Responses to Comments Document (RCOM) on ECHA’s Draft 5th Recommendation for Aluminosilicate Refractory Ceramic Fibres (Al-RCF) (EC number: - )

This document provides ECHA’s responses to the comments received during the public consultation on the draft 5th recommendation for inclusion of substances in Annex XIV of REACH, which took place between 24 June and 23 September 2013. In addition to this Response to Comments table, on ECHA’s website there are available zip-file(s) including all attachments to the individual comments (as far as not confidential):

PUBLIC VERSION

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## I - General comments on the recommendation to include the substance in Annex XIV, including the prioritisation of the substance:

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<tr>
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<th>Submitted by (name, Organisation/MS CA)</th>
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<tr>
<td>2492</td>
<td>2013/09/24 00:18</td>
<td>Association of European Airlines (AEA), Industry or trade association, Belgium</td>
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<td>See also responses to comments no. 2409 and 2459</td>
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<td>Regarding the exemption request/coverage by other legislation:</td>
<td>See reply to comment 2361 in section III</td>
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<td>Regarding the review periods:</td>
<td>See reply to comment 2444 in section IV</td>
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<td>Regarding the burden of authorisation on certain industry sectors/prolong LADs</td>
<td>See reply to comment 2272 in section I</td>
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<td>2489</td>
<td>2013/09/23 23:24</td>
<td>The Federation of Finnish Technology Industries, Industry or trade association, Finland</td>
<td></td>
<td>Thank you for your comment.</td>
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<td>Regarding the description of uses:</td>
<td>See reply to comment 2272 in section I</td>
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<td>Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:</td>
<td>See reply to comment 2272 in section I</td>
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<td>Regarding the non-availability of alternatives/information on alternatives in background document:</td>
<td>See reply to comment 2272 in section I</td>
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</table>
Regarding the exemption request/coverage by other legislation:

### Article 58(2) exemption response

As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Art 58(2) of REACH, unless they are already explicitly exempted in REACH Art 2(5 or 8) or in Art 56 (3-6).

Please note that according to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses "provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled".

ECHA considers the following elements when deciding whether to include an exemption of a use of a substance in its recommendation:
- There is existing EU legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question, compared to the REACH definitions in accordance with Art. 3(24). Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- This EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to, e.g. by referring to the classification criteria or the Annex
XIII criteria;
- This EU legislation imposes minimum requirements\(^1\) for the control of risks of the use. Legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the lifecycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s) as relevant) are covered by the legislation.

On the basis of the criteria above, it is considered that:
(i) Only existing EU legislation is relevant in the context to be assessed (no national legislation).
(ii) Minimum requirements for controlling risks to human health and/or the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question.
(iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used.

The relevant EU legislation referred to by the commenting party is assessed below.

Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) sets out a framework based on the determination and assessment of risk and general principles for the prevention of risk, associated with hazardous chemical agents. The

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\(^1\) Legislation imposing minimum requirements means that:
- The Member States may establish more stringent but not less stringent requirements when implementing the specific EU legislation in question.
- The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as appropriate.
Carcinogens or mutagens at work Directive 2004/37/EC (CMD) introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is that the employer shall reduce the use of a carcinogen or mutagen (CM) at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its condition of use, is not dangerous or is less dangerous to workers’ health and safety. Where substitution is not possible, CMs should be used in closed systems, where technically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used.

Both Directives outline a hierarchy of control and risk reduction measures (with substitution at the top), however, they leave the determination of the measures to be imposed to the employer and do not provide sufficient indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. On this basis it is not considered that CAD or CMD impose binding minimum requirements for controlling risks to human health. Therefore, these Directives may not be regarded as a sufficient basis for exempting uses of Al-RCF from authorisation in accordance with Article 58(2) REACH Regulation.

It is noted in that there is on-going discussion on the establishment of an occupational exposure limit at European Union level. Please note that at this time the status of this limit, indicative or binding, is not yet concluded and the measure is not yet in place. In case the ongoing discussions under the Carcinogens Directive 2004/37/EC will result in setting of a binding Occupational Exposure Limit for RCF for protection of workers, the conclusion that the Carcinogens Directive is not considered as sufficient basis for exemption under Article 58(2) REACH may be revisited.
In relation to the Classification Labelling and Packaging (CLP) of Substances and Mixtures Regulation (EC) No 1272/2008, this Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through the classification and labelling of chemicals. According to Recital 10 CLP Regulation "the objective of this Regulation should be to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated." However, this Regulation may not be regarded as a sufficient basis for exempting uses of Al-RCF from authorisation in accordance with Article 58(2) REACH Regulation.

In relation to the claim that ASW/RCF should be reclassified, please see Article 37(6) CLP, i.e. the relevant procedure for amendments of existing entries in Annex VI to CLP Regulation.

<table>
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<tr>
<th>2485</th>
<th>2013/09/23 23:14</th>
<th>IMA-Europe, Industry or trade association, Belgium</th>
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<tr>
<td>General comments</td>
<td>RCF products are a low mass insulating material and typically used as thermal insulation, heat shields, heat containment, and expansion joints at temperatures up to 1400°C in industrial furnaces, ovens, kilns, boilers, heating systems and other process equipment. These insulating materials in general are in use in high-temperature processes (mainly for thermal treatment above 900 °C) in the internal linings of furnaces and kilns. The insulating materials protect the integrity of the thermal installations and provide a suitable solution to reduce the energy consumption which results in cost savings and reduction in CO2 emissions. Substance identity unclear</td>
<td>The unclear and complex description of RCF(s) in the Candidate List entries is confusing. As it stands for now, the definition/description could embrace other fibres not listed in the proposed Annex XIV. This issue should be fixed before recommending the substances for authorisation. Inter-substitutability Other RCF products that exhibit similar hazards have not been considered. This would result (i) in unfair competition and (ii) in</td>
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<td>Regarding description of uses:</td>
<td>See reply to comment 2272 in section I</td>
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<td>Regarding the unclear substance identity:</td>
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<td>Regarding the inter-substitutability with RCFs not identified as SVHC:</td>
<td>See reply to comment 2272 in section I</td>
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<td>Regarding the existing threshold for RCFs</td>
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<td>Regarding the low or controlled exposure/risk of RCFs:</td>
<td>See reply to comment 2272 in section I</td>
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uncertainty for industry future investments (usually made for 20-30 years) as the substitute could be proposed later on for authorisation. The issue of intersubstitutability should thus be addressed before proceeding further, even at the cost of a postponement so as to avoid a failure of the Authorisation policy. 

Prioritisation scoring 

The exposure to RCF is very low as these products are used by professionals and industrial workers highly protective personal equipment. Therefore, the exposure level should be review from 'significant' to 'controlled'. According to the SCOEL opinion (SCOEL/SUM/165, September 2011), RCF is a carcinogen that has a "no observed adverse effect level" (NOAEL) and is a carcinogen of group C i.e. genotoxic carcinogen for which a practical threshold is supported. The scoring of RCF as a non-threshold substance is therefore unjustified and in contradiction with the SCOEL opinion. It is therefore proposed to amend the scoring alongside the two above comments. The overall conclusion is that it is premature to recommend RCF (as it stand for now) for inclusion in Annex XIV. Some corrections need to be done that could lead to a re-assessment including priority scoring and best Risk Management Options (RMO).

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<tr>
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<td>2480</td>
<td>2013/09/23 20:28</td>
<td>European Automobile Manufacturers' Association – ACEA , Industry or trade association, Belgium</td>
<td>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), please see also attachment under point IV.</td>
<td></td>
<td>Regarding description of uses: See reply to comment 2272 in section I Regarding the unclear substance identity: See reply to comment 2272 in section I Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I</td>
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Corrected comment:
I am a toxicologist and occupational hygienist working a Caesar Consult Nijmegen in The Netherlands. Currently, I am working on an article that provides an update on both the hazards and risks of fibres in the working atmosphere. The reason for this update is that the last few years several evaluations have been published on the carcinogenic properties and health risk related to fibres exposure in the working environment, including refractory ceramic fibres. In 2010, the Health Council in The Netherlands published an update on the risks related to asbestos fibres. In 2011, the Health Council in The Netherlands, or more precise a subcommittee named DECOS, published an update on the carcinogenicity of Refractory Ceramic Fibres (RCF) as a follow up of their evaluation published in 1995. And also in 2011, the Scientific Committee on Occupational Exposure Limits (SCOEL) published an evaluation resulting in an recommendation for a Occupational Exposure limit for RCF. The recent publications from the Health Council/DECOS (2011) and SCOEL (2011) are attached/uploaded with this comment.

One of the most important findings is that both the Health Council (DECOS) in The Netherlands and the SCOEL on EU level concluded that RCF should be considered as a threshold carcinogen. Based on the evaluations of the Health Council, The Netherlands have adopted a occupational exposure limit value for RCF of 0,5 fibres/ml (8-hr twa). SCOEL advises an occupational exposure limit for RCF that is slightly more stringent: 0,3 fibres/ml. The EU commission (DG Employment) is currently working on a so-called Binding Occupational Exposure Limit Value (BOELV) for RCF for all the EU member states.

Another relevant finding is that RCF is used in industrial settings only and that the concentrations of RCF fibres in the breathing zone of workers in these environments, both in RCF manufacturing and facilities where the RCF isolation material is used, show a strongly declining tendency since 1990. In these work environments the current exposure levels of RCF are below the occupational exposure limits that were recently proposed by DECOS and SCOEL. Only during installation and demolition of RCF containing isolation material, the exposures may exceed these values. But the use of respiratory protection will prevent these workers from health damage.

It is advised to postpone the decision on inclusion of RCF in Annex XIV until the decision process in the EU on a Binding Occupational Exposure Limit Value (BOELV) for all the EU member states is

| Regarding the exemption request/coverage by other legislation: |
| See reply to comment 2361 in section III |
The decision on inclusion of RCF in Annex XIV has been finished. Postponing the decision on inclusion of RCF in Annex XIV allows a decision that is based on the latest insights on the risks of RCF rather than a decision based on outdated and incomplete hazard information. Nijmegen, The Netherlands, 23 September 2013

dr Joost G.M. van Rooij (toxicologist/occupational hygienist)

Attachments:

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<tr>
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<th>Author</th>
<th>Text</th>
<th>Additional Information</th>
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| 2475       | 2013/09/23 19:41 | Industry or trade association, Belgium | See attachment, section IV (common paper with Zr-RCF, previously submitted under the Zr-RCF draft recommendation) | **Regarding description of uses:**
See reply to comment 2272 in section I

**Regarding the unclear substance identity:**
See reply to comment 2272 in section I

**Regarding the non-availability of alternatives/information on alternatives in background document:**
See reply to comment 2272 in section I

**Regarding the low or controlled exposure/risk of RCFs:**
See reply to comment 2272 in section I

**Regarding the perception of authorisation being a ban of the substance:**
See reply to comment 2292 in section I

**Regarding the exemption request/coverage by other legislation:**
See reply to comment 2361 in section III |

| 2472       | 2013/09/23 19:28 | ChemSec, International NGO, Sweden | ChemSec supports the listing and prioritisation of this substance to the Authorisation list (Annex XIV) due to its wide dispersive use and high volumes. Wide dispersive use:
Al RCF is used in high temperature insulation / fire protection and in |

Thank you for providing your opinion.
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<th>No</th>
<th>Date/Time</th>
<th>Entity or association, Country</th>
<th>Text</th>
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<td>2467</td>
<td>2013/09/23 19:13</td>
<td>Industry or trade association, Austria</td>
<td>Austrian companies manufacture aluminum silicate wool and demand that the inclusion in the candidate list for authorization (Annex XIV REACH) is withdrawn. Basis for this requirement are good quality scientific arguments and years of experience in the industrial practice. The manufacturing industry has Al- RCF registered in 2010 as „substance” because Al- RCF was classified as &quot;substance&quot; in 1997 in Annex 1 of the „Directive 67/548/EEC on dangerous substances”. Marketing without a registration after December 2010 would not have been possible. Therefore, the registration was a precaution of the industry to further production and placing on the market in accordance with the REACH motto: „No registration - No Market” ! Argument: ( ZI ) Al- RCF is considered by REACH definition as “product” and therefore not subject to the approval, see argument above. At the time of classification (1997) the distinction between “SUBSTANCE “ and “ PRODUCT” was not decisive for further concern in REACH / CLP. This categorization changed with REACH/CLP because there you have a difference between “SUBSTANCE” and „PRODUCT”. Due to the production mechanism you can easily explain and demonstrate that Al- RCF are &quot;products&quot;. This legal uncertainty concerning the formalism for the classification in the &quot;Directive</td>
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Regarding the status of RCFs as substance or article: See reply to comment 2292 in section I

Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I

Regarding the hazard property of RCFs: See reply to comment 2314 in section I

Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I

the automotive industry.
It is widely used in combustion plants / furnaces and high exposure to workers are expected during maintenance. There is a high number of large scale industrial installations in the EU (about 2. 000) where presence of Al RCF is likely (SOURCE E-PRTR facility search activity "1 Energy Sector” 2011).
Exposures are also expected in the assembly and cutting processes of the fibres.
It is expected that a high volume of articles containing Al RCF is imported in the EU. ECHA has received 16 notifications according to Art. 7.2 of REACH regarding presence of Al RCF exceeding the threshold of 0,1% W/W in articles which may be used by consumers and that may also be used in workplaces: these include airbag and seatbelt systems of cars, electric ovens, hobs, plaster/cement, glass and ceramic articles as well as "other" articles.
High volumes:
Al RCF is used in high volumes (up to 100.000tonnes per year). The substance should therefore be prioritised for listing in Annex XIV on this basis.

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Al RCF is used in high volumes (up to 100.000tonnes per year). The substance should therefore be prioritised for listing in Annex XIV on this basis.
67/548/EEC on dangerous substances should be clarified before any further steps in the REACH process are set.

The distinction between substance / product in connection with Al-RCF is obviously not clear and requires ultimately a legal clarification of Justice.

2 Argument: Limited use
Al-RCF are used industrially. They are for general use by the general public no longer allowed. In the consumer area Al-RCF are no longer used. The products are processed by specialists observe the appropriate safety precautions. Especially the fibrous dust which an employee might be exposed is the most important fact. The operation of industrial furnaces and high temperature industrial equipment are done by experts who are only exposed while installing and replacing insulation. Appropriate Safety precautions ensure that the acting people are protected.

3 Argument: Are Al-RCF dangerous?
Even after more than 60 years of documented use there is no aware of any adverse health effects in humans. Potential chronic effects through inhalation of fibrous dusts are minimized through adequate labour protection. With the use of Al-RCF in high-temperature processes no fiber dust is released, so there is no risk. Each potential hazard for those workers while handling these products has long been governed by existing regulations and worker protection.

Arguments from the side of the operators
The affected operators are from the Machinery and Metalware Industries. These are producers of high temperature kilns which are using materials for isolation and gaskets. The Recommendation for inclusion in the Authorisation List would develop different problems for the industry. In the temperature range under 900°C we have substitutes. Test have shown that substitutes at the level of higher temperatures especially over 1100°C in terms of stability, flexibility, durability and price cannot achieve the qualities of Al-RCF. The use of Al-RCF in the high temperature range is also energy efficient, reducing CO2 emissions and sustainable - both economically and ecologically.

| 2465 | 2013/09/23 18:30 | AIR LIQUIDE, Company, France | In addition to EIGA comment submitted on 16th of September, Air Liquide would like to emphasize the specificities and the safety rules related to the use of Refractory Ceramic fibers in our Steam Methane Reforming units (SMR).
Air Liquide is the world leader in gases for industry, health and the Regarding the description of uses: See reply to comment 2272 in section I
Regarding the non-availability of alternatives/information on alternatives in |
environment with a turnover of €15.3 Billion. The Group is present in over 80 countries (25 in Europe) with 50,000 employees worldwide. Oxygen, nitrogen, hydrogen and rare gases have been at the core of Air Liquide’s activities since its creation in 1902. In Europe, over the last 25 years, Air Liquide has installed and operates around 20 units, making us one of the major European producers for hydrogen, carbon monoxide and syngas from steam methane reforming supplying its customers in extremely diverse industries such as chemicals, oil industry, steel industry or electronics.

The recommendation proposed by Echa is made on the survey of a large panel of industries with very different activities and very different human exposure to the product. The RCF manufacturing industry and the industries with batch operation present the largest exposure to RCFs. For our reformer application, we shall try to develop in this paragraph and in the next ones the limited use and limited exposure that, in our opinion, cannot justify a recommendation for inclusion in Annex XIV.

Limited use:
As soon as the information on potential health risks appeared, Air Liquide engaged into a program to evaluate potential substitutes. 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. In the meantime, the use of RCFs has been limited to the bare minimum required to conform to the safety and reliability criterias required for industrial operation. The amount of RCF's used to build the refractory lining of a SMR furnace does not exceed 20 Tons for the largest and most recent units. Approximately 80% of them are located on the roof of the furnace where light weight and holding system are critical for the good operation of the furnace. The remaining 20% are mainly located at the expansion joints on the other walls and floor. The main performance criterias required for this material are double:
- insulating and physical stability (shrinkage and structural changes in particular) properties for the roof, lasting in time in the reducing atmosphere and high temperature ambiance.
- for the other parts, the material is mainly used to fill the gaps required for expansion of the brick system; in this case, the required additional properties are the compressibility and the flexibility of the fibers that must fill the gap without falling off, when the gap width varies in accordance with the operating temperature. The lifetime of the refractory lining is usually more than 15 years with very limited maintenance related to RCF modules erosion.

**background document:**
See reply to comment 2272 in section I

**Regarding the low or controlled exposure/risk of RCFs:**
See reply to comment 2272 in section I
Maintenance operation is normally limited to the filling of gaps that may appear in the roof between insulating elements (shrinkage of the material), or replacement of parts of the material in the expansion joints; these operations, taking place every 3 to 5 years, only require little amounts (from 10 to 500 kg typically per furnace and per maintenance operation).

