Contribution to the impact study on the revision of the Carcinogens Directive (2004/37/EC) undertaken by European Commission DG EMPL Unit B3

30 August 2013

Signed on behalf of:

- **BIBM –** The International Bureau for Precast Concrete
- **CEMBUREAU** - The European Cement Association
- **CEPE** – The European Council of producers and importers of paints, printing inks and artists' colours
- **CERAME-UNIE** – The European Ceramic Industry Association
- **EDG** – The European Domestic Glass Association
- **ERMCO -** The European Ready-Mixed Concrete Organisation.
- **ESGA** – The European Special Glass Association
- **EURACOAL** –The European Association for Coal and Lignite
- **EURIMA** -The European Insulation Manufacturers Association
- **EUROALLIAGES** – The Association of European ferro-Alloy producers
- **EUROGYPSUM** – The European manufacturers of gypsum products
- **EUROMINES** – The European Association of Mining Industries
- **EXCA** – The European Expanded Clay Association
- **FEVE** – The European Container Glass Federation
- **GlassFibreEurope** – The European Glass Fibre Producers Association
- **Glass for Europe** – The Association for Europe's manufacturers of building, automotive and transport glass
- **IMA-Europe** – The European Industrial Minerals Association
- **UEPG** - Union Européenne des Producteurs de Granulats (European Aggregates Association)

Preamble

Respirable Crystalline Silica terminology

Silica (SiO_2) is commonly found in nature as sand. Silica exists in many different forms that can be crystalline as well as non-crystalline (amorphous). There exist also forms of synthetic amorphous silica.

The tree major forms of **crystalline silica** are the polymorphs: quartz (CAS 14808-60-7), cristobalite (CAS 14464-46-1) and tridymite (CAS 15468-32-3). **Quartz** is the most common form of crystalline silica and is the second most common mineral on the earth's surface. It is found in almost every type of rock i.e. igneous, metamorphic and sedimentary.

Respirable crystalline silica is the respirable dust fraction of crystalline silica which enters the body by inhalation and penetrates to the pulmonary alveolar region of the lungs, it is defined in the European standard EN 481.

In occupational circumstances, it is respirable crystalline silica the agent of concern.

Executive Summary

In this contribution, the signatories wish to communicate their opinion that:

- Introducing a European Binding Occupational Exposure Limit for process-generated Respirable Crystalline Silica (RCS) will be beneficial to workers' health. The cost / benefit ratio justifies such a measure, as demonstrated by the SHECan report, and the level of 0.1 mg/m³ (8hr TWA) is agreed by the industry.

- The frame of the Carcinogens Directive for this OEL is inappropriate because RCS is a substance for which a scientific threshold -- under which no effects are observed -- has been established and there is currently an unresolved debate on how to regulate such substances.

- Introducing the OEL in the "Carcinogens at work Directive" would
    - Affect sectors where the RCS hazard is not observed (no increased risk of lung cancer at all)
    - Undermine the established NEPSI Social Dialogue Agreement between the unions and industry, which is working well, and potentially discourage other initiatives of this kind.
    - Increase the cost without increasing the benefits in creating inter alia useless or impossible substitution obligations.
    - Therefore degrade the cost / benefit ratio of the OEL.
    - Affect national occupational disease compensation systems through a growing number of claims.

- Although the option of setting the OEL for RCS (process generated) in the Chemical Agents Directive was mentioned by several EU governing bodies (European Council, ACSH), it has not been the subject of any social partners' consultation, nor any impact assessment. Only the Carcinogens Directive option has been investigated so far and only partially.

- The Social Dialogue Consultation should be repeated before any action is taken on RCS according to Directive 98/24 or Directive 2004/37, ensuring that both options are fully considered.

The concerned industries wish to reiterate their call for the setting of a European Binding Limit Value at 0.1 mg/m³ for process-generated RCS **in the Chemical Agents Directive** which provides the right frame for an optimal workers protection, and this paper develops the reasons why this is a more appropriate option.

The possible inclusion of RCS in the Carcinogens Directive or in the Chemical Agents Directive should cover **process-generated RCS** and more precisely work processes involving exposure to respirable crystalline silica in the form of freshly fractured particles in a concentration above 0.1 mg/m³. This paper provides examples of such processes.

The paper also develops some comments on the figures and statistics provided by the SHECan RCS Report.

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Background

On December 5, 2012, the European Commission's Advisory Committee for Safety and Health ('ACSH') issued an 'Opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace' [1].

