-69 Jan/Feb 2014

http://onlinelibrary.wiley.com/doi/10.3322/caac.21214/full

[242] Cherrie JW, Van Tongeron M., Semple S Annals Exposure to occupational carcinogens in Great Britain Occ Hyg Vol 51 No8 pages 653-664 2007

http://annhyg.oxfordjournals.org/content/51/8/653.full.pdf+html

[243] Hutchings S., Rushton L, Towards risk reduction: Predicting the future burden of occupational cancer American Journal of Epidemiology March28 2011

studies model the likely outcomes in terms of number of cases from 2010 up to 2060. One study uses RCS as the example in modelling of future cancer burdens.

With respect to RCS attributed cancers in the UK, by 2010 there were 837 cases of lung cancer attributed to RCS, with an Attributable Fraction (AF) of 2.07%. If current conditions of employment, and exposure were to continue, in 2060 it is estimated that there will be 794 lung cancer registrations attributed to CRS exposure. That is very little change in incidence. If, in 2010 an Occupational Exposure Limit (OEL) of 0.05 mg/m3 (currently 0.1 mg/m3) was introduced with a 33% compliance (similar to current estimated compliance rate), then the number of attributable cancers would reduce to 592, avoiding 202 cases, with AF 0.8%. A number of further scenarios are considered including introduction of an OEL of 0.05 mg/m3 with a 90% compliance rate for all workplaces. This would result in an estimated 49 cases attributed to CRS and avoiding 745 cases, AF 0.07%. Another scenario kept the OEL at 0.1 mg/m3 until 2060, but by ensuring a 90% compliance rate this would result in an estimated 102 attributable cases, with AF 0.14%. Therefore, it is compliance with the OEL, which is crucial to ensure that workers are protected from exposure to RCS, not necessarily the level at which the limit is set. It is therefore important to ensure that where OELs are set, that they are also enforced by the various regulators. It can be seen that the numbers of recorded cancers, and also the attribution fraction can be significantly reduced by the wider application of the current OEL or reducing the OEL by a half and securing a similar compliance rate. Therefore, it is clear that actions to reduce exposure to RCS will have a direct impact on the health outcomes of those exposed[245][246].

OSHA USA is proposing a rule change to occupational exposure to RCS[247]. Implementation of this new rule would reduce the Permissible Exposure Limit (PEL) for RCS from the current level of 0.1 mg/m3 to 0.05 mg/m3 TWA (Time Weighed Average), over an eight- hour reference period. By introducing the new reduced PEL it is calculated it will save 700 lives and avoid 1600 new cases of silicosis a year. However, even at this new proposed level the excess life time risk will exceed the OSHA's stated aim of one in 1,000. It is also interesting to note that PELs are mandatory, but other USA organisations have recommended more stringent standards[248] . These include American Conference of Industrial Hygienists (ACGIH) Threshold limit Value (TLV) of 0.025 mg/m3 (TWA based upon an eight-hour reference period) and National Institute for Occupational Safety and Health Recommended Exposure limit (REL) of 0.05 mg/m3 (TWA based on a 10-hour reference period).

The literature provides compelling evidence that RCS is a significant health risk and that exposure is proportionate to risk, therefore it is clear that there are significant health benefits in reducing occupational exposure. Control of exposure is more effective if amount of dust

http://aje.oxfordjournals.org/content/173/9/1069.full.pdf+html

[244] Hutchings, S., Cherrie JW, Van Tongeron M, Ruston L, Intervening to Reduce the Future Burden of Occupational Cancer in Britain: What Could Work? Cancer Prevention Research September 7 2012 http://cancerpreventionresearch.aacrjournals.org/content/5/10/1213.full

[245] Hutchings S., Rushton L, Towards risk reduction: Predicting the future burden of occupational cancer

American Journal of Epidemiology March28 2011

http://aje.oxfordjournals.org/content/173/9/1069.full.pdf+html

[246] Hutchings, S., Cherrie JW, Van Tongeron M, Ruston L, Intervening to Reduce the Future Burden of Occupational Cancer in Britain: What Could Work? Cancer Prevention Research September 7 2012 http://cancerpreventionresearch.aacrjournals.org/content/5/10/1213.full

[247] Occupational Exposure to Respirable Crystalline Silica; A Proposed Rule by the Occupational Safety and Health Administration, Federal Register 09/12/2013

https://www.federalregister.gov/articles/2013/09/12/2013-20997/occupational-exposure-to-respirable-crystalline-silica

[248] United States Department for Labor, OSHA, Chemical Sampling Information, Silica, Crystalline Quartz (Respirable Fraction)

https://www.osha.gov/dts/chemicalsampling/data/CH_266740.html

produced can be reduced, rather by protecting the person with respiratory protection equipment. Engineering controls include local exhaust ventilation, to capture the dust, and wet suppression techniques to reduce the amount of dust produced by the use of water sprays or mists.

