Towards an appropriate regulatory solution for respirable crystalline silica
Position Paper
November 2012

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
- **ECI** – The European Copper Institute
- **EFFCM** – The European Federation of Fibre-Cement Manufacturers
- **EMO** – The European Mortar Industry Organization
- **ESGA** – The European Special Glass Association
- **EURIMA** - 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
- **EUROROC** – The European and International Federation of Natural Stones Industries
- **EXCA** – The European Expanded Clay Association
- **FEVE** – The European Container Glass Federation
- **GlassFibreEurope** – The European Glass Fibre Producers Association
- **Glass for Europe** – 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)

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The signatories to this paper would like to highlight their position regarding the discussion on a possible inclusion of Respirable Crystalline Silica (RCS) in the Carcinogens Directive (2004/37/EC) to the European Commission and its Committees.

The respirable crystalline silica (RCS) dossier is complex and this ubiquitous, generally non-substitutable, substance deserves a thorough assessment and a proper regulatory decision.

Summary

In the context of the current revision of the Carcinogens Directive, the signatories wish to highlight their opinion that this Directive is not the suitable regulatory solution for RCS handling and use at the workplace, for the reasons developed below.

The best regulatory solution would be to include a **Binding European OEL (BLV) of 0.1 mg/m³ in the Chemical Agents Directive (98/24/EC).**

This conclusion is the result of careful consideration of the need to:

- Recognise the fact that the main health risk due to RCS exposure is silicosis and that prevention of such exposure is essential to manage it;
- Acknowledge that a BLV in the Chemical Agents Directive is a more suitable regulatory solution for such a ubiquitous exposure at work and in the environment;
- Avoid penalising sectors where RCS exposure exists but in which the RCS hazard does not arise;
- Take into account that some of the requirements of the Carcinogens Directive are not relevant for RCS;
- Focus EU-level regulation of RCS on dry situations/processes that generate airborne RCS;
- Ensure that an occupational exposure limit (OEL) value is proportionate to the occupational risk and consistent with the feasibility of measurement.

Explanation of supporting arguments

1. **The main health risk due to RCS exposure is silicosis and prevention is essential to manage it**

Prevention is crucial and is the focus of the Social Dialogue Agreement on Crystalline Silica Good Handling and Use (in short, NEPSi SDA).

It is widely agreed that the NEPSi SDA provides adequate control measures and workers' protection. This was notably recognised by the EC second stage consultation of the social partners on the protection of workers from carcinogens.

The IOM SHECan Report[1] acknowledges the benefit of the control strategies put in place by NEPSi (p.37 and p.71) inferring that it provides adequate workers' protection.

In reality, the biennal NEPSi Reporting provides ***unique*** incentives to companies to improve continuously the protection of workers.

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

2. **Setting a limit value for RCS in the Chemical Agents Directive would be appropriate, because it would recognise the fact that the main health effect of RCS exposure is silicosis, while implementing a standard threshold level (OEL) protecting workers from silicosis in Europe.**

RCS carcinogenicity is expressed through a secondary mechanism. Regulating RCS in the EU Carcinogens Directive would not take into account the evidence acknowledged by all scientific experts and regulatory committees.[2] [3] [4]

Lung cancer excess risk due to RCS exposure is restricted to workers who contracted silicosis and therefore, by preventing silicosis, lung cancer is also prevented.

In that respect, the 2002 Scientific Committee for Occupational Exposure Limits (SCOEL) recommendation [5] remains valid: *"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 IARC Monograph 100 C [6] (2010) affirms that **the most prominent mechanism of lung cancer development is based on inflammation** *"which results in macrophage activation and the sustained release of chemokines and cytokines".* The mechanism described by IARC is the same pathogenetic mechanism as that for silicosis.

Any decision on the regulatory status of RCS should explore the relevance of an exposure threshold for silicosis and lung cancer effects. The Carcinogens Directive is not the right framework for such a secondary carcinogen, as the substitution principle is not necessary when the silicosis risk is controlled.