Limited exposure: ambient measurements have been made for evaluating the amount of fibers present on site for our operators, and the results (see Eiga PP) show values in the order of magnitude of 10–4 times the strictest OEL given today in Europe. The only significant exposure, where OELs can be exceeded, is during installation / repair / demolition works of the RCFs. These works are carried out by specialized companies. Those companies are aware of the product properties and have processes in place to address the risks associated and train the employees intervening on Air Liquide companies’ sites. Air Liquide companies select the specialized companies based on their undertaking to give priority to safety and standard compliance. More specifically, Air Liquide finalised a procedure based on the latest publication from INRS, NIOSHH and other reputable organizations, imposing on subcontractors strict conditions such as full enclosure of the working place, extraction fan with highest filtration level to avoid dispersion, changing rooms inside the enclosure, as well as on controlled storage of new and old materials.

2459 2013/09/23 17:49 Aerospace Industries Association, Industry or trade association, United States

Aluminosilicate Refractory Ceramic Fibres are currently used as heat and fire shields and as friction and thermal insulation materials, which are critical for aerospace and defense products such as engines, wheels, brakes, and engine nacelles. Other known applications include, but are not limited to high temperature coatings, foams, papers, adhesive tapes, and blankets. Al-RCF is a critical substance that introduces serious safety and economic viability concerns if unavailable. Currently offered Al-RCF alternatives are limited and not suitable for all aerospace applications. In one specific aerospace application, smoke was generated, which was an unacceptable result. Other proposed alternatives have proven deficient in strength, friction, thermal protection, and fibre sizing (treatment) properties. Metallic replacements are heavier and do not provide comparable thermal insulation characteristics. Additional time is needed by the aerospace industry to continue to seek suitable alternatives for each application. Where potential alternatives have been identified, the evaluation, qualification and certification will take an additional five years.

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding the burden of authorisation on certain industry sectors/prolong LADs
See reply to comment 2272 in section I

Regarding the unclear substance identity:
to ten years to complete, as extensive validation and certification for these systems is required by the United States Federal Aviation Administration (FAA) and the European Aviation Safety Agency (EASA). Implementation following certification takes several additional years. Developing alternatives for maintenance of legacy, out-of-production products is even more challenging, since the original design basis and requirements may not be fully understood or readily available. The aerospace industry is committed to reducing the use of Al-RCFs where technically feasible. AIA member companies employ state of the art control and protective measures that minimize risks to workers and the environment. However, the extensive industry resources are currently focused on chromates authorization application development. Furthermore, the lack of EC or CAS numbers associated with this category of substance presents significant added burden to industry needing to identify all uses and users of these substances in complex supply chains. Given the critical need for ongoing uses of Al-RCFs, the AIA asks for consideration of the industry’s challenges as downstream users and establish application and sunset dates that are a minimum of five years after the chromate authorization dates in order to minimize the impact and allow industry to apply the lessons learned from the prior authorization applications to the process for Al-RCFs.

See reply to comment 2272 in section I

<table>
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<th>2452</th>
<th>2013/09/23 17:21</th>
<th>Industry or trade association, Belgium</th>
<th>please see comments in joint SEMI/ESIA response attached</th>
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Regarding the description of uses: See reply to comment 2272 in section I

Regarding the use of the substance as an article: See reply to comment 2292 in section I

Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I

Regarding the unclear substance identity: See reply to comment 2272 in section I

Regarding the status of RCFs as substance or article: See reply to comment 2292 in section I
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<tr>
<td>2445</td>
<td>2013/09/23 16:47</td>
<td>SSAB EMEA AB, Company, Sweden</td>
<td>SSAB also support the EUROFER position paper on (Zr) Alumino silicate RCF-Aluminosilicate wool (ASW) and the answer made by EUROFER in this public consultation.</td>
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<tr>
<td>2444</td>
<td>2013/09/23 16:45</td>
<td>Company, Switzerland</td>
<td>EIGA challenges the scoring for wide-dispersiveness of uses (number of sites X exposure) as being the highest score possible: 3*3=9. This score rates all sites with the highest rating for exposure. This evaluation does not correspond to the data from the Annex XV report summarised in the ECHA prioritisation document. There is clearly a difference of exposure for the workers at the 3 European manufacturers and those of the installation contractors with the workers of the operating furnaces (67% of the uses) and related applications (high temperature insulation: 5% of the uses). - The first group consists of a limited number of sites where the potential exposure could be higher than the OEL although it should be understood that the workers are working in controlled conditions and the RCF is mostly installed in furnaces as prefabricated articles, while - the workers of the second group are at down-stream users site with negligible or no exposure because of controlled conditions, See reply to comment 2130 in this section. Regarding the description of uses: See reply to comment 2272 in section I.</td>
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<td>Regarding the priority assessment/scoring: Inherent properties (threshold/non-threshold effects) The question as to whether the carcinogenic effects of RCFs are elicited by a mechanism for which it is possible to determine an effect threshold is important for the next stage of the authorisation process, namely application for and granting of the authorisations. However, ECHA does not assess at this stage of the authorisation process (i.e. recommendation for inclusion in Annex XIV) whether on the basis of the available scientific evidence it can be concluded that an effect level for the carcinogenic effects of the RCFs exists. This is an issue to be</td>
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continuous process operations and low frequency of inspection. The numbers of workers of the first group is estimated in the prioritisation document at 2350 workers (850 + 1500 workers) while the number of workers of the second group is estimated at 21 000, or a ratio in terms of workers of 6% and 94%.

The rating for wide-dispersiveness of uses should be weighted taking into account the ratios of the two groups of workers (6% and 94%):

<table>
<thead>
<tr>
<th>Group of workers</th>
<th>Nb. of sites</th>
<th>Rating</th>
<th>Nb. of sites</th>
<th>Rating</th>
<th>Nb. of sites</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: manuf., contractors</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>0.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Furnaces operators</td>
<td>3</td>
<td>1</td>
<td>94</td>
<td>2.82</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total score for wide-dispersiveness of uses: 0.36 + 2.82 = 3.18 or 3
Total score for RCF: 1 + 9 + 3 = 13 instead of 19

addressed in the authorisation applications and to be scrutinised by the Risk Assessment Committee when preparing its opinions on the authorisation applications.

Keeping this in mind, i.e. that no assessment of the mode of action was done at this stage by ECHA, information cited during the public consultation, such as the recommendations by the Scientific Committee on Occupational Exposure Limits (SCOEL) and the report by the Health Council of the Netherlands (DECOS), are fully acknowledged. However, in our view that information does not seem to conclusively demonstrate a threshold mechanism of action but rather discusses the relative contribution of different mechanisms of action. Therefore, for the sole purpose of the prioritisation step a score of “1” (carcinogenic without threshold) will be assigned to the RCFs, as is the default value given for carcinogens in the past.

As mentioned above, this score does not imply a conclusive assessment by ECHA on whether it is possible to determine a no-effect threshold for RCFs. Information brought in applications for authorisation will of course in any case be taken into account by RAC while preparing its opinions. While for substances included in Annex XIV, ECHA may also publish proposals for the mechanism of action (i.e. threshold / non-threshold) and the respective DNELs / dose-response curves, prior to receiving applications for authorisation - as is at least the current practice in the context of a trial exercise. The purpose of such publications is to provide applicants with a clear signal as to how RAC is likely to evaluate these important elements of the risk assessment of applications.^

Volume: only 2% of fibres are inhalable and this
The substance identity as displayed in the Candidate List on ECHA’s website is relevant for the prioritisation assessment. The fraction of fibres fulfilling the dimension criteria given in the Candidate List entry is only relevant to determine whether the substance fulfils the classification criteria. Where the concentration of inhalable fibres is above the relevant concentration limit set out in Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, the substance is classified as carcinogen and covered by the Candidate List entry. Therefore, if the substance is classified, the volume of that substance needs to be taken into account.

Regarding the RCFs, based on the substance identity information given in the registration dossiers, the relevant volume was deduced.

WDU – weighting of WDU acc. to industry’s estimate of number of sites and % of workers exposed

Please note that the current prioritisation approach (28 May 2010) which was agreed with MSC members and stakeholder was applied to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV. That approach is intended to provide a general assessment of the use pattern and exposure potential a substance may have for humans (workers, consumers) or/and the environment. Please note further that the assessment of priority needs to be performed substance-specific since also the inclusion in Annex XIV is per substance. It is important to keep in mind that all uses of a substance in the scope of authorisation need to be assessed.
According to that approach the wide-dispersive use (WDU) criterion is assessed based on the estimated number of sites from which the substance may be released and on the estimated potential for releases in all steps of the life-cycle. In doing so, a conservative approach should be applied.

In past ECHA has used worst case assumptions in cases where specific life-cycle steps of a substance have very different release and site number situations, i.e. the life-cycle step resulting in the highest WDU score was taken as relevant to assess the WDU score of the whole substance. The basis for this is that it is that life-cycle step which determines the wide dispersiveness of a use.

Furthermore, we note that the numbers of workers you refer to which are mentioned in the background document are estimates provided by an industrial association (published in 1999). These numbers are given as illustration rather than as basis for an assessment. Therefore, ECHA does not consider it justified to assume that potential for exposure to RCFs concerns only a medium number of sites.

**WDU – controlled exposure condition**

ECHA had assessed that there are uses of RCFs which have a potential for significant occupational exposure. In particular, potential for exposure cannot be excluded during operations such as maintenance activities as also stated in the background document and mentioned in a number of comments received.

It needs to be considered that RCFs are used at many different sites. At the same time there are also aspects which indicate that control of risks may not be obvious in all cases, and that the proper implementation of recommended Risk Management Measures (RMM) such as “wearing of protective
equipment by experienced workers” or “LEV” is very often essential. The overall potential for inhalation exposure can therefore, although it may be low at particular sites, not a priori be neglected. Therefore, taking account of the comments received during consultation, ECHA still considers the original assessment of the wide dispersiveness of uses appropriate.

**Note of change of assessment compared to 2009**

The first REACH registration deadline was 1 December 2010. The assessment of priority of SVHC’s on the Candidate List published on 1 July 2010 was done before the majority of registrations were submitted.

Therefore, the information used in 2010 was mainly drawn from the Annex XV dossiers of the substances and from the comments received during the public consultation on the SVHC identification process in accordance with Article 59 of the REACH-Regulation.

The priority assessment done in 2013 is mainly based on registration information.

In addition, experience has been built up in assessing the priority of substances. For example, the conclusion drawn in 2010 that “exposure should normally be controlled but not clear whether exposure controls are in all cases sufficient to prevent health effects” was nowadays rather scored with the highest release score, in particular if the substance has a “wide-dispersive use pattern”. This is also due to the need to apply a conservative approach.

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<tbody>
<tr>
<td>2437</td>
<td>2013/09/23 16:01</td>
<td>Company, Spain</td>
<td>PORCELANOSA S.A. is a company that manufactures ceramic tiles, and within this group of materials, it directs its production to cladding tiles, stoneware, and porcelain stoneware made with white</td>
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</tbody>
</table>

**Regarding the description of uses:**

See reply to comment 2272 in section I
clay. We are opposed to the inclusion of Al-Si RCF in annex XIV for the following reasons:

- Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.
- No adequate substitutes are as yet available for these uses.
- RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2.
- The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).
- Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding the low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

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<th>ID</th>
<th>Date</th>
<th>Organization</th>
<th>Text</th>
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| 2433| 2013/09/23 | Unión de Empresas Siderúrgicas - UNESID, Industry or trade association, Spain | These comments refers to both, Al-RCF and Zr-RCF since they are often sharing the same uses, they are not clearly distinguished in the processes themselves. In addition the REACH Consultation processes run in parallel. Alumino-silicate RCF and Zirconia-Silicate-RCF products are one of the most energy efficient insulation materials available so far for industrial applications which require of resistance to high-temperature, thermal stress, lightweight and also durability and flexibility. Common uses in our sectors are insulation and fire protection for high temperature devices subjects also to mechanical demanding operation: seals and linings for furnaces doors, These devices quite often work above 1200ºC, but can reach 1600-1700ºC Some material have claimed so far that could substitute the Al/Zr – RCF but none of them offers similar properties nor are widely available to a reasonable price in order to substitute the referred substances. It should be remembered that for all the Energy Intensive industries as Steel making is, energy efficiency is a must. Energy constitutes

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long use time, disadvantage for EU industry:
See reply to comment 2272 in section I
the main and more expensive input after the raw material. Therefore thermal insulation is a priority to fulfill whatever objective on both energy efficiency and climate change policies, while allowing the sector to keep the competitiveness in this parameter. Additionally internal measurements carried out by some Spanish steel companies within their plants, in spite of being carried out as "all together” (without distinguish between different kind of fibers), show levels of exposition between one and two orders of magnitude below the more often used occupational exposure reference(0.5 fibers/cm³) of respirable-sized fibers: 0.1-0.01 fibers/cm³ If in a future whatever claimed substitution is found, it should prove technical endurance, financially viability and demonstrate much lesser risk to health and safety or the environment.

| 2429 | 2013/09/23 15:26 | Company, France | Our company supports the general comments transmitted by professional associations, especially Eurofer and Eurometaux. Our company requests that RCF fibres are removed from the recommendation of ECHA for inclusion in Annex XIV of REACH. For many years, our industry has been involved in a substitution process of RCF; however, cost and technically effective solutions are not yet fully available; time is needed both for developing these solutions and implement the necessary financial resources without impairing the competitiveness of our industry. Since many RCF products are mainly used as articles, Annex XIV listing will not be an efficient mean to achieve the goal of the legislation; in our industry, technical solutions are available to control the exposure of workers and the implementation of a binding OEL at EU level would probably prove more efficient. | Regarding the description of uses: See reply to comment 2272 in section I
   
   Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I
   
   Regarding the energy efficiency: See reply to comment 2272 in section I
   
   Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I
   
   Regarding the use of the substance as an article: See reply to comment 2292 in section I
   
   Regarding your proposal of a different risk management option/other measures: See reply to comment 2169 in section I |

| 2426 | 2013/09/23 15:08 | Hijos Fco GayaFores S.L., Company, Spain | GAYAFORES is a company dedicated to the production of ceramic products with a staff of about 165 workers. We have different product lines: Double Firing Wall tiles, and Complementary pieces, single firing White body Wall and Floor tiles, but also the line of Porcelain floor tiles. We are opposed to the inclusion of Al-Si-RCF in annex XIV for the | See reply to comment 2437 in this section. |
following reasons:
- Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.
- No adequate substitutes are as yet available for these uses.
- RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2.
- The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).
- Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.
- During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).

<table>
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<tr>
<th>2421</th>
<th>2013/09/23 14:55</th>
<th>Company, Slovakia</th>
<th>U. S. Steel Kosice CONTRIBUTION TO PUBLIC CONSULTATION: (Zr) ALUMINOSILICATE REFRACTORY CERAMIC FIBRES (RCF/ASW)</th>
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<td>In relation to the ECHA’s recommendation to prioritise (Zr) Aluminosilicate RCF for their inclusion in Annex XIV of REACH Regulation, U. S. Steel Kosice, as member of EUROFER (The European Steel Association) would like to highlight the following points:</td>
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<td>Industrial use: In the steel industry, RCF/ASW are used for insulation and fire protection purposes in furnaces, heaters, lining for furnace doors and other high temperature applications (up to 1600°C). These materials are also used in a number of niche applications such as in high pressure steam mains on a blast furnace. Due to the nature of its use, only trained operators handle and work with these materials which are handled under high levels of control.</td>
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<td>Alternatives: Article 4 of Carcinogens and Mutagens Directive 2004/37/EC requires carcinogens and mutagens to be replaced by other substances which are non-dangerous or less dangerous to workers health and safety. Following these provisions, we have been in the process of replacing RCF/ASW as far as technically and economically feasible. However, for a number of applications, these</td>
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<td>Regarding the description of uses: See reply to comment 2272 in section I</td>
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<td>Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I</td>
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<td>Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I</td>
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<td>Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I</td>
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<td>Regarding the use of the substance as an article: See reply to comment 2292 in section I</td>
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<td>Regarding the priority assessment/scoring:</td>
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materials remain the best solution to date. Substitutes have been investigated but, in many cases no alternatives have been found with the same performance capable to withstand the high thermal and mechanical stresses experienced in the iron and steel production processes. The replacement of RCF/ASW for these applications would require the need to carry out more frequent maintenance programs, which would be detrimental for the competitiveness of the European Iron and Steel industry. In other cases, where alternatives can be used, it is the high price and the lack of availability from a quantitative point of view that would put the European steel industry in a commercial disadvantage in terms of competitiveness. RCF/ASW are the most energy efficient insulation materials available to date.

The steel industry is an energy intensive sector in which the energy costs represent up to 40% of total operational costs (depending on the segment of the value chain). RCF/ASW are the best solution not only to rationalise our energy use but also to meet the CO2 reduction and energy efficiency objectives envisaged in the Commission climate and energy targets for 2050. CO2 emissions reduction can be achieved through innovation, however, it is important to bear in mind that to reach these objectives a globally competitive European Steel industry is also a key element.

The above mentioned arguments are supported by a recently published study [1] on Industrial and Laboratory Furnaces and Ovens carried out for the European Commission DG Enterprise in the context of the Ecodesign Directive which states that: 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. AES HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user’s business to be uncompetitive with non-EU competitors who would not need to comply with REACH authorisation obligations. If alumino-silicate wool (ASW/RCF) could not be used, EU energy consumption would increase very significantly. (Final report can be found here: http://eco-furnace.org/documents.php ).