The Opinion includes a chapter regarding the proposed regulatory approach towards Respirable Crystalline Silica ('RCS'). In particular, the Opinion notes that it is agreed that there should be a **binding occupational limit value of 0.1 mg/m^3** introduced for RCS and that **there are legal possibilities to introduce this limit through Directive 2004/37, Carcinogenic Agents at Work Directive or through Directive 98/24, Chemical Agents at Work Directive.**

The Opinion further states that "if the Occupational Exposure Limit (OEL) for RCS is to be adopted under the Carcinogens at Work directive it will also be necessary to include **process generated RCS** in Annex I to give legal certainty to its inclusion in the scope of the directive." This is because RCS does not have a harmonised or self-classification as carcinogen.
Following this ACSH Opinion, Unit B3 – Health, Safety and Hygiene at Work - of DG Employment in the European Commission intends to prepare an impact study on the revision of the Carcinogens at work Directive (2004/37/EC). We were informed that Unit B3 welcomes contributions from stakeholders for the impact study by 30 August 2013. We offer here the contribution of eighteen industry sectors.

Introduction

We ask the Commission to take on board in its impact assessment **three important aspects** on which there is a consensus within the Advisory Committee for Safety and Health:

1. The agreed level for a European **binding occupational limit value for RCS is of 0.1 mg/m^3.** Details are recalled in **annex 1** of the present document.

2. The inclusion of RCS in the Carcinogens Directive or in the Chemical Agents Directive should address **process generated RCS**, and more precisely in our opinion: work processes involving occupational exposure to respirable crystalline silica in the form of freshly fractured particles generated through dry processes such as dry cutting, grinding, drilling, crushing, sand and abrasive blasting operations in a concentration above 0.1 mg/m^3.

3. The Advisory Committee underlines that there are two legal possibilities available, namely inclusion of the limit value for RCS into Annex III to Directive 2004/37 (Carcinogens Directive), or introduction of binding limit value into Directive 98/24 (Chemical Agents Directive).
   We urge the Commission to consider and compare the impact and benefits of <u>both</u> options in its assessment. Hence, with respect to the European Commission's Impact Assessment Guidelines (2009) [2], it is required to weigh-up the positive <u>and</u> negative impacts for <u>each</u> option on the basis of criteria clearly linked to the objectives (see page 5 of the Guidelines).

Prior to the Advisory Committee Opinion, the European Commission already commissioned a "Socioeconomic, health and environmental impact of possible amendments to the European Carcinogens and Mutagens Directive", the SHECan study [3], which was finalised in 2011. The SHECan study includes a report on respirable crystalline silica.

Whereas the SHECan RCS report provides a good analysis of the consequences of setting a European Limit Value for RCS at different levels, it does not analyse the impact of the application of the strict hierarchy of obligations resulting from the Carcinogens Directive, nor does it provide an estimation of the benefits that the inclusion and the obligations would bring. We urge the European Commission to consider these consequences in the coming impact study and we are pleased to provide below some elements of information.

Although the option of setting the OEL for RCS (process generated) in the Chemical Agents Directive was mentioned by several EU governing bodies (European Council, ACSH), it has not been the subject of any social partners' consultation so far. Until now, only the Carcinogens Directive option has been investigated, and only partially (see development of this legal point in **annex 2** of this document).

We believe that the frame of the Chemical Agents Directive is a more appropriate one for process generated RCS and we will develop the reasons why.

A. Analysis of the obligations of the Carcinogens Directive and their relevance for respirable crystalline silica

The Chemical Agents Directive (98/24/EC) which is based on risk assessment and risk minimisation provides the right frame for an optimal workers protection to respirable crystalline silica exposure, whereas the Carcinogens Directive (2004/37/EC) would impose unnecessary and impracticable obligations.

As a first obligation, Directive 2004/37/EC imposes '**Reduction and replacement'** (art. 4): *reduce the use of a carcinogen, particularly by replacing it, as far as is technically possible*. The second obligation (art. 5) is '**Prevention and reduction of exposure'***: when replacement is not technically possible, ensure that the carcinogen is manufactured and used in a* ***closed system****. If this is not technically possible, ensure that the level of exposure is* ***as low as is technically possible***.
To prevent RCS exposure, these obligations set by the Carcinogens Directive are (I) **unnecessary** and (II) **impracticable** in many circumstances:

I. Unnecessary

- **The respirable crystalline silica (RCS) cancer hazard varies widely and is not observed in all industrial sectors where RCS may be present**

Regulators should take into account the impact of the proposed legislative options on industrial circumstances where no excess of lung cancer risk is observed: e.g. coal mines [1] (IARC evaluation [4]), farming, quarries and ceramics (SCOEL recommendation [5]) [2].