A number of studies have been undertaken to evaluate the effectiveness of engineering controls in reducing dust generated and there-by exposure, these have focused on field and laboratory based measurements of dust generated during various construction activities.

A study published in 2003[249] looked at dust control measures used, the extent of their use in the construction sector, and their effectiveness in controlling exposure to CRS. The study observed that due to the transient nature of construction work, and the numerous sources of the application of simple dust control measures is not straight forward. Full-shift and short-term measurements were made together with a questionnaire administered to more than 1,300 construction workers. Extremely high full-shift concentration measurements were observed with more than half the samples exceeding the Maximum Allowable Concentration (MAC) in Holland of 0.075 mg/m3. However, it was noted that during short-term monitoring the use of local exhaust ventilation and wet suppression control techniques were effective and achieved >70% reduction in dust, and were used by a significant number of workers. However, the most commonly used exposure control was respiratory protection equipment, which may not be effective on its own in controlling exposure to an adequate level.

An American study[250] examined exposures at eight common construction activities and came to similar conclusions, that RPE provided inadequate protection when used in isolation. Exposures were excessive in a high proportion of activities, and significant improvement in exposure can be achieved by using ventilation. However, they observed that control measures were infrequently used.

A review of 16 papers examined the effectiveness of engineering controls in construction activities including brick and concrete block cutting, grinding mortar joints and drilling and surface finishing of concrete was published in 2003[251]. The review concluded that engineering controls could reduce CRS exposure significantly, but not to a level where the TLV inforce at the time could be complied with using engineering controls alone.

Cut-off saws are commonly used in the construction sector for cutting materials, which can produce large quantities of dust. The on-site application of wet suppression and local exhaust ventilation dust control techniques used on cut-off saws can reduce respirable dust production by at least 90%. Further, where the correct use of wet suppression techniques is employed under laboratory conditions, dust levels of < 4% of uncontrolled levels were achieved[252]. Other laboratory studies of dust generated in brick cutting operations have confirmed that water misting can be used to control dust generation[253].

[249] Niji, E. T., Hilorst, S., Spee, T., Spierings, J., Steffens, F, Lumens, M., and Heederik, D., Dust Control Measures in the Construction Industry, Annuls of Occupational Hygiene (2003) 47 (3):211-218 http://annhyg.oxfordjournals.org/content/47/3/211.full

[250] Flanagan, M. E., Seixas, N., Majar, M., Janice Camp, J., & Morgan, M., Silica Dust Exposures during selected construction activities, AIHA Journal Vol 64, Issue 3 2003

http://www.tandfonline.com/doi/abs/10.1080/15428110308984823#.VcDEGPl-0xJ

[251] Flynn, M.R., and Susi, P. Engineering Controls for Selected Silica and Dust Exposures in the Construction Industry -- A Review Applied Occupational and Environmental Hygiene Vol 18 Issue 4 2003

http://www.tandfonline.com/doi/abs/10.1080/10473220301406#.VcCW1vl-0xJ

[252] Thorpe, A., Ritchie, A.S., Gibson. M.J. and Brown R.C. Measurements of the effectiveness of dust control on cut-off saws used in the construction industry, The Annals of Occupational Hygiene, (1999) 43 (7) 443-456

http://annhyg.oxfordjournals.org/content/43/7/443.short

[253] Beamer, B.R., Shulman, S., Maynard, A., Williams, D., Watkins, D., Evaluation of Misting Controls to Reduce Respirable Silica Exposure for Brick Cutting, The Annals of Occupational Hygiene August 2005 49 (6) 503-510

RCS is released in large quantities during concrete finishing activities and a number of studies have investigated the effectiveness of engineering controls in controlling dust emission at source. A study of the effectiveness of commercially available local exhaust ventilation systems used on Seattle construction sites indicated a reduction in mean respirable dust from 4.5 to 0.14 mg/m3; representing a 92% reduction in dust exposure. However, despite the use of effective dust control 22 and 26% of samples exceeded the OSHA PEL and ACGIH TLV for RCS[254]; suggesting that additional controls were required.