Risk Management: Suppliers provide information on the Safe Use to their customers securing in this way the safety instructions flow down the supply chain and that workers in the iron and steel industry handle RCF/ASW in a safe and professional way. In addition to this, workers protection is required when working with RCF/ASW. These materials are already regulated by the Chemicals Agents

See reply to comment 2444 in section I

Regarding the exemption request/coverage by other legislation:
See reply to comment 2361 in section III
Directive 98/24/EC (CAD) and the Carcinogens Mutagens Directive 2004/37/EC which, at the same time, also promotes its substitution. Finally, a number of member states have also established national OELs in order to control the exposure. The European Steel Industry believes that RCF/ASW do not need further regulation as the existing legislation and the regulatory risk management measures in place are sufficient to handle the risk and control the exposure in the workplace. Most of the RCF/ASW are used as articles in the sense of REACH: These materials are most often used in the industry in the form of articles (e.g. sheets, bricks, blankets, rolls, modules). While the whole production of RCF/ASW in the EU will be concerned by the Authorisation process, end-uses of the substance, once processed into shapes, would not be submitted to it, and those represent in our industry the vast majority of the volumes. So, to the contrary of what is said in the Draft background documents for (Zirconia) Aluminosilicate Refractory Ceramic Fibres of ECHA’s fifth Recommendation, the whole volume does not fall under Authorisation. This means that the Authorisation process is not the adequate tool to regulate the exposure situation of end-users and, is not an effective tool to manage the risk and protect the human health in industries like ours. U. S. Steel Kosice, as member of EUROFER believes that more emphasis has to be put on the improvement of the existing risk management tools rather than imposing additional burdens that will be inefficient for the purpose of protecting the human health and the environment. Scoring: The volumes used to estimate the use of RCF/ASW in the annex XV dossier and in the scoring approach are based on their manufacture and imports. The considerations about the volumes of RCF/ASW used as bulk versus articles also mean that the score attributed to the volume criteria is largely overestimated with respect to the factual amounts of RCF’s potentially concerned by Authorisation and effectively in-use in this industry. Therefore, the global score of this substance should be much lower to reflect this situation, meaning that these substances would likely not be prioritised vs. other substances. Consequences of non-availability: Installations using RCF/ASW as a thermal insulation material have a service life between 10 and 30 years, the replacement of these materials by other solutions in existing installations is not a straightforward issue and would require an important economical investment for industry. In addition to this, and as mentioned before, for many applications RCF/ASW
remain as one of the best solutions to achieve the EU climate and energy targets. 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. 

source: Ecorys Study on European Energy-Intensive Industries - The Usefulness of Estimating Sectoral price Elasticities

Besides this common position paper of steel industry, we would like to state that according to measurements performed this year there is no exposure of workers during normal operating conditions. See attached the report in Section V.

| 2417 | 2013/09/23 14:15 | Company, Spain | Ceramic tiles factory, number of employees 160. We manufacture floor and wall tiles. We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons:  
• Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.  
• No adequate substitutes are as yet available for these uses.  
• RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2.  
• The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).  
• Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.  
• During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD). | See reply to comment 2437 in this section. |
| 2413 | 2013/09/23 13:37 | Company, Spain | Brancos Ceramics is a company that manufactures klinker tiles for internal and external floorings and walls since 1949. In the company work 49 people. We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons: | See reply to comment 2437 in this section. |
I am a toxicologist and occupational hygienist working at Caesar Consult Nijmegen in The Netherlands. Currently, I am working on an article that provides an update on both the hazards and risks of fibres in the working atmosphere. The reason for this update is that the last few years several evaluations have been published on the carcinogenic properties and health risk related to fibres exposure in the working environment, including refractory ceramic fibres.

In 2010, the Health Council in The Netherlands published an update on the risks related to asbestos fibres. In 2011, the Health Council in The Netherlands, or more precise a subcommittee named DECOS, published an update on the carcinogenicity of Refractory Ceramic Fibres (RCF) as a follow up of their evaluation published in 1995. And also in 2011, the Scientific Committee on Occupational Exposure Limits (SCOEL) published an evaluation resulting in a recommendation for a Occupational Exposure limit for RCF. The recent publications from the Health Council/DECOS (2011) and SCOEL (2011) are attached/uploaded with this comment.

One of the most important findings is that both the Health Council (DECOS) in The Netherlands and the SCOEL on EU level concluded that RCF should be considered as a non/threshold carcinogen. Based on the evaluations of the Health Council, The Netherlands have adopted a occupational exposure limit value for RCF of 0.5 fibres/ml (8 hr average). SCOEL advises an occupational exposure limit for RCF that is slightly more stringent: 0.3 fibres/ml. The EU commission (DG Employment) is currently working on a so-called Binding Occupational Exposure Limit Value (BOELV) for RCF for all the EU member states.

Another relevant finding is that RCF is used in industrial settings only and that the concentrations of RCF fibres in the breathing zone of workers in these environments, both in RCF manufacturing and facilities where the RCF isolation material is used, show a strongly declining tendency since 1990. In these work environments the current exposure levels of RCF are below the occupational exposure limits that were recently proposed by DECOS and SCOEL. Only during installation and demolition of RCF containing isolation material, the exposures may exceed these values. But the use of respiratory protection will prevent these workers from health

The submitter has requested to delete this comment and submitted comment 2477 instead
It is advised to postpone the decision on inclusion of RCF in Annex XIV until the decision process in the EU on a Binding Occupational Exposure Limit Value (BOELV) for all the EU member states is finished. Postponing the decision on inclusion of RCF in Annex XIV allows a decision that is based on the latest insights on the risks of RCF rather than a decision based on outdated and incomplete hazard information.

Nijmegen, The Netherlands, 23 September 2013
Dr Joost G.M. van Rooij (toxicologist/occupational hygienist)

Attachments:
- SCOEL - Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic Fibres, SCOEL/SUM/165, September 2011.

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2409 2013/09/23 13:28  ASD, Industry or trade association, Belgium  See attachment  Regarding the description of uses: See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I

Regarding the burden of authorisation on certain industry sectors/prolong LADs See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I

Regarding the request to prolong sunset date to further develop alternatives: See reply to comment 2459 in section II

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2400 2013/09/23 12:53  Glencore Nikkelverk AS former Xstrata Nikkelverk AS,  Comments on the recommendation to include the substance in Annex XIV has been provided by Eurometaux on behalf of the metals industry in EU. As a company we would like to support the comments submitted by Eurometaux as they very well describes  No comment was provided by EUROMETAUX during this public consultation.
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<th>Author/Group</th>
<th>Message</th>
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| 2398  | 2013/09/23 | 12:47    | Company, Norway, REALONDA, S.A., Company, Spain  | Realonda’s history can be traced back to 80 years ago. During this period, the factory has adapted to the technological advances in order to offer its customers the best quality in our products, and a conscientious service. Actually we are 70 workers. Realonda produces Wall and floor ceramic tiles. We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons:  
  • Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.  
  • No adequate substitutes are as yet available for these uses.  
  • RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2.  
  • The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).  
  • Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.  
  • During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).  
  See reply to comment 2437 in this section. |
| 2394  | 2013/09/23 | 12:31    | Industry or trade association, Netherlands       | I agree with the position of CerameUnie  
  See reply to comment 2361 in this section.                                                                                                                                  |
| 2392  | 2013/09/23 | 12:22    | Confédération des Industries Céramiques de France-CICF, Trade union, France | We share the position and concerns supported by Cerame-Unie the European Ceramic Industry Association:  
  The European Ceramic Industry covers a wide range of products including abrasives, brick & roof tiles, clay pipes, wall & floor tiles, refractory products, sanitary ware, table & decorative ware, technical ceramics. It accounts for more than 200.000 direct employments and a production value of € 25 billion within the EU in 2012.  
  Use (Zirconia) Aluminosilicate RCF based articles are used in ceramic installations as insulating material in the kilns (furnaces). During kiln  
  Please see response to comment 2489.                                                                                                                                                                                                                              |
operation, exposure to workers is insignificant. The vast majority of kilns used in the ceramic industry operate continuously. The kiln is a closed 'tunnel' with a pre/heating and cooling zone and a firing zone in the middle. The highest temperatures can be found in this firing zone. The ceramic products to be fired pass through rollers on the kiln or are placed on a kiln car on rails. For reasons of energy efficiency, these kilns operate continuously, the ceramic products move in and out but the kiln walls remain unreachable by humans. Therefore exposure to RCF inside the kiln is strictly limited to defined moments during inspection/maintenance and demolition. Before entering a kiln there is a defined time where the burners are stopped and the kiln can cool down. After maintenance the kiln needs to be heated again. This heat-up and cool down can take several hours to days. Due to the specific industrial nature of these activities this is a well-defined and well-prepared activity, carried out by trained operators under highly controlled conditions. In the ceramic industry, a typical inspection/maintenance would take place once a year or less. There are also kilns which are not shut down once in almost 30 years. The (zirconia) aluminosilicate RCF is 'used' in the ceramic industry in the sense that articles consisting of these fibres are a part of the kiln furniture i.e. they cover the walls and/or roof of the kiln (furnace). These articles can be sheets, bricks, blankets, rolls, modules. The ceramic industry is a customer for these articles, not a downstream user of the substances according to the REACH definition.

Substitution and alternatives
The (zirconia) aluminosilicate RCF which are currently described on the candidate list and which are currently proposed for authorisation, do not cover chromia aluminosilicate RCF. These chromia based RCF are covered by the same case number as the two existing dossiers on RCF and hence have the same hazard profile. These three types of RCF are intersubstitutable but only two types are added to the candidate list. This is a consequence of the wrong substance ID which has already been highlighted in comments made on the candidate listing in 2009 and 2011. Substitution of RCF by substances with a different hazard profile has taken place where possible, however, there are a number of high temperature uses where this is not the case. Substitution is a requirement under the Carcinogens and Mutagens Directive. Because of the high investment costs and long lifetime of the kiln any substitution possibilities are well considered and the choice of (zirconia) aluminosilicate RCF is used only where no alternatives can

In addition, regarding the reference in your comment to Directive 2001/41/EC, Al-RCF is restricted in accordance with entry 28 of Annex XVII of the REACH Regulation.

Pursuant to entry 28 of Annex XVII of REACH Regulation substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP Regulation) classified as carcinogen category 1A or 1B (Table 3.1), shall not be placed on the market, or used, as substances, as constituents of other substances or in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than either the relevant specific concentration limit specified in Part 3 of Annex VI to the CLP Regulation, or the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of the CLP Regulation.

Al-RCF was identified as a Substance of Very High Concern (SVHC) according to Article 57 (a) REACH as it is classified in Annex VI, Part 3, Table 3.1 of CLP Regulation as carcinogen 1B, and was therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011 (consolidated by ED/95/2012). Table 3.1 in Part 3 of Annex VI to CLP Regulation does not set out a specific concentration limit; thus, the concentration limit specified in Directive 1999/45/EC applies (i.e. ≥0.1%).

Article 56(6)(b) of REACH provides that the authorisation requirement does not apply to the use of substances when they are present in mixtures below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to the CLP Regulation.

Accordingly, the concentration limits specified for Al-RCF in Annex XVII of REACH are in fact the same as
deliver the same performance for the particular technical application. We also refer to the study on Industrial and Laboratory Furnaces and Ovens carried out for the European Commission DG Enterprise in the context of the Ecodesign Directive which states that: 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. AES HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user's business to be uncompetitive with non-EU competitors who would not need to comply with REACH authorisation obligations. If alumino-silicate wool (ASW/RCF) could not be used, EU energy consumption would increase very significantly. The final report can be found here: http://eco-furnace.org/documents.php).

Exemptions
The use of RCF is already well regulated. At first, a restriction applies under Directive 2001/41/EC, limiting the use to industrial applications only. Furthermore, as regards industrial applications, the risk is properly controlled. National OELs (occupational emission limit) exist for RCF and a European binding OEL for RCF under the Carcinogens and Mutagens Directive is currently under discussion as part of the overall review of this Directive. A binding OEL for RCF is expected by the end of 2014, i.e. before authorisation would start. We therefore believe the criteria mentioned in REACH article 58 (2) are met as concerns the use of (zirconia) aluminosilicate RCF in the production of articles used for the ceramic industry. In addition, this binding OEL will be applicable throughout the supply chain and cover all types of RCF covered by CAS number (142844-00-6) and EU number (604-314-4). As mentioned before, the current two dossiers put forward for prioritisation do not cover this full scope.

Cerame-Unie welcomes the SVHC-Roadmap which was published in 2013 and advocates a RMO (Risk Management Options) assessment before substances are proposed for the candidate list. As such assessment was not carried out in 2009 or 2011, we strongly recommend a proper RMO assessment for these materials before any further action is taken in respect of authorisation. An authorization process will not bring an added-value in terms of environment or human health but will have a negative impact on the energy efficiency of the ceramic industry and hence the competitiveness of this industry. It is therefore in conflict with the aim of REACH to enhance competitiveness and the aim of

the concentration limits referred to in Article 56(6)(b) REACH. Therefore, the use of Al-RCF below the concentration limits set out in Annex XVII of REACH does not need to be subject to an exemption from authorisation.
Review periods
The lifetime of ceramic kilns using (zirconia) aluminosilicate RCF is up to 30 years. Due to the high investment costs and the fact that most kilns are individually custom designed it is not possible to change to a different (and possibly less energy efficient) kiln before the kiln has been written off.

| Date       | Time   | Company, Liechtenstein | The international competitors of Ivoclar Vivadent AG likewise use AlSi - RCF products as thermal insulation in their ceramic and press furnaces. Our competitors have also found that the use of alternative products is associated with unjustifiable efforts, costs and compromises with regard to technical properties and performance. Furthermore, a short service life represents a certain occupational safety hazard for the end customer. The fabrication, procurement and processing of alternative thermal insulation materials is considerably more expensive than that of the products already in use. At the same time, their service life is shorter, which negatively influences occupational health and safety aspects. Furthermore, our customers would be faced with the additional cost of having to replace the insulation components during the technical lifetime of their press and ceramic furnaces. Changes in the thermal insulation and slow failure of the furnace can lead to process changes which remain undetected, but cause invisible damage to the end product. Dental restorations made by dental lab technicians are the end products that come out of our press and ceramic furnaces. These restorations are ultimately placed in a patient’s mouth by a dentist. Ivoclar Vivadent AG consistently monitors the developments of manufacturers who supply thermal insulation materials that are not classified as AlSi - RCF fibres. To date, however, no alternative material, which entirely meets our technical and economical requirements, has been identified. The occupational health and safety measures that apply to the handling of thermal insulation materials and the reduction of possible risks (occupational health and safety) remain the same, irrespective of the fire-proof product used, in order to protect the health of employees and end users. The health and safety of internal and external staff and customers is of major importance to Ivoclar Vivadent. For this purpose, the company adheres to the described measures and the existing regulations. Currently a European wide binding occupational exposure limit value (BOELV) specifically for aluminosilicate RCF is in discussion on European Commission-Level (DG-Employment). Nevertheless, the company is required to maintain a competitive edge at an |

| 2386 | 2013/09/23 11:48 | Company, Liechtenstein | The international competitors of Ivoclar Vivadent AG likewise use AlSi - RCF products as thermal insulation in their ceramic and press furnaces. Our competitors have also found that the use of alternative products is associated with unjustifiable efforts, costs and compromises with regard to technical properties and performance. Furthermore, a short service life represents a certain occupational safety hazard for the end customer. The fabrication, procurement and processing of alternative thermal insulation materials is considerably more expensive than that of the products already in use. At the same time, their service life is shorter, which negatively influences occupational health and safety aspects. Furthermore, our customers would be faced with the additional cost of having to replace the insulation components during the technical lifetime of their press and ceramic furnaces. Changes in the thermal insulation and slow failure of the furnace can lead to process changes which remain undetected, but cause invisible damage to the end product. Dental restorations made by dental lab technicians are the end products that come out of our press and ceramic furnaces. These restorations are ultimately placed in a patient’s mouth by a dentist. Ivoclar Vivadent AG consistently monitors the developments of manufacturers who supply thermal insulation materials that are not classified as AlSi - RCF fibres. To date, however, no alternative material, which entirely meets our technical and economical requirements, has been identified. The occupational health and safety measures that apply to the handling of thermal insulation materials and the reduction of possible risks (occupational health and safety) remain the same, irrespective of the fire-proof product used, in order to protect the health of employees and end users. The health and safety of internal and external staff and customers is of major importance to Ivoclar Vivadent. For this purpose, the company adheres to the described measures and the existing regulations. Currently a European wide binding occupational exposure limit value (BOELV) specifically for aluminosilicate RCF is in discussion on European Commission-Level (DG-Employment). Nevertheless, the company is required to maintain a competitive edge at an |

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the exemption request/coverage by other legislation:
See reply to comment 2361 in section III
Fedustria is the federation of the Belgian textile, wood and furniture industries and represents consequently the textile companies using Refractory Ceramic Fibres. These companies are specialized in making high temperature resistant products. As the identity described in the annex XV is not straightforward and confusing, Zr-RCF and also Al-RCF can so far not be recommended for inclusion in annex XIV. It is unclear which types of RCF are aimed for inclusion in the Authorisation List, as some can be considered as articles and others as substances. Without a clear definition there will be a lot of confusion both for producers and downstream users whether the RCF they produce/use should be authorized. Moreover the draft recommendation for the inclusion of RCF in the Authorisation List seems to be arbitrary as not all types of RCF are covered. So is Chrome RCF not yet included in the candidate list and hence not yet recommended for authorisation. In other words 'identical' substances with the same properties are treated in a different way by ECHA. By doing so ECHA is distorting the market and hence creates unfair competition. This is totally in conflict with article 55 of REACH, aiming to ensure a.o. the good functioning of the internal market. As industry we urge that a same approach is being taken for all RCF at the same time. Consequently we are of the opinion that the current dossiers are not complete. Zr-RCF and Al-RCF can at this very moment not be recommended for inclusion in annex XIV. We suggest that for consistency reason all RCF should be combined in one dossier and be submitted again for a now comprehensive RMO-analysis.