[1] The IARC Working Group concluded that coal dust cannot be classified as to its carcinogenicity to humans (Group 3) since there is inadequate evidence in human and animal experiments. Typically, 40% or more of the mineral matter in coal is crystalline silica and the respirable crystalline silica fraction found in coal dust is often 3%-7%, in some ores up to 12%.

[2] SCOEL 2002 recommendation for RCS: "the main effect in humans of the inhalation of respirable silica dust is silicosis. There is sufficient information to conclude that the relative lung cancer risk is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry)".

The EU Carcinogens Directive (if used as the frame for an OEL for RCS) would thus impose inappropriate, unnecessary and unfair constraints in sectors where the hazard does not exist.

- **There exists a threshold below which the cancer risk is controlled**

As recognized by scientific experts and regulatory committees [6] (including the SCOEL [5] and the IARC [4]), RCS carcinogenicity is expressed through a secondary mechanism. Lung cancer excess risk due to RCS exposure is restricted to workers who previously contracted silicosis and therefore, by preventing silicosis, RCS-related lung cancer is also prevented. This is in accordance with industry decision to classify RCS (quartz respirable fraction and cristobalite respirable fraction) as a STOT RE 1 (Specific Target Organ Toxicity Repeated Exposure)[3] to address the silicosis risk when implementing the CLP Regulation (EC) No 1272/2008.

It is therefore not necessary to substitute the substance as long as the silicosis risk is controlled.

The prevention of the silicosis risk would be ensured by the Chemical Agents Directive which provides a complete risk assessment and management procedure.

As documented by a recent scientific study published in JOEM [7] (see copy enclosed), there is a concentration threshold for the silicosis risk at 0.25 mg/m³ observed in this cohort of German porcelain workers. So a Binding Limit Value of 0.1 mg/m³ in the Chemical Agents Directive would be on the safe side for workers health protection.

The article "Quantitative relationship between silica exposure and lung cancer mortality in German uranium miners, 1946–2003" by Sogl et al. [8] reaches similar conclusions.

- **As already acknowledged for other agents, because of this threshold mechanism, the concept, purpose and scope of the Carcinogens Directive do not apply to RCS**

We note that on 30 May 2013 the ACSH adopted a supplementary Opinion [9].
The Supplementary Opinion notably outlines future regulatory approaches with respect to reprotoxic substances as follows: *"it is agreed that exposure to reprotoxic substances at the workplace needs to be effectively controlled and that this is a priority issue. However, at this stage, it is not yet possible to agree on the most appropriate approach at EU level. This is because of divergent views on the concept, purpose and scope of Chemical Agents Directive and Carcinogens and Mutagens Directive, including how to regulate substances for which a scientific threshold can be established."*

As developed above, RCS is a substance for which a scientific threshold has been established, therefore the situation is exactly the same and it should also be recognised that the question on the best approach at EU level is still to be solved.

- **The added-value of the approach followed in the NEPSi Social Dialogue Agreement needs to be acknowledged.**

Prevention is crucial and is the focus of the Social Dialogue Agreement on Crystalline Silica Good Handling and Use [10] (in short NEPSi SDA) concluded in 2006 between 16 industry sectors and their Unions. NEPSi (the European network for Silica) has in the last seven years considerably increased the amount of risk assessment, protective measures and reporting regarding the exposure of workers to Respirable Crystalline Silica.

[3] See website www.crystallinesilica.eu for more information on the classification.

The SHECan Report [3] acknowledges the benefit of the control strategies put in place by NEPSi inferring that it provides the adequate workers' protection. See p.37 and p.71: *Conduct of Employers:"There is unlikely to be any significant change for those already adhering to the NEPSI good practice guide […]"*

The added-value of the approach proposed in the NEPSi SDA which is based on risk assessment and awareness raising, dissemination of good practices and monitoring of application needs to be acknowledged.

