27TH NOVEMBER, 2014

INCLUSION OF RCF ON REACH ANNEX XIV?

SOCIO-ECONOMIC IMPLICATIONS

ACEA European Automobile Manufacturers Association

CAEF

CECOF

Association Européenne du Ciment The European Cement Association CEMBUREAU

Cerame-Unie The European Ceramic Industry Association

CLEPA European Association of Automotive Suppliers

european aluminium association

ECFIA

EIGA

Euro Alliages Comité de Liaison des Industries de Ferro-Alliages

EUROFER The European Steel Association

EUROFORGE

EUROMETAUX EUROPEAN ASSOCIATION OF METALS

Glass Alliance Europe

PRE

OVERVIEW

RCF products are indispensable in modern industrial high temperature processes due to their unique combination of thermal and physical characteristics. Any potential human health risk related to RCF use is limited to occupational settings and no excess of respiratory disease has been observed in exposed workers after more than 60 years of production and use. There is no consumer exposure. RCF has been successfully substituted where technically and economically feasible. There are no viable substitutes for the remaining applications. The "non-use" of RCF could lead to a wide range of undesired socio-economic implications; negative impacts are expected in terms of environmental sustainability, competitiveness, employment, process safety and legal compliance with plant emission regulations.

Rather than causing environmental concerns, the use of RCF products is environmentally beneficial. Authorisation would fail to improve worker protection in down-stream operations as it can be circumvented via article imports. Detailed assessments of alternatives and socio-economic implications are essential elements of an application for authorisation and can only be done on a case-by-case basis. This would lead to an insurmountable number of applications for authorisation, effectively blocking ECHA´s committees for an extended period of time. Even if authorisations could be granted following a more generic approach, the uncertainty for long-term planning driven by short review periods (compared to the service life of the affected industrial installations; typically > 25 years) will have a negative impact on industrial investments in the EU.

In light of the fact that exposure to RCF occurs only in industrial environments, following the principle of regulatory effectiveness, the implementation of a sufficiently protective binding occupational exposure limit value (BOELV) is seen as a much more appropriate regulatory approach. This is fully in line with the 2020 SVHC roadmap process which, besides authorisation and restriction, supports "other regulation" where appropriate.

The combined industry sectors using RCF products stand for more than 20 million employees and a combined turnover of more than € 1500 billion per year.

INTRODUCTION

REACH – Article 55
The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

According to REACH Article 55, the objectives of the authorisation process are twofold: to properly control risk (health and environment) while maintaining a well-functioning internal market. This should primarily be achieved via the substitution of substances of very high concern with safer alternatives – provided these are technically and economically suitable. In this position paper we discuss the potential impact of the inclusion of Refractory Ceramic Fibres (Al-Si-RCF and Zr-Al-Si-RCF) – often also referred to as Alumino-Silicate Wools (ASW) – on Annex XIV, with a focus on potential socio-economic implications.

MANUFACTURING AND USE OF RCF

RCF belongs to the group of high temperature insulation wools (HTIW) and is produced by 3 companies at 4 manufacturing sites in Europe (France, Germany, United Kingdom). In addition to these primary manufacturing sites there is a limited number of reprocessing sites, often operated by the RCF manufacturers, to convert the fibres into a wide range of useful product forms. ECFIA represents all European RCF producers and some of the larger re-processors. ECFIA member companies also produce a range of refractory materials, including other HTIW and IFB (insulating fire bricks and castables).

RCF products are predominantly used for the thermal insulation of industrial high temperature process equipment. RCF products were commercialised in the 1950s and have since generally replaced "traditional" refractory materials where technically possible. The oil crisis in the 1970s, followed by continuously rising energy costs and growing environmental sustainability concerns, made RCF the "material of choice" in industrial thermal process and equipment design. RCF products have a unique combination of properties, such as thermal and chemical stability, insulation performance, low density, thermal shock resistance and the ability to form a wide range of rigid and flexible articles, combined with sufficient availability at relatively low costs. This has resulted in the technical and commercial success of the material in many innovative processes, and at the same time makes it very difficult to find viable alternatives with the same positive effect on equipment performance and reliability as well as energy efficiency for the downstream user.

RCF products are indispensable in modern industrial high temperature processes due to their unique combination of thermal and physical characteristics.

Examples of RCF products

RISK PROFILE – HUMAN HEALTH AND ENVIRONMENT

While the discussion of potential risks is not the primary focus of this position paper, we here briefly summarise the RCF risk profile:

Prof. Dr. Mark Utell (RCOM 2014)
From a clinical perspective, it is appropriate to note that production workers in the University of Cincinnati cohort have up to 43 years of exposure to RCF (25% of all production workers in the cohort have over 20 years of exposure) and no disease above background rates has been observed. [...] the studies demonstrate that with adequate controls, RCF poses a low risk for development of respiratory disease. [...] these results are viewed as encouraging; they certainly neither justify listing RCF as a SVHC nor the inclusion on the Authorisation List.