Regarding the unclear substance identity:
See reply to comment 2272 in section I

Regarding the status of RCFs as substance or article:
See reply to comment 2292 in section I

Regarding the inter-substitutability with RCFs not identified as SVHC:
See reply to comment 2272 in section I

Regarding your request to carry out a risk management option (RMO) analysis:
See reply to comment 2169 in section I

RHI is referring to "Cerame-Unie comments on the ECHA recommendation to prioritise (Zr) Aluminosilicate RCF for their inclusion in Annex XIV of REACH Regulation"

See reply to comment 2361 in this section.

Dear,

As a refractory company, Al-RCF’s are used as part of solutions for our customers in various segments such as iron, steel, foundry, power and incineration. For applications where alternatives are possible, we have made transitions to other solutions. However, there are certain applications in which there is no alternative to the use of such fibers. This relates on the combination of high temperatures with density/thermal conductivity.

We therefore support the position and concerns raised by Cerame-Unie;
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<th>Organization</th>
<th>Message</th>
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<tbody>
<tr>
<td>2373</td>
<td>2013/09/23 04:32</td>
<td>Refractory Ceramic Fiber Association, Industry or trade association, Japan</td>
<td>Refractory Ceramic Fiber Association (RCFA) has the pleasure of providing you with our comments, as per attached file.</td>
</tr>
</tbody>
</table>

**Regarding the use of the substance as an article:**
See reply to comment 2292 in section I

**Regarding the unclear substance identity:**
See reply to comment 2272 in section I

**Regarding the fact that the dossier has been changed during the commenting time:**
The draft background documents for the two RCFs were slightly revised (31 July 2013) after the start of public consultation (24 June 2013) which ended on the 23 September 2013. The revisions were made based on requests to ECHA by an industry association and an academic institution. The amendments did not concern the parts of the document directly relevant to the recommendation. As stated in the amended documents, the revisions regarded a clarification in the wording of one sentence in the section "manufacture and releases from manufacture" and the removal of a brand name in the section "availability of information on alternatives". ECHA decided to make these changes early during the public consultation, in order to avoid any potential misunderstandings.

**Regarding the priority assessment/scoring:**
See reply to comment 2444 in section I

**Regarding the low or controlled exposure/risk of RCFs:**
See reply to comment 2272 in section I

**Regarding the non-availability of alternatives/information on alternatives in background document:**
See reply to comment 2272 in section I

**Regarding your proposal of a different risk**
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<th>ID</th>
<th>Date/Time</th>
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<th>Comment, Key Points</th>
<th>Management Option/Other Measures</th>
</tr>
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</table>
| 2366 | 2013/09/22 23:47 | Deutsche Gesellschaft für Arbeitshygiene DGAH, National NGO, Germany | First we would like to note, that we have recognized a changed Dossier within the time for comments. Second the both RCF Dossiers are about a article following the definition given in REACh. The listing in the Annex CLP is misleading. The justification to deal with listed compounds even if they are not compounds but Articles leads to problems. At first this proposal, submitted by the German Federal Institute for Occupational Safety and health indicate that Refractory ceramic Fibers is a substance. As defined in the REACh regulation EG 1907/2006 a substance means: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition; The chemicals in Refractory ceramic fibers are obtained from nature and can be found for e.g. as kaolin in soil. The given Substance identification can be applied to a big variety of natural soil compounds. But the described ceramic fibers are a man mad article not a substance, even if this roughly described fibers are listed in Annex VI EG 67/548. If this illogical approach would be applied to other products e.g. ceramic glass cooktop can be also judged as substance. But more important is that the chapter uses and release from use is not covering the SHEcan project report May 2011 clearly demonstrate the controlled risk using such RCF fibers in finalized articles. The listed Alternatives are not appllicable for really high temperature applications. So, without proofen alternatives the dossier is lacking on these Details. | Regarding the fact that the dossier has been changed during the commenting time: See reply to comment 2373 in section I  
Regarding the status of RCFs as substance or article: See reply to comment 2292 in section I  
Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I  
Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I |
| 2363 | 2013/09/22 19:52 | Individual, Germany | Missing the target of the REACh – Authorisation! Thank you ECHA for supporting the business of the non-European Al-RCF manufacturer and Al-RCF-importers. More than 95% of the used Al-RCF by downstream users are articles (blankets, modules,....) and the import of articles does not require | Regarding the use of the substance as an article: See reply to comment 2292 in section I  
Regarding addressing imported articles: |
any authorisation. Therefore, the approach ECHA does not meet the target of an authorisation which is the substitution of the substance!

Inobservance of REACH Art. 58 (2)!
AI-RCF are only used by professional and industrial users under well controlled conditions. Most European countries have adopted a workplace limit value for dust of RCF. SCOEL recommended 0.3 f/ml as OEL (May 2011), and a binding occupational exposure limit value (BOELV) is currently under discussion at EU Commission level and will be implemented in Annex III of Directive 2004/37/EC.

| 2361 | 2013/09/21 13:33 | Cerame-Unie - The European Ceramic Industry Association, Industry or trade association, Belgium | The European Ceramic Industry, represented by Cerame-Unie, covers a wide range of products including abrasives, brick & roof tiles, clay pipes, wall & floor tiles, refractory products, sanitary ware, table & decorative ware, technical ceramics. It accounts for more than 200,000 direct employments and a production value of € 25 billion within the EU in 2012. Comments on Use Aluminosilicate RCF based articles are used in ceramic installations as insulating material in the kilns (furnaces). During kiln operation, exposure to workers is insignificant. The vast majority of kilns used in the ceramic industry operate continuously. The kiln is a closed 'tunnel' with a pre-heating and cooling zone and a firing zone in the middle. The highest temperatures can be found in this firing zone. The ceramic products to be fired pass through rollers on the kiln or are placed on a kiln car on rails. For reasons of energy efficiency, these kilns operate continuously, the ceramic products move in and out but the kiln walls remain unreachable by humans. Therefore exposure to RCF inside the kiln is strictly limited to defined moments during inspection/maintenance and demolition. Before entering a kiln there is a defined time where the burners are stopped and the kiln can cool down. After maintenance the kiln needs to be heated again. This heat-up and cool down can take several hours to days. Due to the specific industrial nature of these activities this is a well-defined and well-prepared activity, carried out by trained operators under highly controlled conditions. In the ceramic industry, a typical inspection/maintenence would take place once a year or less. There are also kilns which are not shut down once in almost 30 years. The aluminosilicate RCF is 'used' in the ceramic industry in the sense that articles consisting of these fibres are a part of the kiln furniture i.e. they cover the walls and/or roof of the kiln (furnace). These articles can be sheets, bricks, blankets, rolls, modules. The ceramic industry is a customer for these articles, not a downstream user of | See reply to comment 2272 in section I

Regarding the description of uses: See reply to comment 2272 in section I
Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I
Regarding the use of the substance as an article: See reply to comment 2292 in section I
Regarding the inter-substitutability with RCFs not identified as SVHC: See reply to comment 2272 in section I
Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I
the substances according to the REACH definition.

**Substitution and alternatives**

The aluminosilicate RCF which are currently described on the candidate list and which are currently proposed for authorisation, do not cover chromia aluminosilicate RCF. These chromia based RCF are covered by the same CAS number as the two existing dossiers on RCF and hence have the same hazard profile. These three types of RCF are inter substitutable but only two types are added to the candidate list. This is a consequence of the wrong substance ID which has already been highlighted in comments made on the candidate listing in 2009 and 2011.

Substitution of RCF by substances with a different hazard profile has taken place where possible, however, there are a number of high temperature uses where this is not the case. Substitution is a requirement under the Carcinogens and Mutagens Directive. Because of the high investment costs and long lifetime of the kiln any substitution possibilities are well considered and the choice for RCF is made only where no alternatives can deliver the same performance for the particular technical application.

We also refer to the study on Industrial and Laboratory Furnaces and Ovens carried out for the European Commission DG Enterprise in the context of the Ecodesign Directive which states that: 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. AES HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user’s business to be uncompetitive with non-EU competitors who would not need to comply with REACH authorisation obligations. If alumino-silicate wool (ASW/RCF) could not be used, EU energy consumption would increase very significantly. The final report can be found here: [http://eco-furnace.org/documents.php](http://eco-furnace.org/documents.php).

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<th>2358</th>
<th>2013/09/20 22:32</th>
<th>Carbolite Limited, Company, United Kingdom</th>
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| 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. 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. Because there are no direct alternative materials we would either have to use AES materials which would reduce the thermal efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I
| Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I |
specification of the products and have higher costs, or use PCW material that are significantly more expensive. These redeveloped products would be less competitive compared with manufacturers outside the EU who would continue to use these RCF materials for that market place. Article 55 – states that “alternative have to encompass three kinds of dimensions: i) risks as well as ii) technical and iii) economic feasibility of alternatives”. The alternative materials are not direct replacement for both technical and economic feasibility.

There are already occupational exposure limits for these RCF materials that are used to control the use and applications of these materials in the workplace. Because existing regulation are already in place the risks are being properly controlled. Article 58(2) states that if existing specific Community legislation is in place then uses can be exempt from authorization. The legislation is going to be further enhanced in Europe; discussions are on-going within Europe regarding binding occupational exposure limits (BOEL), which is under review by the EC.

It does not make sense that these RCF materials are included in the REACH regulations. Please check the validity of these RCF being classified as a category 1b carcinogen as there does not appear to be evidence to justify this. I was personally involved in discussions during the creation of a study commissioned by the EC where this classification was shown to be in doubt. The report is titled “Sustainable Industrial Policy – Building on the Eco-design Directive – Energy-Using Products Group Analysis / 2, Lot 4: Industrial and Laboratory Furnaces and Ovens – Tasks 1 – 7 – Draft Report” (Client reference ENTR-2009-35 Contract S12.549003). In section 4.3.1 of that report it includes a section on these RCF materials. The report discusses this classification and makes the statement “The toxicity classification of RCF is outside the scope of this study but as its classification could directly impact on the energy consumed by EU furnaces it is recommended that the available toxicity evidence is re-evaluated.” That section of the report goes on to discuss energy consumption and competitiveness of businesses in the EU saying: “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. AES HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user’s business to be uncompetitive with non-EU
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<th>Company, Poland</th>
<th>Message</th>
<th>Other Information</th>
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<tr>
<td>2351</td>
<td>2013/09/20 19:32</td>
<td>Company, Poland</td>
<td>I represent investment casting foundry producing mostly for aerospace turbine engines. In investment casting process we use Aluminosilicate Refractory Ceramic Fibres for insulation of shells before preheat and pouring. Al-RCF is one of our key material for production process, working in preheat temperature close to 1300 C degrees. Knowing about the restriction for this material we have started few years ago cooperation with our suppliers to substitute Al-RCF by other, more friendly refractory materials. We made many trials, and unfortunately were not able to develop sufficient substitute for 1300 C degrees. That's why we would suggest to postpone inclusion of it in Appendix XIV by 3 years to get time to develop substitute. If Al-RCF will go in Appendix XIV too fast we wouldn't have time to find other solutions and would stop production of equiax castings for aerospace turbine blades and will stop engines build by our customers (i.e. for Airbus A320, Airbus A380).</td>
<td>Regarding the description of uses: See reply to comment 2272 in section I. Regarding the request to prolong sunset date to further develop alternatives: See reply to comment 2459 in section II. Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I.</td>
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<td>2348</td>
<td>2013/09/20 19:14</td>
<td>Confindustria Ceramica, Industry or trade association, Italy</td>
<td>Confindustria Ceramica fully support the position express by his european federation: CerameUnie.</td>
<td>See reply to comment 2361 in this section. Article 58(2) exemption response Please see response to comment 2489 and comment 2392, this section. Regarding the review periods: See reply to comment 2444 in section IV.</td>
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<tr>
<td>2335</td>
<td>2013/09/20 15:55</td>
<td>ADS Group Limited, Industry or trade association, United Kingdom</td>
<td>The aerospace industry is committed to protecting its employees, passengers and the environment. With approximately 93,000 scheduled commercial flights per day world-wide, our industry is held to the highest standards by independent governmental regulators. Our industry is not only monitored externally by these regulators, on a global basis, but internally, by experience/data established policies and procedures to ensure safe, reliable and technically excellent products. Our industry continues to research eco-friendly materials and supports the general intent of REACH with regards to phasing out substances of very high concern. In the case of aluminosilicate and zirconia aluminosilicate refractory ceramic fibres (henceforth referred to as RCF), which are used to provide thermal insulation, electrical insulation, acoustic absorption and composite reinforcement in the aerospace industry, we feel it is important to highlight the complexity of aerospace products and the</td>
<td>Regarding the description of uses: See reply to comment 2272 in section I. Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I. Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I.</td>
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effects of restricting substances essential to meeting our regulatory obligations. The Aerospace industry believes these restrictions will seriously impact airline operations as current alternatives are technically inferior. We must continue to meet the stringent aviation safety requirements as defined by the European Aviation Safety Agency (EASA) and other airworthiness authorities. 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. Our industry is concerned that the resulting constraints of authorisation will interrupt manufacturing, operations and will severely impact the Maintenance, Repair and Overhaul sector, all resulting in disruption risks to aerospace and defence products and systems. While many RCF-containing products are used in other industries, the technical requirements of the aerospace and defence industry are set by EASA and equivalent military regulators. RCF products provide lifetime thermal and electrical insulation to components that are inaccessible after assembly, but nevertheless must continue to function reliably. Additionally, RCF imparts strength and toughness as reinforcement to composite materials yielding the required reliability for structural components. ADS therefore urges the EU and Member States decision makers to support the aviation industry by re/considering the position of RCF products in relation to the Annex XIV.

2332 2013/09/20 15:43 Refratechnik Cement GmbH, Company, Germany Refratechnik Cement GmbH is a global manufacturer of all kind of refractory materials (bricks and castables) used in various industry sectors (manly cement and lime) since more than 60 years. In addition we are offering "turnkey" installations with high investment cost including our refractories as well as supplied products from high temperature insulation wools from other manufacturers. In the overall concept of our turnkey installations there is a need for (zirconia-) Alumino silicate RCF to enable general plant safety including production reliability and worker safety. High temperature insulation wools are used as filling materials for construction-conditioned expansion joints. These expansion joints are part of the construction to give space to the refractory material at thermal or thermo-chemical expansion. Missing or insufficient expansion joints, lead to mechanical overloading of the refractory construction and, as consequence, the steel body of the facility. This

Regarding the description of uses: See reply to comment 2272 in section I

Regarding the unclear substance identity: See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I
effect also aroused in case that cement dust moves into the expansion joints, caused by insufficient resilience of the high temperature insulation. The resilience property of expansion joints filling materials is the main functional request. Finally this thermal or thermo-chemical expansion destroys the dense refractory inside the body, as well the construction framework of the facility. As consequence the plant operators face high cost on loss of production (~ 250,000 €/day) and repair work. Based on that, the high temperature insulation material has to stay process temperatures up to 1400 °C and serious chemical attack from process gases in the kiln atmosphere. (Zirconia-) Alumino silicate fibers, whether as articles like loose wool, blanket or any other kind of shape, are the best available materials to prevent these attacks. AES-wools that have been tested since many years were not durable under those conditions. Facing just thermal limits AES-wools can be used at a maximum service temperature of 900-1000°C, but it has to be noticed that chemical corrosion and physical erosion further limit the use of AES even below these temperatures. Fundamental for our global activities: The documentation used in this public consultation didn’t use CAS numbers for substance identification. Using CAS numbers is an essential support for users to identify whether the material they use is within the inclusion in the authorisation list or not.

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<th>Text</th>
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<tr>
<td>2327</td>
<td>2013/09/20</td>
<td>LINDE</td>
<td>LINDE refers to the input also made from EIGA at 15.9.2013 LINDE also challenges the scoring for wide-dispersiveness of uses and does not agree that the highest score possible of 9 is correct. This score rates all sites with the highest rating for exposure. This evaluation does not correspond to the data from the Annex XV report summarised in the ECHA prioritisation document. The rating should be weighted taking into account the ratios of the two groups of workers and as explained by EIGA should only be 13 instead of 19. See reply to comment 2216 in this section. <strong>Regarding the priority assessment/scoring:</strong> See reply to comment 2444 in section I</td>
<td></td>
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<tr>
<td>2320</td>
<td>2013/09/20</td>
<td>Salzgitter Flachstahl GmbH, Company, Germany</td>
<td>see attached dokument</td>
<td><strong>Regarding the description of uses:</strong> See reply to comment 2272 in section I <strong>Regarding the non-availability of alternatives/information on alternatives in background document:</strong> See reply to comment 2272 in section I <strong>Regarding the low or controlled exposure/risk of RCFs:</strong></td>
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| Date       | Time     | Wirtschaftskammer Österreich (WKÖ), Other contributor, Austria | Please, see document attached. | Regarding the status of RCFs as substance or article:  
See reply to comment 2292 in section I  
Regarding the hazard property of RCFs:  
Your point in regard to the hazardous inherent properties of RCFs is not relevant for this part of the authorisation process, as the identification of the substance as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for this substance and listed in Annex VI of the CLP Regulation (Regulation (EC) No 1272/2008). As the cited harmonised classification is applicable law at present, it will not be questioned or discussed in the context of this recommendation.  
According to Article 37(6) of the CLP Regulation manufactures, importers and downstream users who have new information which may lead to a change of the harmonized classification and labelling elements of a substance in Annex VI shall submit a proposal to the competent authority in one of the Member States in which the substance is placed on the market. The MSCA will then decide if it is appropriate to prepare a CLH dossier and submit it to the Agency in order to review/revise the existing harmonised classification.  
Regarding the low or controlled exposure/risk of RCFs:  
See reply to comment 2272 in section I  
Regarding the non-availability of alternatives/information on alternatives in background document:  
See reply to comment 2272 in section I  
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:  
See reply to comment 2272 in section I |
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<th>ID</th>
<th>Date</th>
<th>Commenter</th>
<th>Text</th>
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<tbody>
<tr>
<td>2308</td>
<td>2013/09/20 12:25 centrotherm photovoltaics AG, Company, Germany</td>
<td>Centrotherm is an equipment manufacturer for the semiconductor and photovoltaics industry, supplying primarily furnace tools for semiconductor processing and photovoltaic cell manufacturing in the temperature range from 300°C to 1350 °C. We use Al-RCF for the linings of our furnace tubes and for the thermal sealing of gaps. The long term stability at high temperatures (&gt; 1000°C), in oxidizing ambient and the extremely low thermal conductivity enable us to build reliable and compact systems. The low thermal mass of the Al-RCF linings is a key factor for process performance, enabling processes with high thermal ramp rates and temperature uniformity. For the production of our products we use approximately 0.5 tonnes per year. Since before 1980 we use Al-RCF in our production without any detectable negative effects on the health of our employees. Consequences for the competitiveness of our major products: We offer our products on a highly competitive international market, were 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 materials like AES fibres. Roughly 30% of the high temperature applications, our customers run currently on our systems would no longer be possible. As our customers are used to run a mix of higher and lower temperature processes on the same system, our loss in market share would be significantly higher than 30%. The ban of ZR-RCF would probably increase our production cost, lead to a decrease in our market share and to location disadvantages against our non-EU competitors.</td>
<td>Regarding your proposal of a different risk management option/other measures: See reply to comment 2169 in section I</td>
</tr>
<tr>
<td>2306</td>
<td>2013/09/20 Bundesverband</td>
<td>The German Fine Ceramic Industry covers a wide range of products including table &amp; decorative ware, technical ceramics, sanitary ware,</td>
<td>Regarding the description of uses: See reply to comment 2272 in section I</td>
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</table>
Keramische Industrie e.V., Industry or trade association, Germany

abrasives. It accounts for more than 16,000 direct employments and a production value of about € 2 billion within Germany in 2012. We are using RCF for insulating kilns (see section use) with the intention to increase the energy efficiency. As long as in most cases no equivalent substitutes are available, we are against the inclusion of RCF in Annex XIV.

