Questions and answers on Directive 2017/2398 revising the European Carcinogens and Mutagens Directive at work

What is the status of respirable crystalline silica in the EU occupational safety and health legislation?

"Works involving exposure to respirable crystalline silica dust generated by a work process" are included in Directive (EU) 2017/2398 of 12 December 2017 amending Directive 2004/37/EC on the Protection of Workers from the risks related to exposure to Carcinogens or Mutagens at work, the so called "CMD". Reference: Official Journal of the European Union (OJ L345) - Article 1(4).

A Binding Limit Value of 0.1 mg/m³ for Respirable Crystalline Silica Dust is set in Annex III.

Link to the Directive available in all EU languages http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.345.01.0087.01.ENG&toc=OJ:L:2017:345:FULL

The other texts relative to respirable crystalline silica in Directive 2017/2398 are:

Recital 18: There is sufficient evidence of the carcinogenicity of respirable crystalline silica dust. On the basis of available information, including scientific and technical data, a limit value for respirable crystalline silica dust should be established. Respirable crystalline silica dust generated by a work process is not subject to classification in accordance with Regulation (EC) No 1272/2008. It is therefore appropriate to include work involving exposure to respirable crystalline silica dust generated by a work process in Annex I to Directive 2004/37/EC and to establish a limit value for respirable crystalline silica dust ('respirable fraction') that should be subject to review, in particular in light of the number of workers exposed.

Recital 19: Guides and examples of good practices produced by the Commission, the Member States or the social partners, or other initiatives, such as the Social Dialogue 'Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it' (NEPSi) are valuable and necessary instruments to complement regulatory measures and in particular to support the effective implementation of limit values, and should therefore be given serious consideration. They include measures to prevent or minimise exposure such as water-assisted suppression to prevent dust from becoming airborne in the case of respirable crystalline silica.

Recital 30: In its opinions, the ACSH has referred to a review period for binding occupational exposure limit values for several substances, such as respirable crystalline silica dust, acrylamide and 1,3-butadiene. The Commission is to take into account those opinions when prioritising substances for scientific evaluation.

Article 1(3): the following Article is inserted:

'Article 18a

Evaluation

The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value for respirable crystalline silica dust. The Commission shall propose, where appropriate, necessary amendments and modifications related to that substance.

'Process generated' respirable crystalline silica means for example "dust created by work processes such as mining, quarrying, or tunneling or cutting, crushing or grinding of silica-containing materials such as concrete, bricks, or rocks", as explained in the European Commission Press Release IP/16/1656.

When will the revised Carcinogens and Mutagens Directive at Work (CMD) take effect?

The Directive enters into force as of 16 January 2018 and the deadline for transposition in Member States' laws is 17 January 2020.

What is the Industrial Minerals industry's view on the Carcinogens and Mutagens at Work Directive 2017/2398?

Protection of workers' health has always been a top priority of the IM industry.

The IM industry welcomes the establishment of a binding limit value at EU level at 0.1 mg/m³ respirable fraction 8h TWA for respirable crystalline silica dust. This European exposure limit value is expected to support the **multi sectoral NEPSI social dialogue agreement** that 15 industry sectors have established with their employees' counterpart in order to protect workers from exposure to respirable crystalline silica dust.

Recital 19 of Directive 2017/2398 states that guides and examples of good practices produced by the Commission, the Member States or the social partners, or other initiatives, such as the Social Dialogue 'Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it' (NEPSi) **are valuable and necessary instruments to complement regulatory measures** and in particular to support the **effective implementation** of limit values, and should therefore be given serious consideration. The industrial minerals industry is very thankful and honored by this official recognition.

What are some examples of substances that contain crystalline silica?

Constituting 12% of the Earth's crust, quartz, the most common of the nine crystalline silica polymorphs, is the second most abundant mineral in nature. Practically all mining and quarrying activities involve crystalline silica. Indeed, it is present in the vast majority of naturally occurring materials that are mined from the ground. Examples include sand, gravel, dimension stones, metallic and non-metallic mineral ores.

Which minerals are concerned by the Carcinogens and Mutagens Directive at Work (CMD) 2017/2398?

All minerals/raw materials containing crystalline silica (whatever the content percentage) are concerned. The IM producers and their customers have to control the potential exposure of workers to the respirable crystalline silica dust generated during their processes in accordance with the minimization obligations of the CMD: i.e. articles 4.1., 5.2. and 5.3. of the consolidated Directive 2004/37/EC.

How will this affect value chain users?

The different Member States will transpose the European Directive in their national legislation and occupational inspectors will be informed on the new law.