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 in the Directive on Chemical Agents at Work (98/24/EC)**.

SCOEL (the Scientific Committee for the setting-up of Occupational Exposure Limits) therefore received the mandate to make a recommendation for an OEL for respirable crystalline silica.

In 2002, SCOEL concluded that *"It arises that an OEL should lie below 0.05 mg/m^3 of respirable silica dust"* but did not make a recommendation for the regulatory framework. The implications of an OEL at this level are discussed on pp. 6 & 7.

We ask the Commission and its Committees to reconsider the possibility of including the OEL for RCS in the Chemical Agents Directive.

In the interim period needed for the adaptation of the Directive, the NEPSi SDA would continue to protect the workers exposed to RCS while the national limit values apply. The signatories of the Agreement undertake to use their best endeavours to persuade the few other industries concerned to adopt the good working practices, including, notably, the construction sector. As foreseen in the NEPSi SDA articles, the impact of legislative provisions to come on the Agreement will be evaluated by the signatories.

The setting up of an OEL in the Chemical Agents Directive would better address the RCS occupational health effects. In the meantime, the NEPSI Agreement will continue to provide efficient protection of workers, the strength of which will grow progressively with the number of sectors covered by its good practices and the number of protected workers.

3. **The respirable crystalline silica (RCS) cancer hazard varies widely and is not observed in all industrial sectors. Regulating RCS in the EU Carcinogens at work Directive would severely impact sectors where the hazard does not exist.**

Constituting 12% of the Earth's crust, quartz, the most common of the crystalline silica polymorphs, is the second most abundant mineral in nature. As a consequence, it is everywhere in our daily environment: on beaches and roads, in the fields, on athletics tracks and in the garden. It is found in almost every type of rock i.e. igneous, metamorphic and sedimentary. Since it is so abundant, quartz is present in nearly all mining operations. Industrial silica is used in a vast array of industries, the main ones being the glass, foundries, construction, ceramics, and the chemical industry. Silica in its finest form is also used as functional filler for paints, plastics, rubber, and silica sand is used in water filtration and agriculture.
In 1997, the International Agency for Research on Cancer (IARC) concluded that crystalline silica, inhaled in the form of quartz or cristobalite from occupational sources, is a group 1 carcinogen (Carcinogenic to humans). However, in its volume 68 Monograph[7] evaluation, IARC states that *"in making their overall evaluation, the IARC Working Group noted that carcinogenicity in humans was <u>not detected in all industrial circumstances studied</u>, and may be dependent on inherent characteristics of the crystalline silica or on external factors affecting its biological activity or distribution of its polymorphs"*.

The different reactivity of different types of crystalline silica was confirmed in the IARC volume 100 C Monograph[6].

Regulation should therefore 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, farming, et al.). The results from the coal mining epidemiology and toxicology, as assessed by IARC in its 1997 Monograph [7] and by the German MAK committee in its coal mine dust evaluation (Greim 2002 [8]) should be taken into account. 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%.

The EU Carcinogens Directive with its strict obligations (e.g. substitution whatever the exposure) would impose inappropriate, unnecessary and unfair constraints in sectors where the hazard does not exist (e.g. coal mines and coal fired plants), has not been observed (e.g. farming, beach watching etc.), or not observed in absence of silicosis (e.g. quarries, ceramics, etc.) **Therefore, the EU Carcinogens Directive may be regarded as a disproportionate regulatory measure if applied to RCS at EU level.**

4. **Some of the requirements of the Carcinogens Directive are irrelevant for Respirable Crystalline Silica (RCS)**

Respirable Crystalline Silica is ubiquitous and present in a large number of industries. Some of the requirements of the Carcinogens Directive – such as the obligation to reduce or replace the use of the substance as far as is technically possible, and to prevent and reduce RCS exposure by deploying closed systems – are not possible in several sectors.