A later study[255] under field laboratory conditions compared the concentrations of respirable dust and RCS produced during uncontrolled concrete grinding with grinding with local exhaust ventilation and wet suppression. Whilst both methods of control successfully reduced the concentration of dust, with local exhaust ventilation proving the most effective at 99.7% reduction for RCS and 99.8% for respirable dust. Both methods again failed to reduce exposure below ACGIH TLV for RCS.

A further study also concluded that during manual surface grinding engineering controls would not reduce the exposure of workers below the ACGIH TLV of 0.025 mg/m3 for RCS. Indicating as had been suggested in other studies that respirators would also be necessary to reduce operative exposure to acceptable levels[256].

Clearly, the use of control measures including wet suppression techniques and local exhaust ventilation will reduce exposure to RCS and respirable dust. The remaining dust is likely to be at a concentration that would still pose a significant risk to health. However, the use of control will significantly reduce the risk of ill health outcomes, when compared to using no controls. It is also recognised that whilst the American studies suggest that the ACGIH TLV could not be met using engineering controls alone, this level is set at 0.025mg/m3, four times lower than the current UK WEL of 0.1mg/m3. As discussed earlier, it is compliance with this standard, which provides the necessary protection, rather than having a lower OEL with poor compliance.

A2.4 Measurement of personal exposure to airborne respirable silica

The accurate and precise measurement of exposure of workers to respirable crystalline silica is essential to estimate the risk of disease formation (the greater the exposure, the greater the risk of disease), demonstrate compliance with any national occupational exposure limit (and in some Member States compliance with the law), and to demonstrate effectiveness of any engineering controls applied to reduce exposure. Exposure measurement will also identify trends in exposure over time and how effective new technology and work processes are in controlling exposure.

Accuracy and precision are particularly important when demonstrating compliance with occupational exposure limits as failure to comply may result in formal action against the

http://annhyg.oxfordjournals.org/content/49/6/503.full

[254] Croteau, G., Flanagan, M. E., Camp, J.E., Seixas, N. The Efficacy of Local Exhaust Ventilation for Controlling Dust Exposures During Concrete Surface Grinding The Annals of Occupational Hygiene 204 (48) 6 509-518

http://annhyg.oxfordjournals.org/content/48/6/509.full

[255] Akbar-Khanzadeh, A., Milz, S., Ames, A., Susi, P.P., Bisesi, M., Sadik A. Khuder, S. A., & Akbar-Khanzadeh, M., Crystalline Silica Dust and Respirable Particulate Matter During Indoor Concrete Grinding—Wet Grinding and Ventilated Grinding Compared with Uncontrolled Conventional Grinding. Journal of Environmental and Occupational Hygiene Vol 4 Issue 10 2007

http://www.tandfonline.com/doi/abs/10.1080/15459620701569708

[256] Akbar-Khanzadeh, F., Milz. S.A., Wagner, C.D., Bisesi, M.S., Ames, A.L., Khuder, S., Susi, P. & Akbar-Khanzadeh, M. Effectiveness of Dust Control Methods for Crystalline Silica and Respirable Suspended Particulate Matter Exposure During Manual Concrete Surface Grinding Journal of Environmental and Occupational Hygiene Vol 7, issue 10, 700-711, 2010

http://www.tandfonline.com/doi/abs/10.1080/15459624.2010.527552#.VcHHpfl-0xI

employer. For example, in the UK, the Workplace Exposure Limit for respirable silica is 0.1mg/m3. The UK regulator suggests that this is the lowest level that can be accurately and precisely measured using the current sample collection and analytical techniques. Therefore, exposure limits below 0.1mg/m3 are not considered appropriate because of the limitations of the available techniques, although some Member states have adopted lower Occupational Exposure Limits.

Personal exposure monitoring will give the best estimate of exposure as the sampling device is carried with the worker as they undertake their daily work tasks. Static or area sampling can also be used to estimate exposure, but is not as reliable because the sampler remains in one location for the sampling period where the workers will move about the workplace. In practice a combination of both personal and static sampling is likely to be used as the two methods are complimentary. Personal exposure measurements will also allow researchers to gather epidemiological data on exposure concentration and disease formation over time.

It is therefore essential that the method chosen gives the required level of accuracy and precision to allow for comparison between results to enable employers and researchers to demonstrate the points raised above.

