Regulatory Management Option Analysis Conclusion Document

Substance Name: Manufacturing and high-energy operations on artificial stone

Artificial stone contains high levels of crystalline silica (CAS nr 7631-86-9). The most common crystal forms are quartz, cristobalite and tridymite.

EC Number: Quartz (238-878-4), cristobalite (238-455-4), tridymite (239-487-1)

CAS Number: Quartz (14808-60-7), cristobalite (14464-46-1), tridymite (15468-32-3)

Authority: The Netherlands

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

In the artificial stone (AS) sector AS slabs are produced and adjusted to customer specifications by high energy operations such as grinding, cutting, abrasing or polishing.

AS slabs have a high crystalline silica (CS) content (up to 90%). During high-energy operations on AS slabs respirable dust (RD) with a high respirable crystalline silica (RCS) % is released. Several young workers in the AS sector (one out of four in Australia) are diagnosed with accelerated silicosis (WorkCover Queensland (2020)). Several other studies also show cases of accelerated silicosis in AS workers in Spain, Belgium, Israel, China, USA and India (reviewed by Hoy (2021); Leso et al. (2019); National Dust Disease Taskforce (2021)). Also AS dust released during high-energy operations is more reactive and toxic than natural stone dust and AS contains other components that can contribute to its toxicity.

Accelerated silicosis has a short latency of <10 years and often progresses quickly to progressive massive fibrosis (Hoy R. , 2021). In this phase of the illness no cure is available. Wu et al. (2020) found that during follow up 38,9% of AS induced silicosis patients were candidates for a lung transplant compared to 3,2% of natural stone induced silicosis cases. Mortality was 3,2% compared to 0%.

Carcinogenic effects of RCS are also well known. Although RCS has no harmonized classification, 'work involving RCS release' is recognized as a carcinogenic process in Directive 2017/2398/EC (CMRD). In 2016, a binding occupational exposure limit (BOEL) of 0.1 mg/m^3 for RCS was established. This BOEL does not represent a safe level. The WPC/ACSH is currently working on a derivation of a new binding occupational limit value for RCS. Within this process, the commission will conduct an impact assessment to evaluate the implications, including technical and economic feasibility, of a possible future limit value, which lies significantly lower than the current EU value of 0.1 mg/m^3. A supportive study will be carried out in 2024.
CS is exempt from registration under REACH.

Although health effects of RCS have been known for a long time, from mining and construction, and has been properly controlled over time, in the relatively new AS sector, RCS-induced silicosis is a new and emerging risk.

Several studies (reviewed by Hoy (2021); Leso et al. (2019); National Dust Disease Taskforce (2021)) show that in workplaces where AS is processed there is a lack of technical controls. Workplaces are often small workshops without industrial conditions or people's homes during in-home installation. The workers are often flex workers or self-employed workers. Dry high-energy operations with very high RCS exposures occur (up to TWA 8h concentrations of 8.7 times the BOEL and short term concentrations of 500 times the BOEL) (Salamon et al. (2021), Cooper et al. 2015, Carrieri et al. 2020). Controls are not present at all, do not function properly or are present but mostly not used. Studies also show that at AS workplaces there is lack of medical surveillance targeted at accelerated silicosis and that when medical surveillance is being performed, medical practitioners do not use the correct method (Hoy R. , 2021). Therefore silicosis is not always detected early.

Studies on the effectiveness of controls (Cooper et al. (2015); Johnson et al. (2017); Philips et al. (2013)) show that RCS concentrations are reduced by using water suppression, either or not in combination with local exhaust ventilation and performing remotely controlled processing. Although, as demonstrated in RCS exposure assessments when processing is performed entirely wet, depending on the task performed, RCS levels above the BOEL are still current practice.