Company, United Kingdom

Given aerospace/defence applications & safety-critical properties of the RCF material, should RCF material progress further within REACH legislation, we kindly request that the EC & ECHA prioritise RCF materials for inclusion onto Annex XVII (Restrictions) with derogations for aerospace & defence applications with particular emphasis on the airworthiness & safety-critical implications (EASA being the EU Regulatory Authority for airworthy articles) of using untested or unvalidated alternatives on aerospace/defence platforms requiring operational functionality in the field over a lifespan, in some cases, of over 30 years minimum.

Deutsche Edelstahlwerke GmbH, Company, Germany

The production of substances and products in our company is mainly based on high-temperature processes. In our plants, such as steel works, rolling mills and forging, refractory and insulation materials must be used, which make it possible to handle these processes safe and energy efficient. These materials are one of the best solution for many industrial insulation needs to achieve, at a reasonable cost, the optimum process conditions to improve product yield, environmental and safety performance and energy efficiency in the steel industry.

In addition to a number of other insulating materials at temperatures up to 1200 ° C, the we use aluminum silicate wool in the temperature range above 1200 ° C. As a lightweight and flexible materials these contribute to a significant energy savings, which is not possible with other materials. This applies particularly for furnaces in the range of hot-rolling processes that require a low density of the insulation materials used. The density also has a direct influence on the static, to the dimensions of the equipment and the physical structure of the foundations.

An additional advantage of alumina silicate wool is the low heat capacity and high thermal shock resistance, which enables a flexible application even with varying operation cycles. Under production conditions that are characterized by many successive heating and cooling processes, the expansion and shrinkage associated with the
heating cooling and would lead to the destruction of alternative massive refractory bricks. Alternative materials have been investigated, but so far no suitable material has been found, corresponding to the thermal and mechanical requirements. With poorer insulation and higher energy consumption such materials may lead in addition to significantly reduced maintenance intervals associated with shutdowns and correspondingly higher costs with increased environmental pollution, energy consumption and CO2 emissions. In the steel industry the protection of workers is of first priority, regardless if it is related to conventional refractory bricks, alumina silicate wool or other fiber materials. Aluminum silicate wool products are used under controlled conditions. Alumina silicate wools are not made for private end use, only for industrial high temperature processes. Reports of occupational diseases related to aluminum silicate wool products are not available.

<table>
<thead>
<tr>
<th>2300</th>
<th>2013/09/20 11:21</th>
<th>European Aluminium Association AISBL, Industry or trade association, Belgium</th>
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<tr>
<td></td>
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<td>- Alumino silicate Refractory Ceramic Fibres (Al-RCF) are used in the aluminum industry mainly as insulating material in melting and holding furnaces, in particular as lining material for furnace walls, roofs and doors. They are also used during the metal transfer and casting operations in specific formats (e.g. launders, moulds, cone fibers and casting tips). These fibers are also used in primary aluminium smelters as insulating material in relining of cathodes and in furnaces used to bake anodes. In addition they are used as lining insulating material inside the pre-heating furnaces for rolling and extrusion operations and in the refining process inside the decoater or the swarf dryer.</td>
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<td></td>
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<td>- The risks for human health associated with RCF are well known and the appropriate countermeasures are in place. In many cases they are used as lining material in closed systems that do not require frequent maintenance intervention (e.g. every 5-7 years).</td>
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<td>- Concerning the alternative:  • No valid alternative has been found for temperatures above 900°C. AES materials are stable at temperatures below 900°C and in some cases they are used in the aluminum sector  • New materials like low cement castable may be used in the future but only few tests are available. Because of their characteristics (i.e. heavy material) they require an upgrade and a reengineering of the current system  • There is no clear way to distinguish Alumino silicate RCF from Zirconia-Alumino silicate RCF and this can create confusion. In fact, both substances were included in the same registration dossier</td>
</tr>
</tbody>
</table>

**Regarding the description of uses:**
See reply to comment 2272 in section I

**Regarding the low or controlled exposure/risk of RCFs:**
See reply to comment 2272 in section I

**Regarding the non-availability of alternatives/information on alternatives in background document:**
See reply to comment 2272 in section I

**Regarding the unclear substance identity:**
See reply to comment 2272 in section I
under REACH
Based on the above information, EAA does not support the prioritization of these substances at this stage.

<table>
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<tr>
<th>2297</th>
<th>2013/09/20 10:59</th>
<th>Company, Germany</th>
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We fully support the comment made by the European Steel Association (EUROFER) and the Verein Deutscher Eisenhüttenleute (VDEh) related to the Aluminosilicate Refractory Ceramic Fibres (Al-RCF)

Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are one of the best solutions for much industrial insulation. Their use is necessary at temperatures above 1000 °C, especially for some niche applications in the iron and steel industry where no alternative exists. A substitution of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) has been done for applications where possible, but substitution is not possible for all applications. Due not only to high temperatures resistance but also chemical and physical conditions in the high temperature applications, important parameters have to be considered in choosing the optimal materials for a specific application.

Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are still allowed optimum process conditions to improve product yield, environmental and safety performance as well as energy efficiency. With the use of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) in high-temperature applications, energy savings can be achieved which also substantially reduce the CO2 emissions in response to the European call for more resource and energy efficiency in the user industries, e.g. iron and steel.

Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are used under controlled conditions (e.g. inside of heaters or furnaces, as linings of furnace doors (or sealings)). The handling of the Aluminosilicate Refractory Ceramic Fibres (Al-RCF) is done under clear defined risk management.

Solely well instructed and trained workers handle Aluminosilicate Refractory Ceramic Fibres (Al-RCF) during maintenance work. Personal protective equipment and protective measures under controlled conditions enable a safe handling.

In conclusion, a restriction to the application of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) would lean to negative consequences for the energy efficiency in Europe and also on the

See reply to comments 2130 and 2143 in this section.

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document: Regarding the energy efficiency:
See reply to comment 2272 in section I
safe insulation for many applications. Hence, the restriction of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) would force the industry to use insufficiently proved or not appropriate substitutes which bear a risk of leakage and could therefore be a danger to the environment and human health.

| 2292 | 2013/09/20 10:29 | CEMBUREAU, Industry or trade association, Belgium | See attachment | **Regarding the description of uses:**
See reply to comment 2272 in section I

**Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:**
See reply to comment 2272 in section I

**Regarding the perception of authorisation being a ban of the substance:**
Please note that use of RCFs will still be possible in the future, i.e. after the sunset date, provided a use-specific and applicant-specific authorisation is applied for and granted.

**Regarding the non-availability of alternatives/information on alternatives in background document:**
See reply to comment 2272 in section I

**Regarding the low or controlled exposure/risk of RCFs:**
See reply to comment 2272 in section I

**Regarding the hazard property of RCFs:**
See reply to comment 2314 in section I

**Regarding the unclear substance identity:**
See reply to comment 2272 in section I

**Regarding the status of RCFs as substance or article:**
Please note that substance identity aspects have been considered in the context of inclusion of the substance in the Candidate List and they are not relevant in the current prioritisation phase. Similar comments on substance identity of RCFs have been
addressed by the dossier submitter during the public consultation of identifying the substance as SVHC.

Furthermore, RCF fibres have been included in Annex VI of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) as substance. REACH and CLP follow the same substance definition, consequently RCF fibres are also understood as substances under REACH.

Nevertheless, as ECHA feels that it is important to make clear which substances are covered by the entry in the Candidate List and which therefore require authorisation in case RCFs are included in Annex XIV, further details are provided here.

The dimension conditions outlined in the substance identity of the RCF entries on the Candidate List refer only to the inhalable fraction of the fibres, which is the responsible for causing the related hazard. These conditions are taken over from the corresponding entry in Annex VI of the CLP regulation.

According to the available information (SVHC Annex XV dossier, SVHC comments, Annex XIV comments), only part of the manufactured fibres in each batch fulfil these dimension conditions (shape). According to information provided in the comments received, this fraction is << 50 % but likely to be above the concentration limit for classifying the substance as carcinogen. From this information the following conclusions can be drawn:

- Where the concentration of inhalable fibres is above the relevant concentration limit (0.1 %), the substance is classified as carcinogen and covered by the Candidate List entry.
- RCF fibres are not manufactured with the aim to achieve the shape provided in the substance identity on the Candidate List, but to fulfil certain substance properties. Therefore, the corresponding process can be considered that of manufacturing a
substance.

**Regarding the use of the substance as an article:**

According to the information provided by industry, the main use of the RCF fibres as substances is to be pressed and formed into specific shapes, such as blankets, boards and others, which are then used as isolation material in high temperature applications. RCF blankets, boards and similar may be (parts of) articles according to Art 3(3). However, also the bulk substance as such is used for isolation. Another use described in the background document is the formulation of textiles, cements or putties, which can then further be used to produce articles.

Based on the available information on the processes the RCFs are put under it is not always possible to conclude at which stage of the lifecycle their status changes from substances to articles. It is further noted that while the uses of articles do not require authorisation, the production of these articles using RCFs is a use requiring authorisation.

Although the uses of RCF blankets, boards and similar (parts of) articles do not, provided that they fulfil the article definition, require authorisation; however, when applying for authorisation for the described uses requiring authorisation, the whole life-cycle of the substance needs to be considered, including the article service life and the waste stages with their respective exposure and related risks. In a similar manner the analysis of socio-economic benefits of the continued use can consider the benefits related to the use of such articles.

RCF fibres imported into Europe in form of articles will be considered, when according to Art. 69(2) REACH, ECHA considers whether the use of the substance in articles poses a risk to human health or the environment that is not adequately controlled. In such cases ECHA shall prepare a restriction proposal.
Registrants are advised to refer to the “Guidance on requirements for substances in articles” to conclude for their use about the status of RCFs (substance vs. article). As stated above, potential applicants for authorisation need to cover the whole life cycle of RCFs. Furthermore, producers and importers of articles containing RCFs need to fulfil the respective obligations for SVHCs in articles (Art. 7(2) and 33).

**Article 58(2) exemption response**

Please see response to comment 2489, this section.

| 2287 | 2013/09/19 21:05 | Unifrax I LLC, Company, United States | The attached comments are provided by Unifrax I LLC, a major global manufacturer of High Temperature Insulation Wools. Unifrax has a strong manufacturing presence in Europe, and was the lead registrant for Refractory Ceramic Fibres / Alumino-Silicate Wool (RCF/ASW). Unifrax supports the comments from our trade association in Europe, ECFIA, Representing the High Temperature Insulation Wool industry, and hereby request an exemption under REACH Article 58(2) for the professional and industrial uses of Al-RCF and Zr-RCF. |

**Regarding legal interpretation of Article 58(2)**

ECHA considers that the legal interpretation of Article 58(2) REACH proposed by Unifrax is not correct and is inconsistent with the objectives of the REACH Regulation and in particular those set out in the Authorisation title. Indeed, in light of the primary objectives of the REACH Regulation to protect human health and the environment and the objective of the authorisation title to ensure that the risks of substances of very high concern should be properly controlled leading to the progressive replacement of these substances, ECHA considers that uses of such substances can only be exempted if other EU legislation controls the human health and environmental risks of the use of the substances in an equivalent way to the REACH Regulation. ECHA’s interpretation of Article 58(2) REACH ensures that these objectives are fully taken into account.

In the following paragraphs the specific arguments raised by UNIFRAX are considered.

1. **On alleged departing of ECHA’s current interpretation of Article 58(2) REACH from the legal text**

   a) Unifrax view: Unifrax claims that the Current Interpretation departs from the
legal text, since it adds the additional requirement to consider whether more stringent measures would have been "technically feasible". According to Unifrax, this additional requirement transforms the evaluation of EU legislation from one of a review of minimum requirements to an exercise in second-guessing whether the legislation could have been more stringent.

**ECHA view:** Unifrax appears to refer to footnote 6 of ECHA’s paper on the Preparation of Draft Annex XIV entries (2013). That footnote provides:

> "Legislation imposing minimum requirements means that:
> - The Member States may establish more stringent but not less stringent requirements when implementing the specific Community legislation in question.
> - The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper."

Contrary to the understanding of Unifrax the text clearly does not introduce a requirement to consider whether the legislation could have been more stringent or that more stringent measures could have been technically possible. The text merely indicates that a piece of EU legislation imposing minimum requirements is *inter alia* a piece of legislation that may allow Member States to impose more stringent requirements than those set out in that legislation but does not allow Member States to impose less stringent requirements than those set out in that piece of EU legislation. In this respect ECHA’s analysis of the EU legislation in question is limited to examining whether the legislation would...
allow Member States to impose less stringent measures than those set out in the EU legislation. If that is the case then that piece of EU legislation cannot be regarded as imposing "minimum requirements".

b) Issue: Under the Current Interpretation it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Unifrax view: According to Unifrax, the Current Interpretation expands the control requirement in Article 58(2) REACH to cover all risks at all stages of the life cycle of a use; such life-cycle considerations are not apparent from a literal reading of Article 58(2) REACH. Furthermore, Unifrax declares to be unaware of any existing EU legislation that deals with all the risks associated with the full life-cycle of a substance. It is also Unifrax’s opinion that this interpretation departs from the Commission’s reasoning when granting an exemption under Article 58(2) REACH, where there is no reference to life cycle concerns.

ECHA view: ECHA notes that the interpretation provided in the Current Interpretation is based on a comprehensive reading of the legal text. REACH Regulation refers to the obligation of consider all stages of the life-cycle of the substance in several provisions, such as sections 0.3 and 5.0 of Annex I to REACH. In an authorisation application applicants need to present a number of exposure scenarios showing whether the risk is properly controlled. Pursuant to Article 3(37) REACH, exposure scenarios are defined as '(...) set of conditions, including operational conditions and risk management measures, that describe how the substance is
manufactured or used during relevant parts of its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate’. Based on the above, ECHA considers that its interpretation of the life-cycle of the substance is correct and in line with the legal text.

Moreover, ECHA does not expect that one single piece of legislation would cover all life-cycle stages in order to fulfil the conditions of Article 58(2). Indeed, as long as there are one or more pieces of EU legislation that read together properly control the environmental/ human health risks of a substance throughout all its life-cycle stages the conditions under art 58(2) would be fulfilled.

c) Issue: Under the Current Interpretation, when reviewing existing EU legislation addressing the use or categories of use that is proposed to be exempted ECHA must pay special attention to the definition of use in the legislation in question compared to the REACH definition.

Unifrax view: Unifrax believes that such approach incorrectly requires legislative definitions to be the same and that it is not reasonable to expect that different legislation enacted at different times will contain definitions that are similar to those contained in REACH. Moreover, the presumption or implication that different definitions suggest inadequate levels of control is without merit.

ECHA view: ECHA notes that Article 3(24) REACH explicitly defines ‘use’ as ‘any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article
or any other utilisation’. Other EU legislation may have different (narrower or wider) definition for ‘use’. Furthermore, uses or activities may be exempted from the scope of legislation. How ‘use’ is defined and which uses/applications are exempted have an impact on whether other EU legislation afford the same/ an equivalent amount of protection as REACH. Thus, the reference to definition of ‘use’ in REACH Regulation is meant to remind users of this provision and of the need to take possible differences between the different legislation into account, without aiming to a harmonisation of terminology between different legislations.

2. On claimed divergence of the Current Interpretation from the Commission Precedent

Issue: The Current Interpretation states that legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2) REACH. Unifrax view: In Unifrax’s opinion such interpretation is at odds with the Commission’s precedent in exempting three plasticizers (DEHP, BBP and DBP) used in the immediate packaging of medicinal products from the authorisation requirements by the adoption of Regulation (EU) No 143/2011. Unifrax quotes Recital 17 of such Regulation, where the Commission finds that existing Directives provide for a framework to properly control risks of immediate packaging materials by imposing requirements on the quality, stability and safety of the immediate packaging materials. According to Unifrax, this indicates that EU legislation needs not to be overly prescriptive or specific to meet the ‘properly control’ criterion of Article 58(2) REACH. In Unifrax’
understanding, by interpreting ‘proper control’ to mean that EU legislation at issue must impose specific non-discretionary measures and contain specific technical details on issues such as effectiveness, ECHA is implicitly concluding that Directives will generally not satisfy the requirements foreseen in Article 58(2) REACH. Furthermore, Unifrax claims that, in light of the Commission’s precedent, the nature of EU law and the special role of the directive, national legislation, such as that which implements Directives, should be considered in relation to requests under Article 58(2) REACH.