The CMD obligations apply to any employer and work processes generating exposure to respirable crystalline silica dust. Every workplace situation where such processes are present will have to apply the obligations – chapter II of Directive 2004/37/EC.

If not done yet, a risk assessment has to be carried out and exposure minimization must be applied in accordance with the obligations of the CMD and to respect the 0.1 mg/m³ exposure limit value. Exposure must be monitored.

The NEPSI good practices guide is a useful and operational reference for applying the CMD obligations. The guide contains tasks sheets with specific advice to apply the minimization obligations. They are freely available in the 23 languages from the www.nepsi.eu website or from mineral suppliers. The Guide is always open for more task sheets.

In most cases, suitable occupational health protection measures are already in place. When they are not, it is suggested to seek support from your mineral supplier who can provide advice on safe handling and use of their products. For those user sectors that are not involved yet, it might be an option to join the NEPSI signatories group.

Will the supply chain of Industrial Minerals be affected?

No, the supply chain of industrial minerals will not be affected by this new Directive. Most measures of the Carcinogens and Mutagens Directive have already been implemented by the manufacturers and the users of crystalline silica or products containing it. Occupational exposure limit values for RCS already existed in all EU Member States, but the Directive requires a higher standard of RCS exposure control in workplaces throughout the value chain. By providing correct and complete information to the customers, there is no reason to expect any wide-ranging effect for the IM supply. IM producers are prepared to help their customers in reducing workers' exposure to process-generated respirable crystalline silica (RCS) and to inform them of the relevant good practices for their particular situation. This will become an integral part of their product stewardship policies.

It is of vital importance that customers of industrial minerals understand that this new European Directive concerns only the control of the exposure of their workers to process-generated RCS, it has nothing to do with the classification and labelling of the products containing crystalline silica.

The supplied products do not have to be substituted or labelled as carcinogens but the exposure of workers to the airborne dust that may be generated by processing mineral products and raw materials containing crystalline silica must be assessed and controlled properly, by applying the new legislation and the NEPSI good practices. Good industry work practices already exist in many downstream industries using mineral products in Europe that are in line with the NEPSI good practices.

How will the replacement obligation apply?

As written under Article 4 of the 2004/37/EC Carcinogens and Mutagens Directive at work (CMD), "in so far as technically possible, employers must reduce the use of a carcinogen / mutagen by replacing it with substances / mixtures / processes which are not or are less dangerous".

In the case of respirable crystalline silica, the entry in Annex I of the Directive 2017/2398 covers:
"Work involving exposure to respirable crystalline silica dust generated by a work process".

It means that the replacement obligation applies to the work processes which generate respirable crystalline silica dust.

In practical terms, the manufacturers and users of crystalline silica and products containing it will do a risk assessment and envisage the replacement of processes which generate RCS dust by other processes not generating RCS dust, if it is technically possible.
A typical example would be wet processes which prevent particles from becoming airborne and thus prevent exposure to respirable crystalline silica.
Good practices such as those of the NEPSI Agreement provide useful guidance on how to implement this replacement obligation and other exposure minimization measures of the CMD in an informed and tailored way.

Which measures does the Carcinogens and Mutagens Directive at Work (CMD) impose?

According to Articles 3 to 6 of Directive 2004/37/EC, the employers have the duty to determine and assess the risks for activities in which workers are or are likely to be exposed to carcinogens or mutagens as a result of their work. They have to supply the responsible authorities at their request with the results of the risk assessment and the measures taken, including the reasons for which carcinogens / mutagens are used.

In so far as technically possible, employers must reduce the use of a carcinogen / mutagen by replacing it with substances / mixtures / processes which are not or are less dangerous and they have to submit the findings of their investigations to the competent authorities at their request.
If substitution (or work in closed system) is not technically possible, the next measure(s) according to the hierarchy of preventive measures (Article 5) have to be taken.

How these obligations will be implemented in Europe will largely depend on how the CMD wording is interpreted and enforced at member state level.

Regarding RCS, it is important to note that the entry in Annex I refers to work processes generating such respirable dust.

Through the NEPSI Social Dialogue Agreement (SDA), the signatory industries have developed a comprehensive set of guidance and assessment techniques that address the minimization measures, taking into account the wide diversity of industrial circumstances and the best ways to address them with specific sectoral expertise. It can be seen that the SDA is complementary to the general requirements of the Directive and, by following the NEPSI Guidance, the signatories implement these requirements in an informed and tailored way.

This means, that if NEPSI employers' industries can demonstrate after their risk assessment to the competent authorities that substitution of the processes generating respirable crystalline silica dust is not possible, then they can go to the next step of the hierarchy of obligations of the CMD. The NEPSI Good Practice Guide contains a tailor-made approach for industrial processes to substitute RCS generating processes by less dangerous ones or at least to minimize exposure as low as technically possible.