Good practices on working safely, reducing RCS exposure and performing medical surveillance for silicosis are available (ILO/WHO GPES 1995[2], NEPSI agreement 2019[3], NEPSI good practice guide[4], NEPSI training materials[5], SLIC 2016[6], Code of practice Victoria, Australia[7]). Also specific guidelines for health monitoring of accelerated silicosis (Perret, et al., 2020); National Guidance in Australia[8]) and early detection methods (Nandi, Lambe, Sarkar, Sawant, & Deshpande, 2021) are available. However, given the situation described above, it seems these are not known and/or implemented largely throughout the AS sector.

ECHA is currently working on a RMOA for a group of 'simple inorganic silicon compounds', including quartz and cristobalite (initial concern carcinogenicity of particles) (date of intention 31-01-2022).

[2] International labour Organization / World Health Organization Global Programme for the Elimination of Silicosis (GPES) https://www.ilo.org/safework/areasofwork/occupational-health/WCMS_108566/lang--en/index.htm
[3] European network on silica (NEPSI) https://nepsi.eu/agreement.html
[4] https://guide.nepsi.eu/wp-content/uploads/2021/08/NEPSI-Good-Practice-Guide.-revised-0821pdf.pdf
[5] NEPSI training materials:
SME toolkit NEPSI | Good Practice Guide
Training & E-learning: Training and E-learning (nepsi.eu)
Training packs: Training and E-learning (nepsi.eu)
[6] Senior Labour Inspectors Committee
https://osha.europa.eu/en/file/108303/download?token=htes0w9P
[7] https://www.worksafe.vic.gov.au/resources/compliance-code-managing-exposure-crystalline-silica-engineered-stone
[8] https://www1.health.gov.au/internet/main/publishing.nsf/content/3F0A34A0342D7925CA2587E3001B4C41/$File/National-Guidance.pdf

2. CONCLUSION OF RMOA

It is concluded that additional regulatory management measures are needed. This conclusion is based on studies on AS workers diagnosed with accelerated silicosis and exposure assessments reporting very high RCS concentrations during high energy operations on AS.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	x
Other EU-wide regulatory measures	
Occupational Safety and Health (OSH) legislation	x
Need for action other than EU regulatory action	
No action needed at this time	

For manufacturing and high energy operations on AS the following regulatory management options are considered relevant. A combination of a restriction under REACH and improving compliance to existing Occupational Safety and Health (OSH) legislation.

- *A restriction under REACH. The following restriction options can be considered:*

  A restriction obliging processing of AS to be performed only in industrial workplaces with proper controls and prohibiting non-industrial processing. It should be taken into consideration that compliance is expected to be low and enforcement will be difficult.

  A restriction prohibiting AS processing unless the employer or self-employed worker ensures that the users have successfully completed training on safe working methods prior to performing high-energy operations on AS articles. This restriction contributes to more knowledge and awareness and improvement of controls in the AS sector.

  A restriction obliging suppliers to provide AS articles with a warning label, hazard information and safe work instructions. This restriction contributes to more knowledge and awareness and improvement of controls in the AS sector.

- *Occupational Safety and Health Legislation*

  Start a dialogue with sector organizations to stimulate compliance and awareness campaigns for employers, employees, occupational physicians and enforcement. Sector organizations could assess the exposure during processing of AS and advise companies on necessary controls for safe AS processing. A warning label on AS articles could be considered as well.

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

We propose simultaneous actions under OSH and REACH for the following reasons:

- Whereas there is no clear addressee for drawing up a plan for improvement under OSH a restriction proposal can be drafted by a Member State.
- A restriction is a way for regulation on a European level.
- With a restriction, self-employed workers as a target group can also be included, while they are not addressed via OSH legislation (this can differ depending on the Member State).

It should be taken into account that, in the case the scope of this RMOA (concerning RCS dust released during AS processing), there are no registrants. This makes it difficult to get in contact with the sector, especially with small workshops and self-employed workers.

3.1 Restriction under REACH

Restriction applies if there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances. RCS is of concern mainly due to repeated exposure in workers in the AS sector (via inhalation). A total ban on the manufacture and use of the substance would prevent all (potential) health risks. However, a total ban may be neither necessary nor proportionate, since best practices are available. AS business should have the chance to demonstrate that they can effectively control RCS exposure.

