



This document and the associated attachments are intended to inform regulatory decision makers about the upsides and downsides of the inclusion of Refractory Ceramic Fibres (RCF, often also referred to as Alumino-Silicate Wools or ASW) on REACH Annex XIV (the Authorisation List) vs. the implementation of an EU wide occupational exposure limit (OEL) in the framework of existing Occupational Safety and Health (OSH) regulation (also referred to as Work Place Legislation or WPL).

The purpose of this document is to present the key conclusions contained in the attached reference documents in the form of a brief summary. The various attachments provide further detail on certain aspects of the ASW/RCF case. Where available, both qualitative and quantitative data and independent third party reports are included.

The graphic shown at the foot of this document lists some relevant milestones, from the invention of ASW/RCF up to the current situation. It depicts

industry activities (●) plus selected key scientific findings and publications (●), as well as regulatory activities under both OSH (●) and REACH (●) regulation.

As shown in the graphic, a lot of research has been done on ASW/RCF and in parallel manufacturers have introduced Recommended Exposure Guidelines (REG) to be used in manufacturing and user plants alike. In some countries, the REG sets a lower exposure level than national regulations. Most important, there has been no report of human disease related to exposure to ASW/RCF dust after more than 60 years of industrial use.

References: *List of epidemiology publications, ECFIA: Product Stewardship Program*

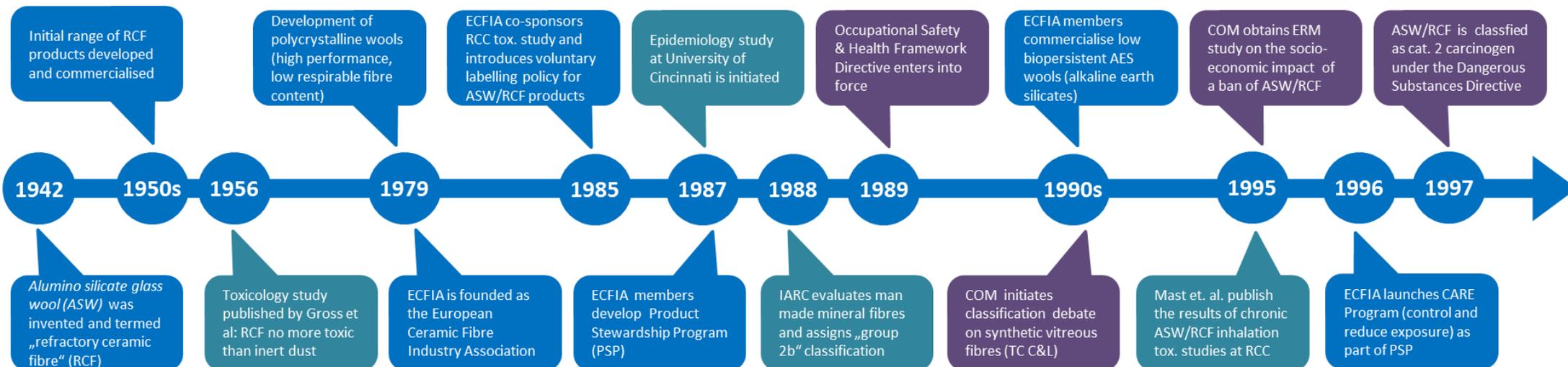
### Hazard and Risk Characterisation

The first step in the process of selecting the most appropriate regulatory instrument is to clearly describe the hazard and – perhaps more

importantly – the affected population at risk. As confirmed by the German Authorities during the Candidate Listing process, “[...] *the focus of the annex XV dossier is occupational exposure rather than public exposure to RCFs.*” (ECHA - RCOM 2011)

The main concern is the release of respirable fibrous dust during handling and use of ASW/RCF products – independent from the product form (substance, mixture, article) – which could be inhaled by workers, potentially leading to health effects in the respiratory tract. Despite some scientific criticism, the applicable hazard classification for ASW/RCF is “CLP carcinogen 1B” (by inhalation). As part of a more detailed hazard assessment SCOEL concluded that ASW/RCF is a “group C” carcinogen with a practical threshold.

ASW/RCF products are designed for industrial use in high temperature processes (typically above 800°C). Sales are restricted to professional users. The population at risk are workers at ASW/RCF





manufacturing and reprocessing sites, and also employees charged with the installation, maintenance and removal of ASW/RCF articles at industrial user sites. While estimates vary, the number of potentially exposed workers in the EU is less than 20,000 in total, with only a fraction being exposed on a regular (i.e. daily or weekly) basis.

There is no consumer exposure or exposure of the general public – neither directly nor indirectly (i.e. via any significant environmental release of fibrous dust). In the USA, the Environmental Protection Agency (EPA) obtained and analysed environmental release data jointly with the ASW/RCF industry under a consent agreement and concluded in 1998 that any potential health risk is limited to occupational settings, formally transferring the regulatory responsibility to the Occupational Safety and Health Administration (OSHA).

Since ASW/RCF is an inert, inorganic material it does not present any environmental hazard (i.e. to

soil, water, aquatic life) during manufacturing and use and when disposed of at the end of its service life.