PSP Agreement between OSHA, EPA and RCFC:
Upon the conclusion of the agreement, RCFC and EPA generally agreed that (1) atmospheric RCF emissions are quantitatively small, and are of negligible concern to general public health or the environment, and (2) any initiatives taken should focus principally towards exposure management in the workplace.

1. Human health risk (occupational risk): The potential risk is related to inhalable fibrous dust. Animal tests conducted in the 1980s, meanwhile scientifically challenged, resulted in fibrosis and lung tumours after chronic inhalation of very high doses of specially prepared fibre samples. This raised concern regarding a possible human health hazard and finally led to the classification of RCF as a cat. 2 carcinogen under the Dangerous Substances Directive in 1997. As a consequence, RCF and its uses are covered by a range of worker protection regulations (e.g. the Carcinogens and Mutagens Directive and its national adoptions in EU Member States). The risk is limited to a relatively small number of industrial professionals actively manufacturing, handling and processing RCF products (10,000 – 20,000 workers in the EU). A long term (> 25 years) epidemiology study involving all current and former workers of RCF manufacturers in the USA detected no increase in fibrosis and lung tumours above background levels. In addition, we are not aware of a single occupational health case related to RCF exposure recorded in any occupational health register after more than 60 years of use.
2. Human risk via environmental release: No relevant release has been detected in a number of studies and environmental measurements, e.g. RCF plant stack emissions, fence line exposure measurements and measurements at landfill sites. The results of these studies showed levels typically below the detection limit and caused US-EPA to conclude that RCF causes no environmental concern; the general public is not exposed to RCF.
3. Environmental risk: RCF is an environmentally inert, inorganic material made of naturally abundant minerals. RCF products do not cause any environmental concerns at any stage of their life cycle. Rather than causing any environmental risk, the use of RCF products is actually environmentally beneficial because they improve resource- and energy efficiency and help to reduce greenhouse gas (GHG) emissions, hence supporting EU climate and energy goals.

Any potential human health risk related to RCF use is limited to occupational settings and no incremental respiratory disease has been observed in exposed workers after more than 60 years of production and use. There is no consumer exposure. Rather than causing environmental concerns, the use of RCF products is environmentally beneficial.

SUBSTITUTION – SUCCESSES AND LIMITATIONS

EuP Directive, Final Report ... 2014
"Alumino-silicate RCF products, better described as alumino-silicate wools, are one of the most energy efficient insulation materials available with, in many applications, no alternatives that have the same performance."

Air Liquide, company, France (RCOM 2014)
"We have not yet identified a substitute with similar level of proven compliance with the safety and reliability standards applied to our use of RCF."

European Aluminium Association, Belgium (RCOM 2014)
"No valid alternative has been found for temperatures above 900°C."

Ivoclar Vivadent AG, company, Liechtenstein (RCOM 2014)
"To date, however, no alternative material, which entirely meets our technical and economical requirements, has been identified."

Carbolite Ltd., company, UK (RCOM 2014)
"We have been evaluating the alternatives as they have become available on the market place (for many years). We can state that they are not direct alternatives."

ThyssenKrupp Steel Europe AG, company, Germany (RCOM 2014)
"A substitution of Aluminosilicate Refractory Ceramic Fibres (AL-RCF) has been done for application where possible, but substitution is not possible for all applications."

A legal requirement to substitute RCF with "less hazardous" alternatives based on the Occupational Safety and Health Framework Directive has resulted from the 1997 carcinogen classification. The High Temperature Insulation Wool industry started developing alternative materials well before this date; less respirable polycrystalline wools (PCW) were commercialised in the 1970s and less bio-persistent alkaline earth silicate wools (AES) were developed in the late 1980s. These products have proven to be technically and economically viable substitutes in a range of applications. The use of RCF products in passive fire protection, catalytic converters, diesel particulate filters and domestic appliances, as well as in several industrial processes, was significantly reduced as a consequence of these developments.

The remaining industrial uses are more technically demanding and cannot be substituted in an economical fashion by these HTIW alternatives. Replacing RCF products with "traditional" refractories is often impossible in modern installations (e.g. because of weight and space constraints) and would lead to a significant step backwards in modern thermal process technology.

RCF has been successfully substituted where technically and economically feasible. There are no viable substitutes for the remaining applications.

SOCIO-ECONOMIC IMPLICATIONS OF A "NON-USE" SCENARIO

The addition of RCF to REACH Annex XIV would have huge implications for European manufacturers and user industries. As imported articles containing RCF are not covered, the authorisation procedure would lead to a highly uncompetitive situation for European manufacturers of RCF. In addition, the relatively short review periods (shorter than the pay-back time of e.g. an industrial furnace) would lead to significant uncertainty for the downstream user. This would impact the possible use of RCF, and in practice lead to non-use situations, even when a REACH authorisation would be granted.