ECHA view: As regards the alleged divergence of the Current Interpretation from Commission precedent, ECHA would like to highlight the particular aspect which brought the COM to exempt the use of DEHP, BBP and DBP in the immediate packaging of medicinal products from authorisation requirements. As stated in Commission Regulation (EU) No 143/2011, aspects of safety of the immediate packaging of medicinal products were already covered by the existing Directives. Therefore, the Commission found that the risks deriving from the use of DEHP, BBP and DBP in the immediate packaging of medicinal products were already properly controlled and could be exempted from the authorisation requirement.

In ECHA’s opinion, this is not a divergence from the Current Interpretation of Article 58(2) REACH. The Commission merely indicated that there is already legislation providing proper protection to human health and the environment for uses of the substances in intermediate packaging.

ECHA would further like to clarify that Directives are not excluded for purposes of fulfilling the exemption requirement, as long as the minimum standards for protection of human health and environment are met in accordance with Article 58(2) REACH. Indeed, Directives by essence impose minimum standards. As long as these minimum standards afford the
same/ an equivalent amount of protection as REACH such Directives can be used to exempt certain uses from the authorisation requirement.

Finally, as regards the claim that national legislation should be taken into account, ECHA notes that Article 58(2) REACH is clear in referring only to existing EU legislation.

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<th>3. On alleged infringement of the principles of proportionality and effectiveness</th>
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**Unifrax view:** In Unifrax’s view and based on previous responses to exemption requests, proportionality is considered improperly by ECHA. Similarly, the Current Interpretation violates the principle of effectiveness by depriving stakeholders of a meaningful opportunity to obtain exemptions.

**ECHA view:** ECHA first noted that Unifrax’s view is based on a misreading of the last sentence of Article 58(2) which provides that “in the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form”.

The term "proportionality" does not refer to the legal principle of proportionality. Rather the term "proportionality of risk" means "level of risk". This sentence was included after first reading by the European Parliament. The justification for including this sentence was that the EP recognised that for metals/alloys the risks to human health and the environment depend on the forms. Thus massive forms of the metals typically have lower risk characteristics, so cannot be treated on a par with the fine powder form. According to the EP applying the same requirements to both forms is disproportionate to the potential risk. Thus, when assessing whether a piece of legislation provides
adequate control on the risks of a substance in its certain life-cycle stage account needs to be taken of the form of the substance that is used. Thus a piece of legislation may provide adequate protection if the substance is used in the massive form, but not provide adequate protection where it is used in powder form.

With respect to Unifrax’s view that ECHA’s Interpretation breached the principle of effectiveness, ECHA notes that REACH Regulation is underpinned by the precautionary principle. Recital 69 REACH states that: ‘To ensure a sufficient level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention’. Therefore, a strict interpretation of the exemptions under Article 58(2) REACH is required so as to meet the objectives of REACH.

**Article 58(2) exemption response**

Please see response to comment 2489, this section.

| 2277 | 2013/09/19 17:48 | Individual, Netherlands | working with RCF: keep it safe and practical | Regarding the description of uses:
See reply to comment 2272 in section I |
|       |                  |                          |                                     | Regarding the low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I |
|       |                  |                          |                                     | Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I |
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<th>ID</th>
<th>Date</th>
<th>Submitter</th>
<th>Message</th>
<th>See reply to comment 2130 in this section.</th>
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</thead>
<tbody>
<tr>
<td>2274</td>
<td>2013/09/19</td>
<td>Pruna Betreiber GmbH, Company, Germany</td>
<td>We fully support the comment made by the European Steel Association (EUROFER) related to the Aluminosilicate Refractory Ceramic Fibres (Al-RCF) and we would like to share our experience of working with these materials. Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are one of the best solutions for heat insulation at temperatures from 900°C up to 1450°C, especially for a number of niche applications where no alternative exists. The range of applications of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) is multifarious and the conditions are divers. A substitution of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) has been done for application where possible, but substitution is not possible for all applications. Where substitution is not possible Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are the best solution for industrial insulation. Risk management options are used to handle Aluminosilicate Refractory Ceramic Fibres (Al-RCF) safe. Solely well instructed and trained workers handle Aluminosilicate Refractory Ceramic Fibres (Al-RCF) during maintenance work. Personal protective equipment and protective measures under controlled conditions enable a safe handling. During production of coke in the coke oven the Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are under controlled conditions (e.g. between refractory brick and the steel construction of the battery, as part of the linings of furnace doors ...) and no exposure takes place. The fibres are needed to ensure structural stability of the battery and tightness of the doors. The use is essential to minimise possible emissions of toxic and carcinogenic coke oven gas throughout the coking process. Therefore the prioritisation of Al-RCF in the authorisation process should be reviewed due to the fact, that there are existing regulatory Risk Management Measures (RMM) in place to control exposures in workplace. Furthermore a ban on Aluminosilicate Refractory Ceramic Fibres (Al-RCF) would have consequences for the energy efficiency in Europe and also on the safe insulation for many applications. Industrial production lines are not necessary inside of buildings. Consequently a ban of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) would force industry to use not well proved or not appropriate substitutes which bear a risk of leakage and could therefore be dangerous for environment and human health.</td>
<td>See reply to comment 2272 in section I</td>
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<td>2272</td>
<td>2013/09/19</td>
<td>Group of</td>
<td>MAJOR POINTS OF THE DOCUMENT ATTACHED TO THIS SUBMISSION</td>
<td>Regarding the description of uses: Thank you for your comment and the additional</td>
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### I. DEFINITIONS AND NUMBER OF ENTRIES

1. **Uncertainties on the definitions**
   - Lack of clarity on the definition of the 2 RCFs and uncertainty why Zr- and Al fibres are covered and others with equal properties not.

2. **Grouping the two entries**
   - The difference between the two current entries is minimal and the hazard profile is the same. Their uses and technical performance are the same and both fibres are covered by the same CSR.
   - The two entries for Authorisation should be regrouped into one. Failure to cover all RCF products with similar properties (in this case, the same C classification) and used for the same applications and conditions, would encourage intersubstitutability with other RCFs. In line with previous cases, the matter of intersubstitutability should be addressed before proceeding further, even at the cost of a postponement so as to avoid a failure of the Authorisation policy.

### II. PRIORITY SCORING

1. **Raising the scorings**
   - The metals sector noted a higher overall scoring for RCF fibres than in a previous assessment report (2 years ago). It is unclear to us how this can be justified given that the potential for exposure, number of users or the hazard properties did not change and the volumes rather declined due to the split entries and somewhat declining market.
   - We would therefore request ECHA and MSC to clarify and motivate the changes to ensure and maintain a transparent and objective prioritisation process.

2. **No significant exposure**
   - The exposure level considered as ‘tolerated’ of 0.1 f/ml in the Annex XV dossier is not in line with the September 2011 SCOEL recommendation. SCOEL concluded, that the “no observed adverse effect level” (NOAEL) can be interpreted as an OEL of 0.3 f/ml. The scoring as ‘significant’ of the exposure is therefore not justifiable and also in contradiction with the fact that only skilled specialised workers wearing highly protective clothing conduct these jobs that could potentially lead to exposure.
   - Instead of “significant” the scoring should be limited to “controlled”, in line with the use situation in the non-ferrous metals installations and others. There is therefore “no uncontrolled exposure” in the installations.
   - The SCOEL recommendation should thus be integrated and the scoring should accordingly be reviewed.

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Information provided. This will be taken into account, where relevant, for finalisation of ECHA’s recommendation of substances to be included in Annex XIV and the corresponding background documentation.

**Regarding the non-availability of alternatives/information on alternatives in background document:**

Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives.

As RCFs are carcinogenic, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for RCFs will accordingly ensure that the health of workers in the EU involved in the uses of RCFs is protected.

Please note further that authorisation, inter alia, is a means to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)).

Therefore, the present lack of alternatives to (some of) the uses of a substance and the need to complete R&D programmes to get qualified alternatives to it is no viable reason for adjourning the subjection of a substance or some of its uses to authorisation.

Information regarding lack of alternatives is however
3. Threshold versus non-threshold
SOCAR concluded in its 2011 assessment, that RCF is a carcinogen that has a “no observed adverse effect level” (NOAEL) and is a carcinogen of group C i.e. genotoxic carcinogen for which a practical threshold is supported. The scoring as a non-threshold substance is therefore unjustified and provides the user with a wrong impression about the Authorisation application route to be followed if the concerned RCFs would be listed on Annex XIV. It is therefore proposed to change the scoring appropriately in line with the scientific evidence and to ensure that a consistent and right signal is provided to industry.

III ADDITIONAL CONCERNS AND QUESTIONS OF PRINCIPLE

1. Reliance on RCFs for some processes and duration of use
Recognising that the potential for substitution is not a criterion considered during the prioritisation discussion, the metals sector considers it worthwhile to mention that there are a number of applications that have remained reliant on RCF materials despite the knowledge of the RCF hazard profile and the development of other insulation products (AES e.g.). The duration of use of the fibres varies significantly from a few months or years (crucibles, canals) to 7 or 8 or even more years (furnace re-linings). These realities of use should also be taken into consideration in the further analysis of the RCF dossiers.

2. Chemicals management and climate policy
The function of refractory fibres including the two listed entries is not restricted to insulation. Indeed they play a crucial role in energy saving policies of pyrometallurgical processes in the metals sector and so in climate policy. The high cost of energy means that companies have carefully investigated the best technical performing materials to achieve the climate targets. Moreover, these policies are relatively new meaning the assessments covered a careful assessment of the materials used including their associated hazards/risks given the carcinogens at work legislation applied when most of them were installed. A constrained view solely focused on hazard, like under the prioritisation scheme, may therefore challenge the possibility for industry to meet its regulatory obligations under the Kyoto convention without gains for the protection of workers. The metals sector believes therefore that this balance should be recognised under the regulatory efficiency assessment of the prioritisation step.

3. Authorisation is not an effective Risk Management tool for important information for inclusion in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the application for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

Regarding the information provided in the background document on alternatives we would like to clarify that this information does not aim to identify potential alternatives or to assess the technical or economic feasibility of such alternatives or risks related to them. The information is collected (and presented) to obtain an overview of the level of information available on the alternatives and the nature of the alternatives. In other words, this part of the assessment is not judging whether the alternatives are feasible or safer or how long it could take to transfer to the alternatives, but whether or not information seems to be available that facilitates compiling an analysis of alternatives by future potential applicants.

Regarding the unclear substance identity:
Please note that substance identity aspects have been considered in the context of inclusion of the substance in the Candidate List and they are not relevant in the current prioritisation phase. Similar comments on substance identity of RCFs have been addressed by the dossier submitter during the public consultation of identifying the substance as SVHC.

Nevertheless, as ECHA finds it important to further clarify which substances are covered by the entry in the Candidate List and which therefore require authorisation in case RCFs are included in Annex XIV, further details are provided here.
As a user sector, the metals sector does not expect that the listing of the 2 concerned RCFs on Annex XIV would increase the level of protection in the European Union given that:

- the high skills required to install or eliminate the RCFs resulted in the development of a specialised expertise provided by external firms that apply the highest safety standards. Exposure to the fibres during these critical phases is consequently completely controlled;
- articles including these fibres can still be imported and will have to be installed by a specialised workforce;
- the lack of clarity around the definition may lead to intersubstitutability to RCF forms with equal hazard properties that are not covered by Annex XIV.

We would therefore like to challenge the value as well as the efficacy of the Authorisation process in terms of an increased level of chemicals management for RCFs. This option, which raises principle concerns, may find its origin in the lack of (or at least not publically available) RMO assessment that would have investigated the efficiency and efficacy of the different tools. If any potential for exposure (even would) exist, this would be limited to the specialised workers that install or remove insulation materials at the plants.

Other Risk Management tools could be more effective although we have no knowledge of uncontrolled exposure. The metals sector is concerned that given the low number of substances available for potential entry into Annex XIV, the pressure to select them all may be very high, independent from the scoring, effectiveness or potential intersubstitutability. The metals sector therefore urges ECHA and MSC to provide a transparent and objective opinion based on the facts presented in the Annex XV dossier and the additional information provided in the public consultation.

**RCFs covered by the Annex VI entry in the CLP Regulation and the Candidate List entries:**

As indicated by the Annex XV dossier submitter in the process of identification of RCFs as SVHC, the entry in Annex VI of the CLP Regulation refers to a group of substances, in line with chapter 1.1.1.5 of that Annex. ECHA reminds that the inclusion of RCFs under one entry in Annex VI of CLP does not imply that the RCFs concerned by the harmonised classification and labelling correspond to one substance. RCFs presenting similar hazard profiles do not necessarily refer to the same substance. The SVHC Annex XV proposals to identify RCFs as Substance of Very High Concern referred to specific fibres, which are a subset of the general Annex VI entry.

**Identification of the RCFs in the candidate list:**

RCFs covered by the Candidate List entry are the ones that fulfil the conditions set out in the entry.

In the case of Al-RCFs, these are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions:

- Oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges.
- Fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).
- Alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight.

Regarding point a): A distinction between the "main"
oxide components and any eventual “minor” oxide also present in the fibre should be made. For this purpose, it is important to take into account the following information:

(i) Firstly, as indicated in the support document for identification of the Al-RCFs as SVHC, "According to the guidance for identification and naming of substances under REACH these UVCB substances are specified with the IUPAC name of their starting materials. "In the case of aluminosilicate RCF those are Al2O3 and SiO2". It is also clear from the support document that the oxide components in the Al-RCFs are not limited to Al2O3 and SiO2. In particular, it is underlined that other oxides can also be added to adjust the properties of the fibres concerned by entries in the candidate list. It should however be noted that the document does not provide an exhaustive list of such other intentionally added "minor" oxides but only gives indicative examples. Accordingly, the information specified in the support document on the identity of these minor oxides, including also the corresponding indicative relative concentration values reported in these examples, does not constitute any requirement regarding the content of other minor oxides in the fibres concerned by the candidate list entry.

(ii) Secondly, the support document indicates that the intentional addition of oxides (e.g. to change the fibre properties of the fibre) is not a reason as such to qualify the oxide used as a main component. Quantitative criteria need to be followed to represent the overall composition in oxides by its main components. In line with the principles in the Guidance on substance identification, ECHA considers that for defined compositions which include more than one

\[2\text{ The support document refers to “Other oxides like potassium oxide […] are sometimes added to change the fibre properties” (emphasis added).} \]
“main” component, as in the case of a composition, when represented in terms of the oxide components, for the RCF entries in the Candidate List, such components should normally be understood as those individually contributing to ≥ 10 % (w/w) and <80% (w/w) of the composition. This means that substances that would have other components (e.g. Cr₂O₃), with less than 10 % (w/w) would normally still be covered by this entry.

Regarding point b): To be covered, such type of fibres have to be contained in the substance above the concentration limit relevant for its classification as carcinogen 1B (classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances).

The entry in the Candidate List for Zr-RCFs defers from this point in condition a) which reads:

a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges.

This allows to clearly distinguish between the two entries: the contribution of the zirconium oxide as one of the main components, i.e. as a component contributing to ≥10 % (w/w) and <80% in the RCF, needs to be considered when determining whether an aluminosilicate-type of RCF is covered by the Zr-RCF entry or the Al-RCF entry.

The only additional necessary information for establishing whether a substance covered by the RCF entry in Annex VI of the CLP Regulation corresponds to one of the two RCFs in the candidate list is the identity of the main components in the fibres. This information is expected to be available in the supply chain, the identity of the main components being normally determined by the identity and ratio of starting materials used for the manufacturing of the
RCFs. This information can also be derived from elemental analysis of the fibres. Establishing whether an RCF is listed in the candidate list is therefore expected to be straightforward. Furthermore, it is to be stressed that the aim of REACH to ensure a high level of protection of human health and the environment requires also, in ECHA’s understanding, a sufficient knowledge from the registrants (and downstream users) of the chemistry and the naming of substances.

Please also note that, in case the two RCF entries are included in Annex XIV, if an authorisation is sought for more than one substances falling under different RCF entries, a single application based on Art. 60(2) of REACH may be possible (see Annex I of ECHA’s Guidance on the preparation of an application for authorisation: http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf).

**Numerical identifiers for RCFs:**

There are currently no numerical identifiers such as EC or CAS numbers available to define the substances described in the Candidate List. The absence of such identifiers is however not a deterrent factor for the inclusion of a substance in the candidate list or Annex XIV. Regarding the availability of CAS number for the identification of RCFs, it is to be stressed that CAS numbers are provided by the Chemical Abstract Service, a division of the non-profit organization “American Chemical Society”. The Chemical Abstract Service, when assigning CAS numbers, follows its own rules and is not bound by the substance definition under REACH.

**Identification of additional RCFs as SVHC**

Any significant change in the source or the manufacturing process that would lead to e.g. changes in the identity of the “main components”
would be likely to lead to a different substance that should be registered separately. The submission of such registrations can then be taken into account when assessing the need for further risk management activities by authorities.

So far, no Member State or the Commission has initiated the identification of other fibres covered by the CLP entry as Substances of Very high Concern.

**Regarding the inter-substitutability with RCFs not identified as SVHC:**

Following the above, it is clear that fibres containing less than 10 % (w/w) of other components (e.g. chromium oxide) but more than 10 % of the defined main components, fall under the Candidate List entries of Al-RCFs/Zr-RCFs and would therefore require authorisation in case the substances are included in Annex XIV of REACH.