A good illustration is the case of glass. Any new glass manufacture requires the use of silica sand, and there is no alternative. Even when glass is recycled, the use of some fresh 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. Most aggregates (crushed stones, sand and gravel) generally have minimal silica fraction.

The substitution of RCS is impracticable in many circumstances, nor is it necessary, since a specific threshold level may be used to protect the workers. Therefore, the inclusion of an OEL for RCS in the Chemical Agents Directive would be more appropriate.

5. **Only certain types of processes handling respirable crystalline silica should be regulated at EU level.**

The RCS hazard is limited to a few dry processes (e.g. drilling, cutting, grinding, etc.) generating freshly fractured quartz.

In 1997, the International Agency for Research on Cancer (IARC) [7] recognised that the RCS hazard "*depends on external or intrinsic factors influencing the toxicity of the polymorphs".* Examples of these include free electrons at the surface or crystallinity.

The toxicity of these particles may be inhibited by several factors, such as the particle ageing process, free electron quenching by hydroxide ions, the presence of aluminium or other metal ions, etc. Several toxicological studies demonstrated that RCS is not biologically available in certain situations, i.e. when it is embedded in other materials or crystals.

The differing reactivity of different types of crystalline silica was confirmed in the IARC volume 100 C Monograph[6]. Indeed, it is reported that *"the pathogenic potential of quartz seems to be related to its surface properties, and the surface properties may vary depending on the origin of the quartz" e*.g. grinding procedure, the particle shape, the thermal treatment and impurities.

Setting an OEL for RCS in the Chemical Agents Directive should address the '**Work involving exposure to RCS produced during dry processes (drilling, cutting, grinding, etc.)'.**

6. **The OEL value must be proportionate to the occupational risk and be measurable in order to be effectively implemented.**

- 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[1] 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: *"there is a genuine risk that SMEs could close rather than incur the costs of compliance with the more stringent OEL options"* [1]*.*

The IOM SHEcan report[1] (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). The signatories agree with the generally accepted notion that health issues are far beyond monetary calculations. Nevertheless 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 [1] 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."*

RCS OELs have already been set by law in the 27 Member States[1], even at lower levels than those envisaged by the SHEcan project, see table on page 9 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. To be effective, OELs need to be scrupulously implemented.

A recent article by Peter Stacey et al [9] highlights the difficulties in making reliable measurements of RCS at very low OELs.

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

<u>Conclusion</u>

The signatory industry sectors ask the Commission and its Committees to consider a more suitable regulatory framework than the Carcinogens Directive for this very common, generally non-substituable, substance used by a wide variety of industries, the hazard from which varies widely and the carcinogenicity of which is expressed through a secondary mechanism.

The setting of an OEL in the Chemical Agents Directive would better address the RCS health effects, i.e. both the secondary mechanism of action and the variable hazard.

Any OEL for RCS should address the dry occupational work processes that generate airborne RCS (e.g. drilling, cutting, grinding, etc.).

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.

[1] 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.

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Occupational Exposure Limits in mg/m³ 8 hours TWA – Respirable dust – in EU 27[2] + Norway & Switzerland

Country/Authority (See caption p.2)	Inert dust	Quartz (q)	Cristobalite (c)	Tridymite (t)
Austria / I	6	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[3]	/	/
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	/[4]	/	/
Greece/XI	5	0,1	0,05	0,05
Hungary		0,15	0,1	0,15
Ireland/ XII	4	0,1	0,1	0,1
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[5]	/	/	/	/
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

[2] Missing information for Latvia. – To be completed.
[3] Q : quartz percentage – K=1
[4] Germany no longer has OEL for quartz, cristobalite, tridymite. Employers are obliged to minimize exposure as much as possible, and to follow certain protective measures.
[5] When needed, Maltese authorities refer to values from the UK for OELVs which do not exist in 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**	2011 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