The energy, time and resources that the industry would spend fulfilling regulatory consequences of the inclusion of an OEL in the Carcinogens at work Directive could be much better used by further developing the actual protection of the workers through limitation of exposures, and development of innovative protection systems. Investments in prevention prove to be more effective than looking for substitution of a substance for which health risks are fully known and preventable, and for which a threshold exists. Regulating RCS under the Carcinogens Directive would undermine the NEPSi Social Dialogue Agreement as it would deter the industry from good implementation of technical measures, and this would be contradictory with the encouragements of the Commission to launch social dialogue initiatives in the field of workers' health and safety.

NEPSI and its good practice guide offer pragmatic guidance for industry; something that the Carcinogens Directive would not provide. An illustration of this is the situation recently experienced by a UK industrial minerals company: at one of their sites, they have built an enclosure around an automated bagging plant, in order to reduce exposure to RCS for the plant operator. Apparently this has resulted in no improvement in the operator's exposure; it is much more difficult for him to clean the plant now and he is exposed to high levels in the process. New risks have been created by the enclosure, which also impacts upon access for maintenance and, potentially, increased wear and tear on machine components. This gives an indication of the kinds of problems that would result if the requirements of the carcinogens directive would be retrofitted onto existing plants.

The implementation of the Social Dialogue Agreement's principles coupled with a Binding Limit Value in the Chemical Agents Directive in the whole European industry would provide an optimal protection to workers' health while not imposing to industry a series of unnecessary and unfair measures which would hamper the involved sectors' economy.

II. Impracticable

- **The obligation to reduce or replace the use of the substance (process) as far as is technically possible, and to prevent/reduce RCS exposure by deploying closed systems are not possible in several sectors**

Respirable Crystalline Silica is ubiquitous and present in a large number of industries. The SHEcan report rightly recognizes that a European OEL for RCS would impact a large number of European materials and manufacturing industries (e.g. quarries and mines, ceramics and bricks, glass, concrete, foundries, etc.). Some of the requirements of the Carcinogens Directive – such as the obligation to reduce or replace the use of the substance as far as it is technically possible, and to prevent and reduce RCS exposure by deploying closed systems – are not possible in several sectors, nor are they necessary since a specific threshold level may be used to protect the workers.

A good illustration is the case of glass: glass production requires the incorporation of silica sand in the batch, and there is no alternative.

Even when glass is recycled, the use of some sand is necessary in order to reach the required quality.

Another illustration is the case of construction. The entire construction environment is based on products containing crystalline silica, and construction works cannot be encapsulated. Most construction materials are sourced from open-air quarries, and deployment of closed systems on quarry excavations or haul roads, for example, would be both impracticable and unnecessary.

It is technically impossible for metallurgical production of Silicon and Ferroalloys, using crystalline quartz as a raw material, to operate in a completely closed system.

Some workers that are not under scrutiny for the time being, and that are exposed to the respirable crystalline silica are agricultural workers. Measurements made in cultivated fields have shown a non negligible concentration of crystalline silica (see article by Swanepoel AJ et al. 2010 [11], and industry data are available upon request). The consequences of inclusion in the Carcinogens at work Directive have not been estimated for those industries. To carry out agriculture in a “closed system” just does not make sense.

- **The number of spurious claims for unspecified lung cancer compensations will dramatically increase and the burden will be shared by Member States and European industry**

Currently, on the basis of the available scientific and medical evidence, lung cancer in workers exposed to RCS at work is compensated, in all Member States who have debated the issue, only in circumstances where silicosis is observed. The inclusion of a Binding Limit Value for RCS in the Carcinogens at work Directive would have substantial consequences in this regard. Due to the ubiquitous presence of crystalline silica in industrial settings and the fact that the lung cancer is not specific to the possible exposure to the agent, any patient suffering from a lung disease, including tobacco related lung cancer, even after having worked a short time in an industry where silica is manipulated, would be able to claim occupational disease compensation. Furthermore, these compensation claims would be difficult, if not impossible, for employers to defend due to the inability to specify causation. This could lead to an unfair split of liabilities and an unfair financial burden on employers.

Occupational disease compensation is not the responsibility of corporations everywhere in the EU. So the corresponding liability may affect public economies of Member States that are already struggling with budgetary issues and this needs to be properly assessed.

B. Analysis of the figures of the SHECan Report

Although we agree with the general outcome of the SHECan report which concludes that there is a need for a European limit value and that the level of 0.1 mg/m³ is appropriate for process-generated RCS, we have some comments on the figures and statistics provided by the SHECan RCS Report.