For comparison and as a practical consideration, the inclusion of wood dust in Annex I & III (with OEL) has not materially affected the capacity of the woodworking industries to continue to function whilst at the same time providing the necessary level of protection of workers' health.

What is the definition of a closed system?

A closed system is a process system with equipment designed and operated in such a way that the potential contact of operators with the substance they contain is limited to maintenance operations.

What is the NEPSI Agreement

In 2006, industry (employers and employees of 14 industry sectors) developed a **Good Practice Guide on Workers' Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it**. This is the basis of a **Social Dialogue Agreement** and contains more than 65 task sheets describing good practice techniques for many work activities. The task sheets identify appropriate

control measures that will assist employers in reducing exposure levels to respirable crystalline silica to a minimum.

Published in the EC Official Journal (OJ 2006/C279/02), translated into 22 languages, the Agreement gave rise to the biggest ever awareness campaign on the risks related to exposure to RCS. The Agreement includes a mandatory reporting every two years of its application on site and the effects are already visible on the workplaces concerned. The signatories of the Agreement are committed to pursue more research related to the risks of exposure and to regularly update and complete the good practices.

The NEPSI Agreement is a unique preventive tool to improve workers' protection on the workplace thanks to the RCS dust reduction measures described in the evolving Good Practices Guide. Recital 19 of Directive 2017/2398 expressly states that: Guides and examples of good practices produced by the Commission, the Member States or the social partners, or other initiatives, such as the Social Dialogue 'Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it' (NEPSi) **are valuable and necessary instruments to complement regulatory measures and in particular to support the effective implementation of limit values**, and should therefore be given serious consideration. They include measures to prevent or minimise exposure such as water-assisted suppression to prevent dust from becoming airborne in the case of respirable crystalline silica.

Who are the signatories of the NEPSI Agreement?

In 2006, the employers and employees of 14 industry sectors signed the Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it (so called NEPSI Agreement – European Network for Silica, published in the EC Official Journal (OJ 2006/C279/02).

The Employees are represented by: IndustriAll. The Employers are represented by: GlassFibreEurope (Glass Fibre), BIBM (Precast Concrete), CAEF (Foundry), CEEMET (Metal, Engineering and Technology-Based Industries), CEMBUREAU (Cement), CERAME-UNIE (Ceramics), EMO (Mortar), EUROMINES (Mining), EUROROC (Natural Stones), EURIMA (Insulation Mineral Wool), EXCA (Expanded Clay), FEVE (Container Glass), Glass for Europe (Flat Glass), IMA-Europe (Industrial Minerals), UEPG (Aggregates).

The Agreement is always open for more signatories and the following new employer associations joined NEPSI more recently: the European Calcium Silicate Producers Association (ECSPA), the European Ready Mixed Organisation (ERMCO) and the Engineered Stone Manufacturers Association (AstA Worldwide).

What is the added value to become a NEPSI Signatory?

'**NEPSI'**, the European Network on Silica, has facilitated the implementation of good practices in dust reduction measures and also monitored the application of the Agreement through five biennial reports of key performance indicators.

The Multi-Sectoral Social Dialogue Agreement on Workers' Health Protection through the Good handling and Use of Crystalline Silica, as mentioned in Directive 2017/2398 Recital 19, "**is a valuable and necessary instrument to complement the regulatory measures and support their effective implementation".** This means that the members of NEPSI should have already a wealth of information and guidelines available on how to handle the substance in line with the provisions of the Directive, which can be shared and used by other non NEPSI Signatories.

Social dialogue is a fundamental component of the European social model that gained full recognition in the Treaty of Amsterdam. The social partners (representatives of management and labour) are thus able to contribute actively to designing European social policy.

This NEPSI Agreement aims at:
- protection of health of Employees and other individuals occupationally exposed at the workplace to Respirable crystalline silica dust from materials / products / raw materials containing crystalline silica.
- minimisation of 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.
- increasing the knowledge about potential health effects of Respirable crystalline silica dust and about Good Practices.

The NEPSI Agreement is a unique preventive tool to improve workers' protection on the work floor thanks to the respirable crystalline silica dust reduction measures described in the evolving Good Practice Guide. It incentives sites, companies, even countries, to improve the results of their subsequent NEPSI reporting.

Being part of NEPSI increases health & safety in the premises of the signatories and enhances one's capability to further influence the good practices of the future, to share experience with other users and manufacturers of crystalline silica and to be kept up to speed as to evolution of the good practices.

Does Directive 2017/2398 have an impact on product labelling?