Annex Two to the NEPSI Agreement[257] contains a description of a sampling methodology based upon various European standards[258][259][260].The method refers to personal and static sampling techniques and suggests that as a minimum the technique used must assess the exposure of the workers to respirable dust. It is respirable dust that reaches the gas exchange region of the lung where it causes inflammation and subsequently disease. The sampling devices used must conform to the appropriate particle collection performance standards and jobs should be segregated by function. Sampling should be performed during a full shift and the number of samples taken should give a representative assessment of worker exposure. The samples should be analysed to identify the quartz content by either X-ray diffraction or IR spectroscopy. Full records must be kept and the laboratory should belong to a quality control system and/or be accredited.

The method also draws the reader's attention to the possible availability of other technical guidance, which might exist in Member States, which advise on appropriate methods to meet national requirements or standards. There is additional information of exposure monitoring in the Good Practice guide 2.1.6[261], which forms part of the NEPSI Agreement. Additional information is given here, but essentially describes personal monitoring based upon the European standards mentioned earlier.

The method described uses a size selective sampling head usually, a cyclone, this collects the respirable fraction of the dust by spinning the airflow, thereby removing the larger particles from the airstream, with the smaller respirable particles being collected on a filter which is then sent for laboratory analysis. Other samplers use foams to collect the various fractions simultaneously such as the IOM and CIS samplers[262]. It is important that the

[257] Agreement on Workers health protection through the good handling, and use of crystalline silica and products containing it 25th April 2006 http://www.nepsi.eu/media/2097/agreement%20-%20english%20.pdf

[258] EN 689 Workplace atmospheres-Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, 1995, CEN

[259] EN 481 Workplace atmospheres-Size fraction definitions for measurement of airborne particles, 1993, CEN

[260] EN 1232 Workplace atmospheres-Pumps for personal sampling of chemical agents-Requirements and test methods, 1997

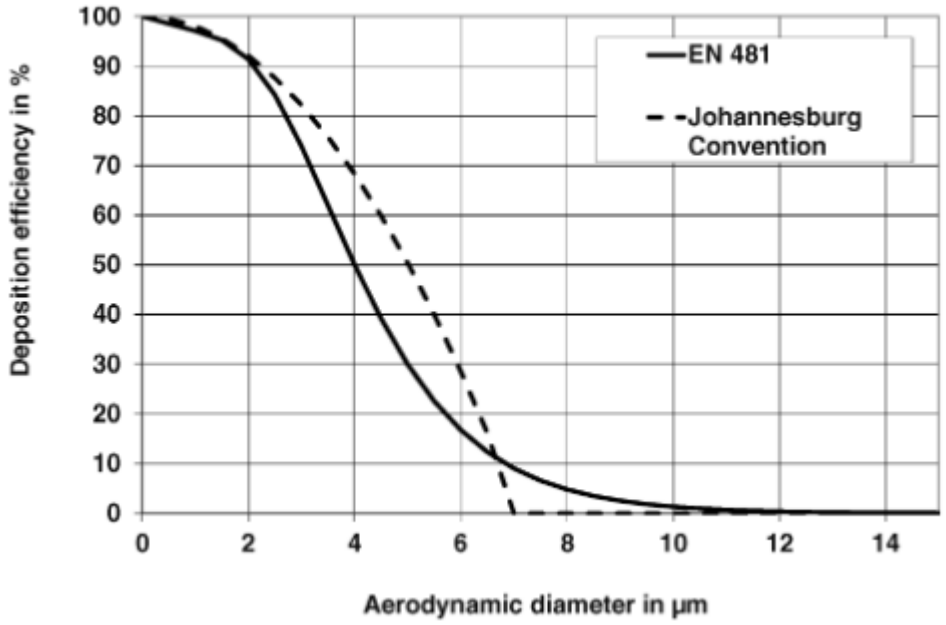
[261] Dust monitoring 2.1.6 March 2006

http://www.nepsi.eu/media/2276/good%20practice%20guide%20-%20english%20original%20additional%20task%20sheets%20%28251006%20modified%2016072012%29.pdf

[262] General methods for sampling and gravimetric analysis of respirable, thoracic and inhalable dust MDHS 14/4 HSE 06/14 http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs14-4.pdf

cyclone or other sampler used performs within the parameter stated in EN 481 listed above as other conventions exist such as the Johannesburg convention. See graph below.