The following type of restrictions can be considered:

- A restriction obliging processing of AS to be performed only in industrial workplaces with proper controls and prohibiting non-industrial processing. In-home installers would order AS slabs that are already adjusted to customer specifications. Compliance to such a restriction is expected to be low. Also enforcement will be difficult in small workshops and during in-home installation. This should be taken into consideration for this regulatory management option.
- A restriction prohibiting the use of AS articles above with CS content above a certain %, obliging businesses to use alternatives with lower CS levels, such as sintered AS or ceramic AS. There is currently no knowledge on the technical feasibility of this option. Also, it is not known if a safe CS level of AS articles exists. Therefore, this is not considered to be an appropriate regulatory management option. However, it can to some extent contribute to limit the RCS exposure.
- A restriction prescribing specific working methods and controls that reduce dust release, for example prescribing only wet operations or automated wet operations. However, studies show that even when only wet processing is applied, RCS concentrations can still exceed the BOEL (Qi & Echt, 2016). Therefore, this is not considered to be an appropriate regulatory management option.
- A restriction prohibiting AS processing unless the employer or self-employed worker ensures that the users have successfully completed training on safe working methods prior to performing high-energy operations on AS articles. This restriction contributes to more knowledge and awareness and improvement of controls in the AS sector. Also, it will apply to employees as well as self-employed workers, whereas OSH legislation does only apply to employees (depending on the

Member State). Therefore this is considered to be an appropriate risk management option. Also it would be beneficial to take lessons learnt into consideration from the mandatory training as part of the diisocyanates restriction. Also it is important to note that the situation for AS is different from that for diisocyanates. For example, there are no registrants and therefore it is unclear who may provide the training. Self-employed workers are a subgroup that are even more difficult to get in contact with.

- A restriction obliging suppliers throughout the supply chain to provide AS articles with a warning label, hazard information (reporting CS %) and safe work instructions to all businesses and self-employed workers that perform high-energy operations on AS. This restriction contributes to more knowledge and awareness and improvement of exposure controls in the AS sector and is therefore considered to be an appropriate risk management option.

3.2 Improving compliance to OSH legislation

Minimizing exposure to RCS is already anchored in Directive 2017/2398/EC (CMRD), which defines 'work involving exposure to RCS by a work process' as carcinogenic. OSH legislation also obliges employers to perform exposure assessment, implement controls and check the effectivity of these controls. Also employers should provide education to workers about safe working methods and they should offer periodic medical examination targeted at the risks present during work.

However, studies show that in workplaces where AS is processed, technical controls are often not applied or do not function properly. Especially in smaller workshops and during in-home installation, controls are often not sufficient.

Studies also show that in many cases medical surveillance targeted at accelerated silicosis is not performed at AS workplaces or the correct method is not applied.

We recommend the following actions to improve compliance of businesses to OSH:

- Communicating available safe work practices and health surveillance guidelines to the AS sector.
- Increased focus on enforcement on a national level could help improve workplace conditions.

Possible parties that can perform compliance campaigns are EU-OSHA and national regulators and labor inspectorates. Possibly, the Agglomerated Stones Association can be an entrance to the sector.

Please note: workers in the AS sector are often flex workers and self-employed workers. OSH legislation does not apply to them and they are difficult to get in contact with. Since there are no registrants it is difficult to get in contact with the sector. It should also be noted that workers at sites where AS objects are manufactured have to be properly protected as well. These workers mix the raw materials, including crushed stone with high CS content, with additives to produce AS.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

An indication of a tentative plan is provided below.

Follow-up action	Date for follow-up	Actor
Improve compliance to OSH legislation by means of awareness campaigns on safe work practices and health surveillance and focus on enforcement.		
Restriction options: -Providing AS articles with warning label and safe work instructions by suppliers throughout the whole supply chain. -Prohibiting AS processing unless workers have successfully completed training on safe working methods. -Restrict AS processing to industrial workplaces.		