*Reference: Environmental release report*

### Risk Management Option Assessment

Since a risk management option assessment (RMOA) was not conducted by the German Competent Authorities as part of the Candidate Listing process, the ASW/RCF manufacturers and user industries jointly performed a RMOA, which concluded that any further regulation of ASW/RCF should take place under applicable OSH Directives. Industry pointed out that the implementation of an EU-wide limit value in Annex III of the Carcinogens and Mutagens Directive (CMD) could be beneficial for the further harmonisation of worker protection across EU Member States.

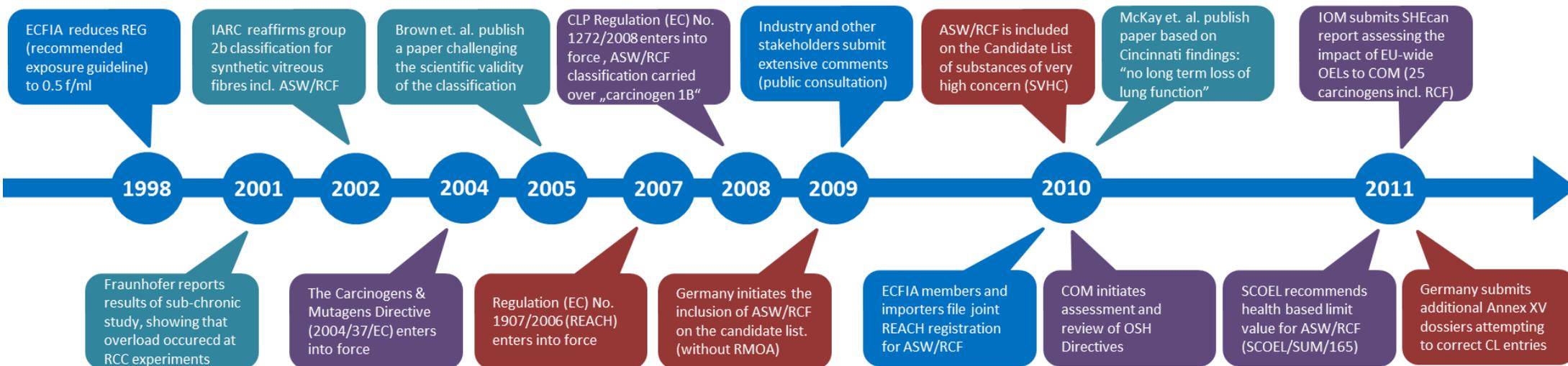
Amongst the various reasons for the suggested approach, the following aspects are key drivers:

OSH (i.e. CMD) is the more proportionate and targeted regulatory framework. While CMD requires employers to avoid or control worker exposure at all stages of the product life cycle, REACH Authorisation only affects the *substance* use stage, not improving worker protection in downstream processes since the material is typically used in the form of *articles* which can be imported from outside the-EU, by-passing the authorisation requirement.

*Reference: Joint industry paper “ASW/RCF – Risk Management Option Assessment”*

### Socio-Economic Implications

The ASW/RCF industry, along with several major user sectors, summarised their concerns relating to socio-economic implications in a joint position paper. Consequences of inclusion of ASW/RCF in Annex XIV include negative impacts on environmental sustainability, competitiveness,





employment, process reliability and workers' safety. Similar concerns were expressed by various stakeholders during the public consultations.

An authoritative third-party report on the potential consequences of the non-use of ASW/RCF was assembled by ERM on behalf of the Commission in 1995. This report has recently been updated by AMEC Foster Wheeler. AMEC concluded that ASW/RCF products still play a vital role in industrial thermal processes and that its non-use could lead to additional costs of "several hundred million Euros per year" for the affected users – without a corresponding health benefit. The anticipated cost increase is predominantly driven by increased energy consumption in the affected industrial processes, along with a corresponding increase of greenhouse gas (GHG) emissions.

*References: AMEC Foster Wheeler: socio-economic importance of aluminosilicate wools (ASW/RCF) in the context of EU regulations*

*Joint industry paper "Inclusion of RCF on Annex XIV: Socio-economic implications"*

### Substitution

Substitution has for many years been driven by market demand, accelerated by legal obligations, i.e. the 'hierarchy of controls' principle embedded in the CMD. A reduction of about 60% of the annual ASW/RCF manufacturing volume in Europe has been achieved over the last two decades through the successful development of AES wools (Alkaline Earth Silicates: non-classified high temperature insulation wools) which have been able to replace ASW/RCF in a number of applications.

The remaining uses of ASW/RCF are in particular highly technically demanding industrial applications for which no truly feasible substitutes are available. REACH Authorisation will not change this, as research and development efforts have been going on for more than 25 years, not resulting in a solution to fully replace ASW/RCF products.

*Reference: BIPRO: Overview on Alternatives for Alumino-silicate Wools/Refractory Ceramic Fibres*

### Conclusion

REACH Authorisation would be ineffective if the objective is to improve worker protection. In the case of ASW/RCF it will fail to achieve this objective due to its inability to address article imports and the limited substitutability of the material. The inclusion of ASW/RCF in Annex XIV would lead to undesired socio-economic consequences for manufacturers and the affected energy intensive user industries. In contrast, OSH Directives provide targeted regulation of health risks occurring at workplace settings – independent of the product form (substance, mixture, article) or origin. An EU wide OEL for ASW/RCF would replace the recommended exposure guideline (REG) used by industry for many years, allowing a rapid and effective implementation across Europe, improving the harmonisation of the current legal framework.