Figure 9.2 Deposition efficiency for the respirable dust fraction in accordance with the Johannesburg Convention ('fine dust') and EN 481 ('respirable dust') [9;12]



Source: S. Gabriel, M. Mattenklott, R. Van Gelder, P. Steinle, P. Rüdin, N. Neiss, C. Ressler, A. Johansson, M. Linnainmaa, D. Dahmann, H. Fricke (2014) Comparison of the determination and evaluation of quartz exposure and exposure levels at workplaces across Europe http://www.dguv.de/medien/ifa/de/pub/grl/pdf/2014_136.pdf

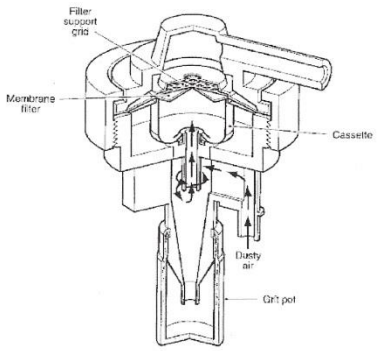
Researchers have explored the variation between sampling heads in collecting representative samples[263]. In this study, a Workplace Atmosphere Multi-sampler was used to compare 12 respirable dust samplers in each run. Significant variations were found between SKC cyclones (under sampled) and CIP10 samplers (oversampled) compared with the median air concentrations.

In the UK, the method for collecting respirable dust is described in MDHS 14/4[264]. Below is a diagram of a cyclone sampler suggested for the collection of the respirable fraction from within a dust cloud.

[263] Verpaelle, S and Jouret, J. A comparison of the performance of samplers for respirable dust in workplaces and laboratory analysis for respirable quartz. Ann. Occup. Hyg., Vol 57 No1 pp54-66 2013 http://annhyg.oxfordjournals.org/content/early/2012/07/17/annhyg.mes038.full

[264] General methods for sampling and gravimetric analysis of respirable, thoracic and inhalable dust MDHS 14/4 HSE 06/14 http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs14-4.pdf

Figure 9.3 Cyclone respirable dust sampler



Source: HSE, General methods for sampling and gravimetric analysis of respirable thoracic and inhalable aerosols http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs14-4.pdf

Work has been undertaken across Europe to determine whether monitoring data collected in different Member States are compatible and can be used in epidemiological studies[265]. The study looked at data collected by institutions from Switzerland, Austria, Finland, and Germany and concluded that while the measurement conventions, sampling and analytical methods were comparable there were significant differences between the measurement strategies. It was concluded therefore that the exposure levels for comparable tasks would similarly vary between countries.

In addition, direct reading instruments are available for monitoring real time exposures to respirable dust. Some companies use these to monitor exposures from continuous processes e.g. truck loading. These devices work on the principle of light scattering, but they will not identify the composition of the dust[266].

The two principal methods of analysis to determine the concentration of respirable silica collected using a respirable dust sampling head is either on filter X-ray diffraction[267] or IR spectroscopy[268]. The IR method is suitable for a concentration range of 10ug to 1mg on a 25mm filter. The detection limit for the method is as follows, qualitatively 0.006mg/m3 and quantitative 0.02mg/m3 for a 500 litre sample[269].

For X-ray diffraction, the detection limit is more problematical and depends on the sample matrix, instrument settings and the performance of the personal sampler. The qualitative detection limit for the strongest diffraction peak for quartz in a 500 litre sample corresponds 0.02mg/m3. The quantitative detection limit for quartz in a 500 litre sample corresponds to 0.05mg/m3[270].

[265] Gabriel S., Mattenklott S.M., Van Gelder R., Steinle P., Rüdin P., Neiss N., Ressler C., Johansson A., Linnainmaa M., Dahmann D., Fricke H. Comparison of the determination and evaluation of quartz exposure and exposure levels at workplaces across Europe Gefahrstoffe - Reinhaltung der Luft 74 (2014) Nr. 9-Septemberhttp://www.dguv.de/medien/ifa/de/pub/grl/pdf/2014_136.pdf

[266] Walsh P, Evans P, Lewis S, Old B, Greenham L, Gorce JP, Simpson P and Tylee B Technical Guide on Direct Reading Devices for Airborne and Surface Chemical Contaminants Technical Guide Series No 15 (3rd Edition) BOHS 2012 www.bohs.org/TG15/

[267] NIOSH 7500: Silica, crystalline by XRD. http://www.cdc.gov/niosh/docs/2003-154/pdfs/7500.pdf

[268] NIOSH 7602: Silica, crystalline by IR. http://www.cdc.gov/niosh/docs/2003-154/pdfs/7602.pdf

[269] MDHS 101/2: Crystalline silica in respirable airborne dusts- Direct-on-filter analyses by infrared spectroscopy and X Ray diffraction HSE 02/15 http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs101.pdf

[270] MDHS 101/2: Crystalline silica in respirable airborne dusts- Direct-on-filter analyses by infrared spectroscopy and X Ray diffraction HSE 02/15 http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs101.pdf

Both methods of analysis would appear to be capable of detecting quartz at levels below 0.1mg/m3 therefore the method could be employed to measure Occupational Exposure Limits set at lower concentrations.