No. The directive is put forward only in the context of occupational workers' health protection legislation. In the EU the classification and labelling of products is ruled by other separate legislation (the CLP Regulation 1278/2008). There is no direct link between these two legislative frameworks. Directive 2017/2398 addresses respirable dust generated by work processes, not the substance itself. Crystalline silica placed on the market is subject to the classification obligation under Regulation (EC) 1272/2008, while crystalline silica dust generated by a work process is not placed on the market and therefore is not classified in accordance with that Regulation.

Does this mean that crystalline silica should be classified and labelled as a Carcinogen?

No. It is the manufacturers and distributors who are responsible for labelling their products according to the CLP rules, and there is nothing new at this level. General product stewardship mechanisms are valuable for workers' health protection throughout the whole value chain.

To comply with the CLP Regulation, industrial minerals producers classify quartz (fine fraction) and cristobalite (fine fraction) products as STOT RE Category 1 for the silicosis hazard. STOT refers to Specific Target Organ Toxicity. RE refers to "Repeated Exposure". This industry classification recognizes that the main health effect of long term workplace exposure to RCS is silicosis and that measures to prevent silicosis will also prevent any associated lung cancer risk.

Does this new legislation mean substances containing RCS are being banned from commerce?

No. The directive 2017/2398 is put forward only in the context of occupational workers' health protection. In the EU the classification and labelling of products is ruled by other separate legislation (the CLP Regulation 1278/2008). There is no direct link between these two legislative frameworks.

Directive 2017/2398 addresses respirable crystalline silica dust generated by work processes, not the substance itself.

Directive 2017/2398 (CMD) covers "work involving exposure to respirable crystalline silica dust generated by a work process". This is a process generated airborne dust which is not placed on the market.

The implementation of the CMD will address protective measures to be taken at the workplace. The implementation of the CMD has no relationship with and will have no consequence on the classification and labelling or the marketing and use of crystalline silica or products containing it.

This is appropriate since health risks associated to high and prolonged exposure to respirable crystalline silica dust are only observed at the workplace and not through consumer uses nor in the general environment.

In its impact assessment (SWD 2016 152 final) accompanying the proposal of amendment of the CMD, the Commission writes on page 29 that the CMD is the more appropriate regulatory instrument for respirable crystalline silica and hardwood dust as compared with REACH authorization or restrictions notably because these are **process generated in the workplace** and are outside the scope of REACH.

For comparison and as a practical consideration, the inclusion of wood dust in Annex I & III (with OEL) has not materially affected the capacity of the woodworking industries to continue to function whilst at the same time providing the necessary level of protection of workers' health.

What will be the impact of the new European Carcinogens and Mutagens Directive at Work (CMD) in countries which have already included RCS in their national Carcinogens at Work legislation?

This will be discussed in each Member State during the transposition period of the European Directive. By 2020, Member States must ensure compliance with the minimum standards established by the Directive. It is expected that the Member States who already treat RCS as a carcinogenic agent at the workplace will not make substantial changes to their national law.

Most European Member States have already set a limit value for RCS. Will Member States with lower or higher limit values have to modify their OEL?

The European Binding Limit Value provides the highest allowed level, Member States cannot set higher OELs. Member States are however free to impose more stringent requirements according to their own practices and definitions and lower OELs may remain applicable in the countries where these are set.

What does this require producers and users to do regarding customer and employee communication?

As a minimum information to customers, the European Binding Limit Value will have to be mentioned in Section 15. 'Regulatory Information' of the Safety Data Sheets.

It is good practice to encourage and help customers to develop their measures and technologies to eliminate or reduce as low as technically possible the exposure to respirable crystalline silica potentially generated by their processes. It is important to specify that it is not a question of substituting the raw material but to control the processes from which airborne dust may potentially be emitted during their handling and use. Joining the NEPSI Agreement and Good Practice Programme, if not already the case, is the best approach.

Employers must give training to their workers, to explain how to use the control measures provided.

The NEPSI good practice guide recommends training topics.

How does the Carcinogens and Mutagens at Work Directive (CMD) apply to the management of waste containing some amount of RCS in its composition?

Exposure to RCS dust generated by the waste management processes in question have to be controlled in accordance with the CMD minimisation obligations and the Binding Limit Value has to be respected.

How does the Carcinogens and Mutagens at Work Directive (CMD) apply to the management of recycled materials containing some amount of RCS in their composition?

Exposure to RCS dust generated by the handling and processing of recycled materials containing some amount of crystalline silica have to be controlled in accordance with the CMD minimization obligations and the Binding Limit Value has to be respected.

Where can I find more information?

www.crystallinesilica.eu

www.nepsi.eu