Carbolite Ltd., company, UK (RCOM 2014)
"This recommendation would have a major impact on our business. We manufacture in the UK and approximately one third of the products we make are exported outside the European Union. If we were no longer able to use these RCF materials it would put us at a serious disadvantage in the market place outside the EU."

EUROFER, association, Belgium (RCOM 2014)
"Therefore, prohibiting the further use of these materials would cause a negative impact in industry affecting not only manufacturers of RCF/ASW but also many downstream users in the supply chain, increase the energy consumption and CO2 emissions which, as mentioned earlier, would turn into a disadvantage position in terms of global competitiveness for the Steel sector."

Glass Alliance Europe, association, Belgium
"...authorisation would lead to negative impacts on energy savings and environmental protection and ultimately undermining the competitiveness of the industry."

ADS Group, association, UK
"If the EU were to prevent the use of RCF from the European market it will negatively impact the EU Aviation industry's ability to contain heat, provide fire protection, reduce engine generated noise and provide high temperature electrical insulation to critical components."

centrotherm photovoltaics AG, company, Germany
"We offer our products on a highly competetive international market, where we already are under considerable pressure to reduce cost. Our customers expect our systems to deliver top quality process results and high productivity at low cost of ownership. All these key success factors are prone to suffer significantly from the substitution or Al- RCF with the currently available alternative..."

The non-use of RCF products in industrial high temperature processes would cause a wide range of socio-economic consequences that cannot be generalised, i.e. they are depending on the specific application parameters of the thermal process in question. One or several of the implications below could result from a non-use scenario:

1. Environmental impact: Even in cases where it could be technically possible to replace RCF products with traditional dense or light weight refractory bricks or concretes, the resulting environmental impact would be significant. The difference in thermal mass (up to 30 fold) not only leads to increased GHG emissions but would also increase resource consumption (i.e. minerals needed to produce refractories) and emissions related to transportation. After a certain time lag it would cause a drastic increase in waste streams (landfill of refractories after their service life). The overall carbon footprint would rise dramatically.
2. Impact on global competitiveness: The use of sub-optimal materials would, in almost all cases, result in increased energy consumption and/or reduced service life and associated cost of down time and repairs (e.g. AES wools in unsuitable thermal/chemical conditions, hard refractories under the influence of cycling temperatures). The associated increase in "cost per unit" would create a competitive disadvantage for an EU based company or industry sector on the global market – with undesired long-term consequences for the European industrial GDP and employment.
3. Impact on innovation: Some modern materials (e.g. high performance steel alloys) and the resulting products require a specific heat treatment, involving steep and well controlled heating and cooling cycles which require the use of RCF. Insulation materials with a higher mass cannot be used to run such processes because of their thermal inertia (they take a longer time to heat up and cool down). As a consequence these innovative processes, along with the required know-how, would be forced outside the EU.
4. Impact on safety: Not all potential alternatives are *a priori* safer. In practice, all refractory materials can release dusts (e.g. persistent granular dust) at certain stages of their life cycle and typically require the same risk management measures as RCF dust. RCF products often offer an immediate plant safety advantage, e.g. due to their flexible nature. Without this flexibility, furnace doors cannot be properly sealed under high temperatures, potentially leading to the release of hazardous fumes into the factory environment.
5. Impact on legal compliance: The European user industry needs to comply with a number of environmental standards such as the IED (Industrial Emissions Directive) and the related BAT conclusions. The non-use of RCF products could result in non-compliance with these legal requirements.

The "non-use" of RCF could lead to a wide range of undesired socio-economic implications. Negative impacts are expected in terms of environmental sustainability, competitiveness, employment, process safety and legal compliance.

PRACTICAL ISSUES IN AN "AUTHORISATION SCENARIO"

CECOF, association, Germany (RCOM 2014)

"ITPE (Industrial Thermal Process Equipment) is usually customized to client preferences, based on process requirements. The life cycle of such plants extends to at least 20 years (see ErP-ITPE).

In the preparatory study of the ErP-Directive, DG Enterprise, Lot 4 (ErP-ITPE) it was considered that is not possible to classify ITPE by furnace type, charge bedding, heating, envelope, production range and material to treat in the furnace. A combination of all these parameters result in an unmanageable variety of possibilities and therefore a clustering of ITPE is not possible. Clustering it under REACH by inside/process temperature in the furnace would not be sufficient because of other main aspects which could lead to serious damages (chemical and physical conditions)."