- **Number of exposed workers**

The RCS SHECan report itself writes *"We recognise that the number of workers and enterprises affected by the proposed reduction in the OEL are likely to be an overestimate since the NACE codes include activities in which workers may not necessarily be exposed to RCS." "Also, CAREX may overestimate the number of exposed workers."* (pp. 11 and 18)

We know indeed that our colleagues from the construction, glass and foundry sectors, notably, disagree with the number of exposed workers reported for their industries.
The Glass sector has some comments on the SHEcan report concerning statistics and assumptions made for the sector, which are submitted separately.

- **Lung cancer deaths estimated to be attributable to RCS exposure**

RCS SHECan report Chapter 4 and 5 + Introduction and Conclusions: The estimates of attributable lung cancer deaths and registrations under various exposure scenarios appear to be based on the "HSE burden" methodology which is criticised in the scientific community.

A recent paper [12] addresses the bias of this methodology used by Hutchings and Rushton for their article on the burden of cancer cases after shift work exposure and calculating these and other numbers that will occur until 2080.

Dr John Tomenson, a renowned epidemiologist, has made thorough comments on the methodology used in the SHECan report. (See copy enclosed).

In summary, he states that the methodology used to estimate attributable lung cancer deaths is not clearly stated. The numbers were derived from another publication, probably the "UK HSE burden" methodology [13].

The 'burden methodology' is based on a number of implausible assumptions,
e.g. (1) one year of exposure to RCS in a 'high' exposed job in the mid-1990s is considered equivalent to 50 years of exposure starting in the mid-1950s;

e.g. (2) exposure in each exposure category conveys the same risk whatever the year, hence 'high' exposure in 2025 is equivalent to 'high' exposure in 1975, when the hygiene conditions were much different.

The results are heavily dependent on the "low/ high exposure" thresholds arbitrarily derived by the authors but these thresholds are unrelated to any risk considerations.

The thresholds derived by Hutchings & Rushton (2011) for the UK study give much lower numbers of estimated attributable lung cancer deaths and registrations than were estimated by SHEcan, and lead to very different conclusions about a suitable OEL.

For example, SHEcan estimated that there will be an additional 337 lung cancer deaths and 345 cancer registrations in 2060, if an OEL of 0.05 mg/m³ is adopted. However, it can be shown that the thresholds of the UK study (Hutchings & Rushton 2011) predict about a third of these numbers if an OEL of 0.2 mg/m³ is adopted!

Comparing with official statistics, these numbers of attributable lung cancer deaths appear to be completely unrealistic.
The table on page 120 of the SHEcan RCS Report assesses a number of 1027 attributable deaths of lung cancer following RCS exposure in 2010.
The French official statistics of the CNAMTS (available at http://www.inrs-mp.fr/mp/cgi-bin/mppage.pl?state=1&acc=5&gs=&rgm=2, see table 25) report the number of 232 cases of occupational diseases due to the inhalation of crystalline silica dust, and the number of 10 deaths. Similar figures are observed over the last five years in France.
Those independent national official statistics cover the great majority of the French workers. Even if we make the hypothesis that these official statistics are underestimated, it is not realistic to believe that they could make an underestimation of a factor of 100 (1027 attributable deaths in the SHEcan versus 10 deaths in the CNAMTS statistics). These 1027 deaths are not coherent with the reality on the field.

Such inaccuracies and over estimations should be corrected or at least recognised as it gives an over alarmist picture of the workers' health situation in Europe.

We thank you for the consideration of these comments and remain at your disposal for any question or discussion.

Annex 1:

Appropriateness of a European Binding Limit Value of 0.1 mg/m³ (8hr TWA) for process generated Respirable Crystalline Silica (RCS)

- A recent study identifies a concentration threshold for silicosis risk at 0.25 mg/m³

A recent scientific study published in JOEM [7] (see copy in annex 2) documents a concentration threshold for the silicosis risk at 0.25 mg/m³. The article "Quantitative relationship between silica exposure and lung cancer mortality in German uranium miners, 1946–2003" by Sogl et al. reaches similar conclusions. Scientific independent assessments (SCOEL – IARC) conclude that there exists a threshold below which the RCS cancer risk is not observed. So a Binding Limit Value of 0.1 mg/m³ in the Chemical Agents Directive would be on the safe side for workers health protection.