Error in determining exposure has two components, sampling error and analytical error. It is clear from earlier references that samplers can vary in performance, and similarly can laboratories in their ability to carry out accurate and precise sample analysis. To improve the precision and accuracy of laboratory analysis in the UK the Health and Safety Laboratory developed and operated WASP (Workplace Analysis Scheme for Proficiency). WASP developed from a scheme to compare performance of Health and Safety Executive's regional laboratories engaged in occupational hygiene analysis. It was intended to provide external quality assurance for UK laboratories engaged in chemical analysis of workplace air samples. The scheme included quartz determination[271].

WASP has been superseded by Air PT, and is jointly operated by Health and Safety Laboratory and LGC[272]. The analysis of quartz remains part of the scheme.

As part of this project, the country report researchers were asked to undertake desk research into the sampling methods and analytical techniques used in the member state to determine exposure to respirable crystalline silica. Research into sampling and analytical techniques was not part of this project's deliverables, but the desk research does indicate some difference of approach across the member state case studies.

The methods used in the UK have been described above. The method used in Germany appears similar as described in BGIA report[273]. Other guidance in Germany describes the methods for measurement and assessment TRGS 402[274] but these are not exclusive to silica, exposure measurement is not necessarily a requirement.

In Spain, a number of documents are referred to in the context of sampling including NTP 060: Silica sample collection. Diffractometer analysis[275], NTP 059: Silica sample collection. Colorimetric analysis[276], and Guide on Methods to measure the respirable fraction and respirable crystalline silica[277].

In Poland, no distinction is made between the respirable fraction and other dust fractions, in line with their normalized chemical method for silica[278].

In France, concerns relating to the evaluation of exposure and the level of the occupational exposure limit have caused concern. The Agency for Food, Environment and Occupational Health and Safety to (ANSES) was charged by the Ministry of Labour to review the method of measurement for RCS. The results of their work will be available in 2016.

In Belgium, no accredited laboratories existed for the analysis of RCS before the Agreement. Subsequently, five laboratories used accredited methods, but comparison between IR and X-ray techniques has indicated wide variation between the methods, up 160% for the same sample. X-ray diffraction has proved to be the most reliable method.

[271] The workplace analysis scheme for efficiency HSL 2013 http://www.hsl.gov.uk/media/230213/14th%20wasp%20participant%20handbook%202013%20v2.pdf

[272] http://www.lgcpt.com/productviewnarrow.aspx?SchemeID=201

[273] Exposure to quartz at the workplace BGIA Report 8-2006e http://www.dguv.de/ifa/Publikationen/Reports-Download/BGIA-Reports-2005-bis-2006/BGIA-Report-8-2006/index-2.jsp

[274] http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/TRGS-402.pdf;jsessionid=BE77ACD237C37982840AC06CF8CB73D4.1_cid343?__blob=publicationFile&v=3

[275] https://www.fundacionmapfre.org/documentacion/publico/i18n/catalogo_imagenes/grupo.cmd?path=1031453

[276] http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasTecnicas/NTP/Ficheros/001a100/ntp_059.pd

[277] http://www.ins.es/documents/10307/10498/Guia+Tecnica+Analisis+SCR.pdf

[278] http://sklep.pkn.pl/pn-z-04018-04-1991p.html

In Sweden, the method for conducting exposure measurement is set out in general guidelines AFS 2011:18[279], though this does not specifically relate to RCS. No analytical method was mentioned.

Clearly, there are a number of approaches to measure exposure to RCS across European Member States, which may result in the data not being comparable. These documents and approaches have not been examined in detail. The NEPSI Agreement contains information on a method for exposure monitoring that refers to relevant standards. It is essential, therefore, that the sampling and analytical method employed should meet or exceed the precision and accuracy of the NEPSI method, including accreditation and/or participation in an external quality assurance programme.

Examination of the methods used was not part of this study. It may therefore be beneficial to review the methods used by Member States with a view to providing a standardised method and sampling strategy that will produce comparable data across Europe and beyond. Further, the use of direct reading instruments for respirable dust is now more common and their effectiveness and limitations could usefully be reviewed in any study of methods.

[279] https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-201118-foreskrifter/

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