Industrial thermal processes are often unique and the required equipment is custom built to fulfil a wide range of technical and environmental requirements in a safe and reliable manner. The insulation material is an important and integral element of the equipment since it drives process design and performance characteristics. The selection of the best combination of refractory materials is a challenging engineering task that cannot be generalised – and this leads to a number of major practical difficulties:

1. Process designers and furnace builders are best placed to make informed substitution assessments – this is already common practice and a legal requirement. Rather than expending their resources in the authorisation process they could, instead, easily import RCF articles from outside the EU. This would have a major impact on the European HTIW manufacturing industry while not improving worker protection in downstream operations (installation, maintenance, removal). The import dependency will also hamper the competitiveness of the European downstream industry.
2. To fully satisfy the "analysis of alternatives" requirement, every industrial thermal process would have to obtain an individual authorisation. This is not only impractical for the affected industries; the resulting number of authorisation requests would likely overload ECHA´s committees and result in a slowdown of the REACH process, hence limiting the ability of RAC and SEAC to address substances with a more relevant risk profile, causing possible negative impacts on the effectiveness and global perception of the REACH authorisation process.
3. Strictly following the REACH legal text and applicable guidance would lead to authorisation requirements covering the "substance use" stage, i.e. the conversion of fibres into useful articles. At this stage of the product life cycle it is, however, impossible to provide more than a generic "analysis of alternatives" since the end use application parameters are typically unknown to the applicant (i.e. the manufacturer of the article).

Industrial process installations often represent multi-million Euro investments, designed to have a useful lifespan of more than 25 years. The long-term planning uncertainty driven by a potential authorisation requirement, including review periods as short as 4 years, would cause a strong "black list" effect, which has in some cases already led to undesired consequences. Strict purchasing policies prohibiting the use of SVHC will force engineering decisions towards the use of less suitable refractory materials and could trigger some or all of the socio-economic implications described above.

Authorisation fails to improve worker protection in down-stream operations as it can be circumvented via article imports. Detailed assessments of alternatives and socio-economic implications are essential elements of an application for authorisation and can only be done on a case-by-case basis. This would lead to an insurmountable number of applications for authorisation, effectively blocking ECHA´s committees for an extended period of time. Even if authorisations could be granted following a more generic approach, the planning uncertainty driven by short review periods (compared to the service life of the affected industrial installations) would have a negative impact on industrial investments in the EU.

SUMMARY & CONCLUSION

ACEA, association, Brussels, (RCOM 2014)

„Caused by lack of risk for human (worker-) health or environment a prioritisation of not clear identified or defined RCF for Annex XIV is not purposeful and can cause in opposite to the aims of REACH negative effects for environment and competitiveness of European Automobile Industry (Art 55). In the case of the industrial use of RCF, REACH is a conflicting regulation with other EU-regulations, programs and initiatives (EU 2020; ETS, EuP-Lot 4 etc.). Therefore this process should be set on hold and be evaluated in an overall view in favour of the environment and economy."

The inclusion of RCF on Annex XIV has a high potential of failing to achieve the objectives outlined in REACH Article 55:

- A reduction of the human health risk is not expected since this risk during fibre production and use (i.e. conversion into articles) is limited to an already well controlled and small occupational cohort. Risks for workers in downstream industry are not tackled as imports of RCF containing articles are not covered.
- There is no environmental risk associated with the production and use of RCF – but massive potential environmental downsides in a non-use situation.
- The potential socio-economic implications related to the inclusion of RCF on Annex XIV are far reaching and include safety, environmental and competitive downsides for European society.
- There are a number of practical issues driven by the broad industrial use of RCF articles in very specific custom designed processes – making individual authorisations impractical and possibly driving RCF users to import articles from non-EU sources.

In summary, in the case of RCF the authorisation requirement appears to be disproportionate, inefficient and potentially damaging to European industry and society as a whole. If there is a remaining occupational health concern – even in light of already existing regulation and despite the observed lack of human health effects – a more targeted regulatory approach is needed.

Following the principle of regulatory effectiveness, the implementation of a sufficiently protective binding occupational exposure limit value (BOELV) is seen as a much more appropriate regulatory approach. This is fully in line with the 2020 SVHC roadmap process which besides authorisation and restriction supports "other regulation" where appropriate.

RCF/ASW - Risk Management Option Assessment February 2014

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 a carcinogen and mutagen, the BOELV is a key risk management option for RCF. Stakeholders from 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 to RCF during fibre production and use (i.e. conversion into articles) are authorisation. 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 1987 (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 of RCF would prevent downstream users from using clear 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 sin-going burden not only for industry but also for authorities and ECHA, as it is a major task for 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.

For further information on the implementation of a BOELV see our position paper on risk management options.

http://www.ecfia.eu/files/RCF-ASW-Risk_Management_Option_Assesment_final.pdf