- Socioeconomic impact, especially on SMEs

When assessing the impact of the inclusion of RCS with the lowest OEL (0.05 mg/m³) in the Carcinogens Directive, the SHEcan[3] authors concluded that this would impact a large number of European materials and manufacturing industries (e.g. quarries and mines, ceramics and bricks, glass, concrete, foundries) and lead to the closure of a number of factories, especially among SMEs; in turn, this would impact several other sectors. To quote the SHEcan report[3]: *"there is a genuine risk that SMEs could close rather than incur the costs of compliance with the more stringent OEL options".*

The IOM SHEcan report[3] (pp. 83-84) shows that the incremental increase in health benefits between an OEL of 0.1 mg/m³ and an OEL of 0.05 mg/m³ is only 8%. By contrast, reducing the OEL from 0.1 mg/m³ to 0.05 mg/m³ involves a 44% incremental increase in costs. The incremental costs (15 billion euros) are more than twice as high as the incremental benefits (6.7 billion euros). Although health issues are far beyond monetary calculations, the results presented by the IOM SHEcan report lead to the conclusion that an **OEL of 0.1 mg/m³ represents the best cost/benefit ratio.**

- Difficulties in measuring and complying with the lowest OEL

The SHECan report [3] also states that (page 71): *"[…] the introduction of an OEL of 0.05 mg/m³ could require workers to be constantly wearing RPE as levels of exposure will be close to the natural background level of RCS in air."*

It should be questioned if it is a realistic option and ergonomically practicable, e.g. in surface quarries, that workers wear Respiratory Protective Equipment (RPE) constantly. Not only are face masks and breathing equipment costly in expenditure, but the constant wearing of these would also result in even more significant costs through loss of productivity.

The cost estimates for achieving very low (we believe unnecessarily low) exposure levels are therefore probably understated.

The benefits of any European OEL for RCS will only be obtained if the limit value is scrupulously implemented. RCS OELs have already been set by law in the 27 Member States[4], even at lower levels than those envisaged by the SHEcan project, see table on page 13 of this paper.

This does not mean, however, that the RCS OELs, especially the lowest ones, are implemented or technically applicable, since there are analytical limitations.

A recent article by Peter Stacey et al [14] highlights the difficulties in making reliable measurements of RCS at very low OELs.

A recent assessment by the British Ceramic Confederation [15] shows that, although there is progress in improved sampling techniques, which may result in higher volume respirable dust samplers, there is much concern about the reliable quantitative determination of crystalline silica in occupational dust samples: the absence of reliable calibration samples and techniques for dusts containing low crystalline silica contents is of particular concern.

Conclusion

The OEL of 0.1 mg/m³ is achievable in terms of compliance and today's measurement techniques.

The European Commission's Advisory Committee for Safety and Health agrees on the level of 0.1 mg/m^3 for a European binding occupational limit value for RCS.

In terms of the combined socio-economic and health impact, as well as technical feasibility, any European OEL for RCS should not be set below 0.1 mg/m³.

[4] With the exception of Germany where, due to a general approach of the law on hazardous substances, there is no OEL for RCS for the time being.

Occupational Exposure Limits in mg/m^3 8 hours TWA – Respirable dust – in EU 27[5] + 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[6]	/	/
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 or 25k/Q		
France / IX	5	0,1	0,05	0,05
Germany/X	3	/[7]	/	/
Greece/XI	5	0,1	0,05	0,05
Hungary		0,15	0,1	0,15
Ireland/ XII	4	0,05	0,05	0,05
Italy/ XIII	3	0,025	0,025	0,025
Lithuania/ XIV	10	0,1	0,05	0,05
Luxembourg/ XV	6	0,15	0,15	0,15
Malta / XVI[8]	/	/	/	/
Netherlands/ XVII	5	0,075	0,075	0,075
Norway/XVIII	5	0,1	0,05	0,05
Poland		0,3	0,3	0,3
Portugal/XIX	5	0,025	0,025	0,025
Romania/XX	10	0,1	0,05	0,05
Slovakia		0,1	0,1	0,1
Slovenia		0,15	0,15	0,15
Spain/ XXI	3	0,1	0,05	0,05
Sweden/XXII	5	0,1	0,05	0,05
Switzerland/XXIII	6	0,15	0,15	0,15
United Kingdom/XXIV	4	0,1	0,1	0,1

[5] Missing information for Latvia. – To be completed.

