RCF/ASW - Risk Management Option Assessment

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Overview

Refractory Ceramic Fibres (RCF) have been included in the ECHA's 5th recommendation for inclusion on Annex XIV and may be subject to authorisation if confirmed by the European Commission. In parallel, following the SCOEL recommendation in 2011 (SCOEL/SUM/165), a proposal for a Europe wide exposure limit (BOELV) is being developed under the Carcinogens and Mutagens Directive (CMD). Since RCF is used professionally and exposure to RCF dust occurs only in the workplace and not to the general public, the above mentioned sectors recommend the adoption of the BOELV as the most appropriate Risk Management Option. This will be simple to implement and apply in all relevant workplaces. By contrast, authorisation will be slower to implement and is unlikely to be as effective in reducing workplace exposure.

Our analysis of risk management options (RMO's) is summarised in the following table:

Score: 0: objective not achieved; 1: objective partially achieved; 2: objective fully achieved

Objective	Annex XIV	CMD + BOELV	Short discussion
Functioning of the EU market	0	1	The authorisation process could lead to a market distortion since RCF article imports from outside the EU will not be affected. Establishing a BOELV (unless fixed at an unfeasible low level) will not have a direct impact on the functioning of the EU market.
Risk control: occupational health effects	1	2	Authorisation can by definition only control "substance use". Exposures resulting from the use of (imported) articles will not be controlled by authorisation.[1] A BOELV would cover exposure at all stages of use (cradle to grave), irrespective of the object´s substance/article status.
Effective substitution	1	1	As substitution has been a legal requirement since 1997 (classification of RCF), neither authorisation nor the implementation of a BOELV will have a major impact on substitution. Competition has already driven substitution of RCF where technically and economically feasible.
Impact on environmental objectives	0	1	Authorisation might lead to technical compromises by pushing user industry to use less efficient insulation materials – which would in turn increase energy consumption and GHG emissions. An appropriate BOELV would not create a conflict with environmental policy targets.
Efficiency: low administrative burden	0	2	The authorisation process is a massive on-going burden not only for industry (many effected "substance users" are SME), but also the regulatory administration. The implementation of a BOELV is a much less bureaucratic and hence more efficient approach.
Effective enforcement	0	1	The enforcement of authorisation will require major national efforts and will fail to identify substance and article imports at the point of entry into the EU (specific customs identification missing). Exposure controls are already in place and supported by the CARE program (see www.ecfia.eu)
Total score	2	8	

[1] This problem could be mitigated by restrictions to be defined and implemented after the sunset date – which would in turn further increase the administrative burden. In the meantime the burden would be solely on the European industry.

Introduction

Refractory Ceramic Fibres (RCF), better described as Alumino-Silicate Wools (ASW), are used to produce high temperature insulation products for industrial applications, typically above 800°C. They comprise alumino silicate and zirconia alumino silicate refractory fibres (further referred to as RCF). A typical example for the end use of these products is the insulation of thermal processes in various key industry sectors such as metal production and heat treatment, ceramics, glass, cement, chemical processing and power generation.

Which risk needs to be managed?

RCF has been classified by the EU as a potential human carcinogen based on the results of animal experiments following the principle of precaution. Chronic exposure to elevated concentrations of respirable RCF dust is suspected to cause lung disease including fibrosis and cancer.[2] RCF is an inorganic material and isn´t soluble in water; hence it doesn´t have any detrimental effect on the environment (i.e. soil or water pollution once put to landfill after its service life).

The potential risk associated with RCF is limited to occupational situations during active handling of RCF products, when respirable fibrous dust can be released and inhaled by workers. Hence the overall objective of risk management measures is to reduce associated workplace risks through the elimination or reduction of workplace exposures. RCF products are part of the industrial equipment in a wide number of high temperature industries, they are not found in the final products which are produced in these industries. Throughout their lifecycle there is no consumer exposure.

Why will authorisation under REACH (Annex XIV) fail to manage the risk?

The authorisation process under the REACH regulation is designed to control risks to the environment and human health via the substitution of substances of very high concern (SVHC). SVHC may only be used if no technically and economically feasible substitute is available, if the use takes place under controlled conditions or if the benefit of continued use outweighs the remaining risks.

As communicated by various industrial user sectors in the public consultation process during the prioritisation of RCF in June 2013, there are no feasible substitutes available for various high temperature processes. Substitution has already taken place where possible starting even before classification in 1997; however RCF products can´t be replaced in the technically demanding remaining applications. The authorisation requirement will therefore not lead to an elimination of RCF products via substitution.