The fact that two substances are covered by the same CAS entry does not imply that these substances should be regarded the same under REACH and CLP. The Chemical Abstract Service, when assigning CAS numbers, follows its own rules and is not bound by the substance definition under REACH. Substances consisting of different "main components" would normally require separate registrations.

It is recognised that there might be other fibres on the market with potentially the same hazard properties and similar uses which are not covered by the current Candidate List entries. However, any such substances need to be first identified as SVHC by submitting an Annex XV dossier and going through the SVHC identification process before their recommendation for inclusion in Annex XIV could be considered. As there is currently no indication of the initiation of such process, ECHA considers it not justified to postpone the recommendation process of RCFs currently identified as SVHC.
Regarding the priority assessment/scoring:

See reply to comments 2444 in section I

Regarding the low or controlled exposure/risk of RCFs:

Please note that the prioritisation approach which was agreed and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV is not intended to assess the risks arising from the uses but to provide a very basic and general assessment of the use pattern and exposure potential a substance may have for humans (workers, consumers) or/and the environment. If a substance is included in Annex XIV it is then the obligation of the applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no alternatives available and the socio economic benefits of the use outweigh its risks.

The inclusion in Annex XIV is per substance and not per use (or installation). Therefore, the estimation of the release potential in the prioritisation phase does not assess the exposure levels from single uses (at specific sites), but aims to deduce whether there are uses/situations where exposure may potentially not be controlled (mainly for workers and consumers in the case of CMR). The use and user specific conditions need to be described in the authorisation application and they will be taken into account by ECHA’s Committees when developing their opinions on the applications and by the Commission when taking the final decisions.

In a potential application for authorisation, the exposure assessment shall consider the emission during all relevant parts of the life-cycle of the substance resulting from each of the uses applied for. The life-cycle stages resulting from identified uses cover, where relevant, also the service life of articles.
Regarding the existing threshold for RCFs:
The question as to whether the carcinogenic effects of RCFs are elicited by a mechanism for which it is possible to determine an effect threshold is important for the next stage of the authorisation process, namely application for and granting of the authorisations. However, ECHA does not assess at this stage of the authorisation process (i.e. recommendation for inclusion in Annex XIV) whether on the basis of the available scientific evidence it can be concluded that a non-effect level for the carcinogenic effects of the RCFs exists. This is an issue to be addressed in the authorisation applications and to be scrutinised by the Risk Assessment Committee when preparing its opinions on the authorisation applications.

Keeping this in mind, i.e. that no assessment of the mode of action was done at this stage by ECHA, information cited during the public consultation, such as the recommendations by the Scientific Committee on Occupational Exposure Limits (SCOEL) and the report by the Health Council of the Netherlands (DECOS), are fully acknowledged. However, in our view that information does not seem to conclusively demonstrate a threshold mechanism of action but rather discusses the relative contribution of different mechanisms of action. Therefore, for the sole purpose of the prioritisation step a score of “1” (carcinogenic without threshold) will be assigned to the RCFs, as is the default value given for carcinogens in the past.

As mentioned above, this score does not imply a conclusive assessment by ECHA on whether it is possible to determine a no-effect threshold for RCFs. Information brought in applications for authorisation will of course in any case be taken into account by RAC while preparing its opinions. While for substances included in Annex XIV, ECHA may also publish proposals for the mechanism of action (i.e.
threshold / non-threshold) and the respective DNELs / dose-response curves, prior to receiving applications for authorisation - as is at least the current practice in the context of a trial exercise. The purpose of such publications is to provide applicants with a clear signal as to how RAC is likely to evaluate these important elements of the risk assessment of applications.”

Regarding the socio-economic impact, e.g. 
energy efficiency, long service time, 
disadvantage for EU industry:
Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics as mentioned above (the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use)
are not considered in the prioritisation for recommending substances for inclusion Annex XIV.

**Regarding addressing imported articles:**

With regard to concerns relating to the import of SVHCs via (semi-)finished articles it should be noted that the REACH Regulation contains provisions that allow to identify and, if deemed necessary, restrict such imports of SVHCs within articles:

- Importers (and producers) of articles are required to notify the presence of candidate list substances (i.e. substances identified in accordance with Article 59 as meeting the criteria of Article 57) in articles when the substances are present in those articles above a concentration of 0.1% (weight/weight) and the quantity of a substance totals over 1 tonne per producer or importer per year. If in addition such a substance is intended to be released, the substance requires registration (see provisions or Article 7.1 and 7.2 of REACH),

- If considered necessary, Community-wide measures restricting the placing on the market (including the import to the EU) of articles containing SVHC substances can be imposed. REACH Article 69(2) requests ECHA to consider whether the use in articles of a substance subjected to authorisation poses a risk to human health or the environment that is not adequately controlled. If ECHA considers that the risk is not adequately controlled, it shall prepare an Annex XV dossier addressing these risks. Further, the Member States can develop restriction proposals addressing such imports of SVHCs with articles. The European Commission can take initiative as well and request ECHA to develop restriction proposals.

**Regarding the burden of authorisation on certain industry sectors/prolong LADs**

Note that in accordance with Art. 62(2) applications for authorisation may be made by the
manufacturer(s), importer(s) and/or downstream users of a substance (or any combination thereof) and that they may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant’s own uses and/or for uses for which he intends to place the substance on the market.

From these specifications of Article 62 it is evident that not each actor on the market has to apply for authorisation of his use(s). A supplier (manufacturer, importer or downstream user) may cover in his application use(s) of his downstream users. Furthermore, it is possible to submit joint applications by a group of actors. To get the required application(s) ready in time is therefore also a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work.

Following the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV, ECHA has used 18 months from the inclusion of the substance into Annex XIV as the standard latest application date (LAD) and then spread the latest application (and sunset dates) for the recommended substances over a period of six months, mainly to account for the anticipated workload of the Agency with regard to processing of authorisation applications – noting that the time differences between the LADs of a recommendation can be considered as minor (i.e. 3 months) compared to the total time reserved for the potential applicants to prepare their applications.

The assignment of the five recommended substances to the three lots (LAD of 18, 21, and 24 months after inclusion) has been based mainly on factors such as interchangeability (with substances already in Annex XIV / recommended for inclusion to Annex XIV; applicable for DMF), grouping (i.e. of the two RCF
entries), and relative considerations (among the five substances) about the time needed to prepare applications for authorisation.

In the context of the latter factor, while ECHA acknowledges the potential complexity of uses of RCFs and their supply chain, it notes that considerable information on research and availability of alternatives seems to be available for certain uses, and that the RCFs have been included in the Candidate List since relatively long time. Therefore, ECHA has assigned RCFs to the 2nd lot (recommended LAD of 21 months after inclusion) and has placed at the 3rd lot the 4/tert-OPnEO; for 4/tert-OPnEO industry may need more time to organise and there is also some uncertainty on the full list of uses occurring in the EU, as it seems that due to the potential fulfilment of the polymer definition under REACH these substances have not been registered as such.

Generally we advise downstream users to aim for a good communication within the supply chain to identify and agree on the most appropriate actor to apply for authorisation for certain use and how the different actors can best contribute to this work – potentially with the further support of industry associations.

Please refer also to the Guidance on preparation of an application for authorisation, especially Appendix 2 on applications by several legal entities (http://www.echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf).

ECHA has created a dedicated webpage "applying for authorisation" the aim of which is to guide applicants in the preparation of their applications (http://echa.europa.eu/web/guest/applying-for-authorisation). A guidance document on how to apply for an authorisation for the use of substances included in Annex XIV is available and can be directly
This guidance is primarily intended for use by manufacturers, importers and downstream users placing on the market or using a substance included in Annex XIV of REACH. The document intends to help and guide potential applicants through the authorisation process. Further guidance to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process. The availability of all this information and guidance shows that even if the authorisation process is perceived as “new” it is nevertheless already a process that has been carefully thought through and for which in-depth documentation and guidance is available.

**Regarding your proposal of a different risk management option/other measures:**
See reply to comment 2169 in section I

**Regarding the description of uses:**
See reply to comment 2272 in section I

**Regarding the non-availability of alternatives/information on alternatives in background document:**
See reply to comment 2272 in section I

**Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:**
See reply to comment 2272 in section I

**Regarding the hazard property of RCFs:**
See reply to comment 2314 in section I


Noch kritischer ist der Einsatz unter chemisch aggressiven Atmosphärenbestandteilen zu sehen. Dies gilt nicht nur für die genannten Beispiele aus der Petrochemie, diese gelten eher generell für alle wärmetechnischen Anlagen. Reine Luft-/Abgasatmosphären kommen weniger häufig vor, da oft eine Verunreinigung durch die Güter als auch durch Hilfsstoffe aus deren Herstellung stattfindet. Saure Medien können die AES-Wollen innerhalb kürzester Zeit auflösen, alkalische Bestandteile die Schmelztemperatur dramatisch senken. Die Einsatztemperaturen in alkalihaltigen Atmosphären sollten 750 °C daher nicht überschreiten, da sich erste Schmelzen bereits bei ~ 800°C bilden können. Diese treten nicht nur in der keramischen Industrie auf, sondern auch sehr häufig in der Wärmebehandlung von Metallen. Leichte Calciumsilikate und Vermikutit können ASW lediglich im kaltseitigen Teil der Dämmung ersetzen. Für einen heißseitigen Einsatz sind Vermikutit nur bedingt, leichte Calciumsilikate gar nicht zu empfehlen. Betone (auch auf CA6-Basis) und Steine sind frontseitig einsetzbar. Dabei muss aber in Kauf genommen werden, dass der Anlagenbetrieb aufgrund der höheren Dichte der Materialien als auch der niedrigeren Temperaturwechselbeständigkeit umgestellt werden muss. Zudem ist die Speicherenergie der Zustellung größer, was sich in einem sehr viel höheren Energiebedarf beim Aufheizen,

Regarding the perception of authorisation being a ban of the substance: See reply to comment 2292 in section I

Promat GmbH
High Performance Insulation
i.V. Volker Krasselt
Technischer Leiter

2270 2013/09/19 15:24 ThyssenKrupp Steel Europe AG, Company, Germany
We fully support the comment made by the European Steel Association (EUROFER) related to the Aluminosilicate Refractory Ceramic Fibres (AL/RCF) and we would like to share our experience of working with these materials. Aluminosilicate Refractory Ceramic Fibres (AL/RCF) are one of the best solutions for heat insulation at temperatures from 900°C up to 1450°C, especially for a number of niche applications where no alternative exists.

The range of applications of Aluminosilicate Refractory Ceramic Fibres (AL/RCF) is multifarious and the conditions are divers. A substitution of Aluminosilicate Refractory Ceramic Fibres (AL/RCF) has been done for application where possible, but substitution is not possible for all applications. Where substitution is not possible Aluminosilicate Refractory Ceramic Fibres (AL/RCF) are the best solution for industrial insulation.

Risk management options are used to handle Aluminosilicate Refractory Ceramic Fibres (AL/RCF) in a safe manner. Solely well instructed and trained workers handle Aluminosilicate Refractory Ceramic Fibres (AL/RCF) during relining and maintenance work. Personal protective equipment and protective measures under controlled conditions enable a safe handling.

On the job in our plants and construction mills irreplaceable Aluminosilicate Refractory Ceramic Fibres (AL/RCF) are under controlled conditions (e.g. inside of heaters or furnaces, as linings of furnace doors ...) We carried out individual related and static occupational exposure measurements under normal production conditions in the ambient working area. No significant numbers of fibres could be found which indicate that no exposure of Al/RCF does take place.

Therefore the prioritisation of AL/RCF in the authorisation process due to the fact, that there are existing regulatory Risk Management Measures (RMM) in place to control exposures in the workplace, should be reviewed.

A ban on Aluminosilicate Refractory Ceramic Fibres (AL/RCF) will have consequences for the energy efficiency in Europe and also on the safe insulation for many applications. Industrial production lines are not necessary inside of buildings. Consequently the ban of Aluminosilicate Refractory Ceramic Fibres (AL/RCF) would force
industry to use not well proved or not appropriate substitute which bear a risk of leakage and could therefore be dangerous for the environment and for the human health.

| 2265 | 2013/09/19 14:24 | Refratechnik Steel GmbH, Company, Germany | Refratechnik Steel GmbH is a global manufacturer of all kind of refractory materials (bricks and castables) used in various industry sectors (manly Steel and alumina) since more than 60 years. In addition we are offering “turnkey” installations with high investment cost including our refractories as well as supplied products from high temperature insulation wools from other manufacturers.

In the overall concept of our turnkey installations there is a need for (zirconia-) Alumino silicate RCF to enable general plant safety including production reliability and worker safety.

High temperature insulation wools are used as filling materials for construction-conditioned expansion joints. These expansion joints are part of the construction to give space to the refractory material at thermal or thermo-chemical expansion. Missing or insufficient expansion joints, lead to mechanical overloading of the refractory construction and, as consequence, the steel body of the facility. This effect also aroused in case that cement dust moves into the expansion joints, caused by insufficient resilience of the high temperature insulation. The resilience property of expansion joints filling materials is the main functional request.

Finally this thermal or thermo-chemical expansion destroys the refractory inside the body, as well the constricting framework of the facility. As consequence the plant operators face high cost on loss of production and repair work.

Based on that, the high temperature insulation material has to stay process temperatures up to 1400 °C and serious chemical attack from process gases in the kiln atmosphere.

(Zirconia-) Alumino silicate fibers, whether as loose wool, blanket or any other kind of shape, are the best available materials to stay these attacks.

Since many years (approx.: more than 20 years) we are testing substitute materials for (zirconia-) Alumino silicate RCF and substitution was realised wherever possible!

High temperature insulation wools like AES and Polycrystalline wools (and mineral wools) were tested. AES and mineral wool failed in practice, were not durable and endangered the structural design of the installation.

Not only temperature but also chemical and physical attack are

|   |   |   | Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I |
<table>
<thead>
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<th>Date/Time</th>
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<td>2260</td>
<td>2013/09/19 13:36</td>
<td>Norway, Member State</td>
<td>The Norwegian CA supports the prioritisation of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) for inclusion in Annex XIV. The substance has high priority due to very high volume and wide dispersive use.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2254</td>
<td>2013/09/19 12:36</td>
<td>Sweden, Member State</td>
<td>We support the prioritisation of aluminosilicate refractory ceramic fibres for inclusion in Annex XIV. The substance has high priority due to very high volume and wide dispersive use.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2251</td>
<td>2013/09/18 15:55</td>
<td>CECOF, Industry or trade association, Germany</td>
<td>(Zirconia-) Aluminosilicate Fibre products (RCF/ASW) are one type of high temperature insulation wools (HTIW). The products are used as an insulation material in industrial thermoprocess equipment (ITPE). Because of the high temperatures (&gt;600°C) the furnaces have to be lined with refractory materials. In most cases traditional heavy materials and insulating firebricks are used. In many applications - batch type as well as continuous furnaces - there is a need for light weight insulating materials made of (HTIW), because of its positive impact on the environment and the competitiveness of the user industries of furnaces. HTIW is used for industrial furnaces which, due to their process operating mode or to cope with the capacity variations (e.g. economic crisis) have to be heated up and cooled down very often. Due to the low specific heat capacity, the necessary amount of primary energy respectively CO2-Emissions can be reduced considerably in comparison to the traditional heavy refractory lining. In case an ITPE manufactures deems the use of RCF/ASW products necessary, a substitution analysis is initiated since many years following existing regulations. The aim is to find a substitution product or to prove it is impossible to find a substitution of the ASW product. In Germany, these inspections are conducted on the basis of technical guidelines for the handling of hazardous materials (TRGS 619). Under the lead management of the German BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) and by involving the aggrieved party the TRGS 619 (Technical Rule on Hazardous Substances ) was reviewed and published by the Federal Ministry of Labour and Social affairs in the &quot;Gemeinsamen Ministerialblatt&quot; edition 34/2013 by 31 July 2013. CECOF (see below) is represented in this expert working group (TRGS 619) by German experts (manufactures of ITPE), who participate to give good practical advice based on their own long term experiences. Their knowledge includes all matters of the design of furnaces which focus on the use of refractory materials including RCF/ASW products. The actual new version (2013) reflects the state.</td>
<td>Regarding the description of uses: See reply to comment 2272 in section I. Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I. Regarding the socio-economic impact, e.g. energy efficiency, long use time, disadvantage for EU industry: See reply to comment 2272 in section I. Regarding the low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I. Regarding your proposal of a different risk management option/other measures: See reply to comment 2169 in section I. Regarding the requested changes to the background document: See reply to comment 2373 in section I.</td>
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One of the main reasons for substitution is to avoid a possible hazard regarding persons at work with possibly hazardous substances. It has to be mentioned that substitution and worker protection is a primary target for ITPE-manufacturers. The manufactures do have responsibility for the health and safety of their own staff and for external workers following existing regulations.

A scientific study of the Research Association of industrial furnace manufactures (FOGI e.V.) and financed by the German Federal Ministry of Economics and Technology has investigated the aspect of substitution of RCF/ASW. One of the main result is, that for high temperature application less bio/persistent material have significant limitation by temperature and chemical and physical properties (full report see attachment).

ITPE 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).

In the preparatory study ErP-ITPE one of the basic requirements is to level the outside wall temperature of the furnace at max. value. Fulfilling these requirements is possible only in combination with insulation materials including RCF/ASW products. By these means an economically reasonable reduction of energy use incl. CO2 emissions could be achieved.

CECOF and its members are stakeholders in the ErP-ITPE and developed the principles of draft proposals of the energy requirements in the preparatory.

At this point an explanatory note referring to CECOF comments on ANNEX XV files in 2009 is included.

Correspondingly, it is said in the Annex XV dossiers, that more than one substitution product on the market is available. This argument is not tenable up to today and gives proof to the fact that the comments were based on the records available (i.e. taking recourse
to promotion flyers of producers or to the internet). Still in 2013, all products listed in RCOM (2009 and 2011) do not withstand the requirements for substitution products in most cases according to daily practical experience of IPTE-producers.