[6] Q : quartz percentage – K=1

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

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

Caption

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 de l'Industrie (RGIE)	Empoussiérage de référence
	IX	Ministère du Travail	Valeur limite de Moyenne d'Exposition
Germany	**X**	Bundesministerium für Arbeit unde Soziales	TRGS 900 Arbeitsplatzgrenzwerte
Greece	**XI**	Legislation for mining activities	
Ireland	**XII**	2002 Code of Practice for the Safety, Health & Welfare at Work (CoP)	
Italy	**XIII**	Associazone Italiana Degli Igienisti Industriali	Threshold Limit Values (based on ACGIH TLVs)
Lithuania	**XIV**	Dėl Lietuvos higienos normos HN 23:2001	Ilgalaikio poveikio ribinė vertė (IPRV)
Luxembourg	**XV**	Bundesministerium für Arbeit	Maximale ArbeitsplatzKoncentration (MAK)
Malta	**XVI**	OHSA – LN120 of 2003, www.ohsa.org.mt	OELVs
Netherlands	**XVII**	Ministerie van Sociale Zaken en Werkgelegenheid	Publieke grenswaarden http://www.ser.nl/en/oel_database.aspx
Norway	**XVIII**	Direktoratet for Arbeidstilsynet	Administrative Normer (8hTWA) for Forurensing I ArbeidsmiljØet
Portugal	**XIX**	Instituto Portuges da Qualidade, Hygiene & Safety at Workplace NP1796:2004	Valores Limite de Exposição (VLE)
Romania	**XX**	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	**XXI**	Instrucciones de Técnicas Complementarias (ITC) Orden ITC/2585/2007	Valores Limites
Sweden	**XXII**	National Board of Occupational Safety and Health	Yrkeshygieniska Gränsvärden
Switzerland	**XXIII**		Valeur limite de Moyenne d'Exposition
United Kingdom	**XXIV**	Health & Safety Executive	Workplace Exposure Limits

Source: IMA-Europe. Date: May 2012

Annex 2

Questions about the legal procedure

In 1998, following a request from France, the Council requested the European Commission to consider whether a respirable crystalline silica exposure limit should be established at EU level either in Annex III of the Directive on Carcinogens at Work (90/394/EEC or 2004/37) or in the Directive on Chemical Agents at Work (98/24/EC).

Only the Directive 2004/37 approach has been subject to consultation of the social partners ('Social Dialogue Consultation') under Article 154 of the Treaty on the Functioning of the European Union (TFEU), even though to a limited extent. The evaluation for the Chemical Agent Directive has not been carried out, and has not even been started yet. Therefore, only half of the mandate given to the Commission has been fulfilled.

Article 154(2) and (3) TFEU require a two-stage consultation before the Commission may submit proposals in the social policy field, including, pursuant to Article 153(1)(a) TFEU, in the field of protection of workers' health and safety.

In the case at hand, the Commission initiated a first stage social dialogue consultation on revision of the carcinogens at work legislation (then Directive 90/394) in March 2004. In April 2007, the Commission launched the second phase consultation [16]. In this second consultation, the Commission requested the opinion of the social partners, among others, on whether Binding Limit Values (BLVs) for additional substances should be inserted into Directive 2004/37. However, no opinion was requested on specific substances.

Furthermore, as regards RCS, the Second Phase Consultation noted:

> *"the Commission will encourage and support sectoral dialogue initiatives that may complement existing legislation in reducing the exposure of workers to carcinogens, mutagens and reprotoxic substances. Recent developments regarding crystalline silica, within the framework of the European social dialogue, are a good example of how the social partners can contribute to the health protection of workers."*

From this statement, it remains unclear whether RCS was considered for inclusion in the revised Carcinogens Directive. It could rather be concluded from it that the Social Dialogue Agreement was considered as a valid regulatory tool complementing the existing legislation, instead of a tool requiring replacement by future legislation.

In addition, the Social Dialogue Consultation was held solely for the proposals according to inclusion of the limit in the Directive 2004/37 (i.e. the Carcinogens at work Directive). The alternative proposals based on Directive 98/24 (Chemical Agents at work) were not considered. Given the fact that, at least as regards RCS, Directive 98/24 was explicitly mentioned as an alternative legislative tool to consider, the Social Dialogue Consultation taking into account only Directive 2004/37 is incomplete.

<u>For all these reasons, the Social Dialogue Consultation should be repeated before any action is taken on RCS according to Directive 98/24 or Directive 2004/37</u>.

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