The authorisation process fails to cover the imports of RCF based articles. In terms of workplace controls, the authorisation process can by definition only regulate the “substance use” stage. The vast majority of RCF is however converted into “articles” (often by the primary manufacturers in semi-closed processes) before it is placed on the market. These articles are also imported from outside the EU. Authorisation might have an impact on the “substance to article” conversion process inside the EU (affecting EU based RCF manufacturers), but it cannot regulate manufacturing outside the EU nor does it regulate the import of RCF articles from non EU countries.

Unlike many other chemical processes, where the substances are no longer present once converted in an article, RCF based articles can still release fibrous dust during further manipulation, installation, maintenance and at the removal stage. Finally authorisation of the “substance” RCF under REACH fails to manage the associated workplace risk – especially in the case of imported articles.

What are the other downsides related to the inclusion of RCF in Annex XIV?

Authorisation is a disproportionate burden on EU-based industry as it can be bypassed by non-EU competitors. It might lead to the re-location of RCF manufacturing and conversion processes to regions outside the EU, along with the loss of employment, revenue and know-how.

[2] It is worth noting here that this “assumed risk” is based on the hazard classification rather than observed human health effects – there has been no known case of occupational disease associated with RCF exposure after more than 60 years of use.

RCF products are used for the purpose of heat management in industrial process equipment such as complex and highly customised industrial furnaces, often representing long term, multi-million Euro investments – the uncertainties associated with the authorisation process (incl. regular reviews) will have a negative impact on investment planning.

Another potential downside is related to the "black list" effect associated with the inclusion of a substance on the authorisation list. Some users might choose to use less efficient "false substitutes", jeopardising their energy efficiency at the cost of increased greenhouse gas emissions and long term global competitiveness. This is clearly at odds with other EU policy objectives.

Are there alternative, more suitable risk management options?

It is worth noting that RCF is already regulated under applicable EU law. The inclusion of RCF in Annex I (Index Nr. 650-017-00-8) of the Dangerous Substances Directive in 1997 triggered a number of regulatory requirements, including the substitution requirement and labelling obligations. The applicable Carcinogen Directive further specifies a "hierarchy of controls" approach which needs to be followed when using the material in industrial and professional settings.

Additional regulatory risk management options under REACH include the instrument of restrictions which might be used as an alternative to authorisation. In fact, a restriction already applies to RCF in that it must not be sold to the general public to avoid uncontrolled consumer exposure. Further restriction will deprive the European market of necessary products without improving the workers' health.

The most direct risk management option is via the definition of an EU-wide workplace exposure limit as part of the Carcinogen Directive (CMD). While national standards are in place in most Member States, further harmonisation and improved workplace risk management could be achieved by the implementation of a binding occupational exposure limit value (BOELV). This approach overcomes the limitations of the authorisation process as it is designed to control exposures to RCF dust during industrial and professional use – independent of the substance/article status. It would hence control the risk associated with RCF dust release throughout the entire product life cycle and independent from the product origin.

As stated above, the overall objective of further regulation is to reduce workplace risks. This objective, along with other important REACH targets such as the EU market functioning effectively and the substitution with economically and technically viable alternatives is included in Article 55 REACH. The adequacy of regulatory options should be checked against these objectives, including some additional aspects to assess their effectiveness and efficiency (see table on page 1).

Conclusion: Based on the discussion above, the introduction of a BOELV under the existing framework of the Carcinogens and Mutagens Directive (CMD) appears to be much more efficient and effective to achieve the overall objective of improved risk management via harmonized workplace controls.

Supporting associations

ACEA European Automobile Manufacturers Association	**European Automobile Manufacturers Association**
CAEF	**European Foundry Association**
CECOF	**European Committee of Industrial Furnace and Heating Equipment Associations**
CEMBUREAU Association Européenne du Ciment The European Cement Association	**European Cement Association**
Cerame-Unie The European Ceramic Industry Association	**European Ceramic Industry Association**
CLEPA European Association of Automotive Suppliers	**European Association of Automotive Suppliers**
ECFIA	**Representing the High Temperature Insulation Wool Industry**
EIGA	**European Industrial Gases Association AISBL**
EUROFER The European Steel Association	**European Confederation of Iron and Steel Industries**
EUROFORGE	**Liaison Committee of European Stamping and Forging Industries**
EUROMETAUX EUROPEAN ASSOCIATION OF METALS	**European Association of Metals**
european aluminium association	**European Aluminium Association**
Glass Alliance Europe	**Glass Alliance Europe**
PRE	**European Refractories Producers Federation**