In this context, it is of use to point to an update of the "draft background document of 24 June 2013" (dated 31 June 2013, footnote, page 1). Producers of the so called substitution products are still listed with their corporate brand names (RCOM 2009). We call to the ECHA to finally find a solution, which does not openly list brand names in their documents.

Furthermore, the producers of "microporous calcium hexaluminate insulating products" (in RCOM 2009 and RCOM 2011) do all receive their raw materials from one single supplier; a promotion for one company. By the way, the material does not constitute a substitution product but is only a raw material for a type of refractory products. Scientific studies and measurements of operators have proven that no or very low fibrous dust expositions exist during operation of industrial furnaces with RCF/ASW or other HTIWs, which would have an effect on operating staff. This aspect has to be considered for inspections as well.

The European industry of furnace manufactures needs this material to achieve the high level set by the European Commissions 2020 programme for energy saving and the reduction of greenhouse gas emissions. More than 30% of energy saving and respectively CO2-reduction can be achieved in industrial high temperature application by using HTIW and specifically RCF/ASW.

Practical advices are given in the VDMA Guide Energy Efficiency (see attachment).

Nevertheless, further discussions should be continued among all involved stakeholders and regulatory bodies in a professional way based on science and practical experience in order to achieve the aims of REACH and the targets from the European climate change programme (ECCP).

CECOF is the European Committee for Industrial Furnace and Heating equipment associations. CECOF incorporates the relevant national associations of industrial furnace and heating equipment in Europe and as such all major companies in this field. Member companies of national CECOF associations produce furnaces and apparatus used in high temperature applications for the heat treatment of products made of steel, nonferrous metals, ceramics, porcelain, glass etc.

Conclusion:
Since 2009 there have been no fundamentally new consolidated findings which would cause us to revise our former statement. Based on our practical experiences these specifications endure. Adequate regulation exists since many years and it is sufficient for worker protection (Art 58.2), an authorisation process give no advantage for workers safety but tremendous disadvantages for the environment and for the competitiveness of the European industry (Art 55 should be taken into account).

In Germany, manufactures of ITPE do a substitution analysis for each of their ITPE, based on the Technischen Regel für Gefahrstoffe TRGS 619 and document these.

CECOF is represented in this expert working group (TRGS 619) by German experts (manufactures of ITPE), who participate to give good practice advice based on their own experiences. Their knowledge includes all matters of the design of furnaces which focus on the use of refractory materials including RCF/ASW products. The actual new version (2013) reflects the state of the art.

In the preparatory study ErP-ITPE one of the basic requirements is to level the outside wall temperature of the furnace at max. value. Fulfilling these requirements is possible only in combination with insulation materials which contain RCF/ASW. By these means an economically reasonable reduction of energy use incl. CO2 could be achieved.

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding the low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the exemption request/coverage by other legislation:
Furthermore, thermal insulation properties influence furnace energy loss and are therefore environmentally relevant. In addition to firmly installed RCF in our furnaces, exposure of our service staff occurs during furnace maintenance activities and removal of RCF (e.g., element exchange, pipe changes, . . . ). The old bulk fiber must be removed and renewed. Annual consumption is approximately 20 kg.

Comments on national legislation: In Germany, the handling with RCF is regulated by legislation TRGS 558 "activities with high temperature wool" and TRGS 619 "substitute for products made of aluminum silicate wool". TRGS 558 assures safeguards for the protection of employees and other persons and is always applied as a legal requirement in activities with products made of RCF. TRGS 619 "Substitute for products made of aluminum silicate wool" describes availability of alternatives and application limitations of substitutes.

Commentary on the availability of alternatives: We have used RCF products for several decades in our high-temperature furnaces. So far, furnace manufacturer(s) cannot provide validated substitutes for high temperature applications (without change of thermal insulation properties at high temperatures for long durations in conjunction with process stability). This was also confirmed by a leading manufacturer of fiber in this temperature range, who themselves researches intensively for substitute products. Also TRGS 619 "Substitute for products made of aluminum silicate wool" indicates that currently no substitutes are available for high temperature applications.

Usage possibilities of molded parts are limited and applied everywhere, where bulk fiber can be avoided.

Comments on employee exposure: Direct staff handling of RCF only occurs during maintenance activities involving changing of heating elements in the furnace, when gaps must be filled with bulk fiber.

Factory exposure: activity 6-8 x per year, 1 hour removing old RCF, refilling new RCF 2-3 hours. Total annual time is thus 24-80 hours. Due to activity spreading over several persons, handling of RCF can be assumed as under 40 hours per person per year. This corresponds to exposure category 1 - low risk according to TRGS 558.

See reply to comment 2361 in section III
For our maintenance activities a measurement report was issued by employers' liability insurance association. This report confirmed that during exchange of high temperature fibers were – as measured - only non-respirable dust / not alveolar fraction (each below the detection limit). The classification by the professional association is that no further activities are required to reduce the inhalable group. It was classified as "protective activities are sufficient". TRGS 558 safeguards for protected handling are mentioned which must be observed and minimize the presence of fiber dust. For our usage we take for granted, that there are other legal provisions in the community with standards for the adequate management of the risks and the protection of human health. Therefore we are advocating that the use of RCF for temperatures more than 1050 °C should be exempted from authorization. 

attachment: confirmation fiber manufacturer

Zirconia-/ Aluminosilicate Fibre products (RCF/ASW) are one type of high temperature insulation wools (HTIW). The products are used as an insulation material in industrial thermoprocess equipment (ITPE). Because of the high temperatures (>600°C) the furnaces have to be lined with refractory materials. In most cases traditional heavy materials and insulating firebricks are used. In many applications – batch type as well as continuous furnaces - there is a need for light weight insulating materials made of (HTIW), because of its positive impact on the environment and the competitiveness of the user industries of furnaces. HTIW is used for industrial furnaces which, due to their process operating mode or to cope with the capacity variations (e.g. economic crisis) have to be heated up and cooled down very often. Due to the low specific heat capacity, the necessary amount of primary energy respectively CO2-Emissions can be reduced considerably in comparison to the traditional heavy refractory lining. In case an ITPE manufactures deems the use of RCF/ASW products necessary, a substitution analysis is initiated since many years following existing regulations. The aim is to find a substitution product or to prove it is impossible to find a substitution of the ASW product. In Germany, these inspections are conducted on the basis of technical guidelines for the handling of hazardous materials (TRGS 619). Under the lead management of the German BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) and by involving the aggrieved party the TRGS 619 (Technical Rule on Hazardous Substances) was

The German Engineering Federation, section Thermoprocess Technology (VDMA) is represented in this expert working group (TRGS 619) by German experts (manufactures of ITPE), who participate to give good practical advice based on their own long term experiences. Their knowledge includes all matters of the design of furnaces which focus on the use of refractory materials including RCF/ASW products. The actual new version (2013) reflects the state of the art.

One of the main reasons for substitution is to avoid a possible hazard regarding persons at work with possibly hazardous substances. It has to be mentioned that substitution and worker protection is a primary target for ITPE-manufacturers. The manufactures do have responsibility for the health and safety of their own staff and for external workers following existing regulations.

A scientific study of the Research Association of industrial furnace manufactures (FOGI e.V.) and financed by the German Federal Ministry of Economics and Technology has investigated the aspect of substitution of RCF/ASW. One of the main result is, that for high temperature application less bio-persistent material have significant limitation by temperature and chemical and physical properties (full report see attachment).

ITPE 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).

In the preparatory study ErP-ITPE one of the basic requirements is to level the outside wall temperature of the furnace at max. value. Fulfilling these requirements is possible only in combination with insulation materials including RCF/ASW products. By these means an economically reasonable reduction of energy use incl. CO2 emissions
could be achieved. VDMA and its members (e.g. VDMA) are stakeholders in the ErP-ITPE and developed the principles of draft proposals of the energy requirements in the preparatory. Scientific studies and measurements of operators have proven that no or very low fibrous dust expositions exist during operation of industrial furnaces with RCF/ASW or other HTIWs, which would have an effect on operating staff. This aspect has to be considered for inspections as well. The European industry of furnace manufactures needs this material to achieve the high level set by the European Commissions 2020 programme for energy saving and the reduction of greenhouse gas emissions. More than 30% of energy saving and respectively CO2-reduction can be achieved in industrial high temperature application by using HTIW and specifically RCF/ASW. Practical advices are given in the VDMA Guide Energy Efficiency (see attachment). Nevertheless, further discussions should be continued among all involved stakeholders and regulatory bodies in a professional way based on science and practical experience in order to achieve the aims of REACH and the targets from the European climate change programme (ECCP). The German Engineering Federation, section Thermoprocess Technology (VDMA) is a member association of the European Committee for Industrial Furnace and Heating equipment associations (CECOF). Conclusion: Since 2009 there have been no fundamentally new consolidated findings which would cause us to revise our former statement. Based on our practical experiences these specifications endure. Adequate regulation exists since many years and it is sufficient for worker protection (Art 58.2), an authorisation process give no advantage for workers safety but tremendous disadvantages for the environment and for the competitiveness of the European industry (Art 55 should be taken into account). In Germany, manufactures of ITPE do a substitution analysis for each of their ITPE, based on the Technischen Regel für Gefahrstoffe TRGS 619 and document these. VDMA is represented in this expert working group (TRGS 619) by German experts (manufactures of ITPE), who participate to give good practice advice based on their own experiences. Their
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Conclusion:
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| 2239 | 2013/09/18 13:52 | Glass Alliance Europe, Industry or trade association, Belgium | For certain industrial insulation applications above 900°C, Refractory Ceramic Fibres products and above 1200 oC aluminosilicate fibrous materials are the best performing materials and substitution is not possible. The use of these materials in the glass industries is limited to a minimum and it is well monitored, controlled and regulated under current legislation. Workers dealing with these materials are experienced and trained and are submitted to regular health surveillance.
Furthermore, the prioritisation with the consequence of authorisation would lead to negative impacts on energy savings and environmental protection and ultimately undermining the competitiveness of the industry.
For these reasons, the glass industries believe that Al-RCFs should not be prioritized and consequently not be included in Annex XIV of REACH, the so called "authorisation list". (please see arguments developed in the attached file) | Regarding the description of uses: See reply to comment 2272 in section I
Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I
Regarding low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I
Regarding the unclear substance identity: See reply to comment 2272 in section I
Regarding the use of the substance as an article: |
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<th>ID</th>
<th>Date</th>
<th>Company, Germany</th>
<th>Response</th>
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<td>2235</td>
<td>2013/09/17</td>
<td>Nordenhammer Zinkhütte GmbH</td>
<td>We operate a Zinc electrolysis plant and produce ~140,000 t/y Zinc. Our raw materials are sulfidic ore concentrates and secondary raw materials. The first process step for treatment of the ore concentrates is the roasting. The ore concentrates react at a temperature of 950 to 1000 °C with air to transform them into Oxides and Sulfur dioxide gas. The reaction is exothermic, and the heat is recovered in a waste heat boiler. Without a suitable heat isolation material it is not possible to operate the process. There are only few materials for heat isolation available for parts of the high temperature sections of the process, where a certain flexibility or the isolation is necessary, and bricklining is not an alternative. All available materials are Al-Si or Zr-Si based. We have Al-Si based isolation material in use and have not found an alternative with less hazardous classification. At least for the use in the roasting of Zinc ore concentrates, we do not think, authorization is an appropriate tool: 1. There is no risk for the general public, because the material is used in industrial applications only. 2. The heat isolation material is encapsulated and emission of fibres can be excluded. There is no risk for workers during operation of the furnace. 3. During maintenance operations this heat isolation material is handled in dedicated areas by especially trained personal under controlled conditions and with adequate safety precautions. Exposure of maintenance personal to fibres is highly unlikely. 4. Handling and waste disposal occur in accordance with German legislation and the guidelines of the German professional associations. In § 2.2.2.2. the number of exposed workers is estimated to 25,000 in the EU. This seems to be overestimated: • 1,500 installation contractors are listed. Working conditions should be similar like in our maintenance operation, where exposure is highly unlikely.</td>
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<td>See reply to comment 2292 in section I, <strong>Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:</strong> See reply to comment 2272 in section I, <strong>Article 58(2) exemption response</strong> Please see response to comment 2489, this section, <strong>Regarding the description of uses:</strong> See reply to comment 2272 in section I, <strong>Regarding the non-availability of alternatives/information on alternatives in background document:</strong> See reply to comment 2272 in section I, <strong>Regarding low or controlled exposure/risk of RCFs:</strong> See reply to comment 2272 in section I, <strong>Regarding the priority assessment/scoring:</strong> See reply to comment 2169 in section I</td>
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is highly unlikely.  
- 21,000 exposed employees are counted in end uses. At least for our end use, an exposure of the employees to fibres can be excluded.  
Our conclusion is, that the risks are overestimated. At least the use in the roasting section of a Zinc electrolysis plant should be exempted.

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| 2230 | 2013/09/17 10:48 | United Kingdom, MemberState | It would appear that there may be problems related to the identification of Refractory Ceramic Fibres (RCF) as currently defined on the Candidate List. The current two entries use descriptions that differ substantially from those more commonly used across the EU. This is confirmed by the ECHA analysis conducted as part of the prioritisation exercise. In this it is conceded that they may have failed to identify all the registrations that may be covered by the entries (ECHA states “This tonnage has to be seen as minimum as there might be more registrations falling under the Candidate List entry”)  
Furthermore, the entries make an artificial division between aluminosilicate RCF and zirconium-aluminosilicate RCF. Whilst two entries exist of the Candidate List, the ‘two’ materials are covered by the same CAS number and so should use a single description.  
Taken together this could lead to problems for duty-holders, regulators and enforcement agencies in clearly identifying which substances are actually subject to authorisation.  
A further complication is that some suppliers may have taken the decision that the RCF-based products they place on the market are articles (e.g., ropes, gaskets, blankets, mats, etc). As authorisation is only applicable to substances, this would mean that the only stages subject to authorisation would be the production of these articles. This could greatly reduce the number of sites at which exposure could occur and significantly alter the assessment of widespread dispersive use.  
Further complications arise as it can also be argued that, as with other man-made fibres, the RCF fibres themselves are articles. The fibrous nature of the RCF materials is the result of a deliberate manufacturing process and unlike some other fibrous minerals (e.g., asbestos) they are not necessarily intrinsically fibrous. |

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| 2222 | 2013/09/16 | Selas-Linde, | Draft: RCF “authorization procedure”  
Introduction:  
Regarding the unclear substance identity:  
See reply to comment 2272 in section I  
Regarding the status of RCFs as substance or article:  
See reply to comment 2292 in section I  
Regarding the use of the substance as an article:  
See reply to comment 2292 in section I |
Selas-Linde is an affiliated company of Linde Engineering and is specialized in designing, fabricating and constructing industrial furnaces / incinerator etc. for refinery and process purpose. In this field of industry we apply refractories for furnace internal insulation. The type of refractory material is designed and selected according to composition of flue-gas-atmosphere, temperature, mechanical load (e.g. friction, resistance against loads etc.) installation requirements and process requirements (e.g. constant operation, turn-down flexibility, heat capacity etc.) and local availability. Temperatures in these furnaces range from approx. 1000°C to 1750°C. We need and use for these types of furnaces all kind of refractories available and suitable for application (e.g. bricks, castables and ceramic fibres (blankets, board, vacuum-formed elements, modules, paper, rope etc.) and other insulating materials.

User Comments:
1. Substitution
Ceramic fibre (RCF) is one of the most important materials we need for a furnace design. A replacement by an alternate material with identic or similar characteristic is not available on the market today. The only available fibre (AES) is applicable for temperatures up to 1000°C. In our experience the fibre cannot be used for temperatures over 1000°C. It becomes brittle and loses strength and its characteristic flexibility. Deterioration will proceed rapidly. Other kind of material mostly cannot be used due to the following reasons: (see par 2-5 below)
2. Design Requirements
For all furnace we have to use fibre for thermal sealing of expansion joints which are indispensible for any kind of insulation, because thermal expansion has to be compensated with some flexible and temperature resistant material! This sealing material must have the characteristic (flexible and high insulating) of RCF-fibre material!
For some areas we need a light efficient insulation because of static requirements (e.g. roof-lining).
3. Process Requirements
For some furnaces we have to minimize heat storage in order to avoid process-pipe damage after plant trip. Otherwise steam quantity has to be increased for cooling purpose, which will reduce competitiveness due to much higher invest cost.
For some furnaces we need fibre insulation for cyclic operation which requires heating up and cooling down easily without perishing refractories. In this operating case a catalyst have to be reactivated! Generally our Client (e.g. BASF, DOW, Shell, BP etc.) require quick
heating up in order to use time for production. Also the time for dry-out necessary for furnaces with castables and bricks can only be reduced by using fibres. If fibres can be used the heating-up- and cooling-down-gradient can be increased and would reduce time for dry-out and time until production can be stared.

4. Safety
For safety reasons we have to apply fibre lining on roofs. Otherwise inspection and repair-work can only be done by using a scaffold for protection, which is hardly to be installed, because it is expensive and time consuming.

5. Consequences
Any authorization request would create immense number of individual technical solutions for which authorization is necessary in order to keep reasonable, economic and solid solutions and to avoid additional technical problems for design resp. quality and operation of furnaces. The impact of cost for lost production due to extended heating up, cooling down period, safety measures etc. can be avoided if “RCF fibres” may be used as everywhere in the world out of Europe.

31.07.2013 Stephan Wild

| 2219 | 2013/09/16 10:22 | Individual Austria | Alumino silicate and Zirconia-Alumino silicate Refractory Ceramic Fibers are used in the aluminum industry mainly as insulating material in melting and holding furnaces, in particular as lining material for furnace walls, roofs and doors. They are also used during the metal transfer and casting operations in specific formats (e.g. launders, moulds, cone fibers and casting tips). Furthermore, these RCF are used as lining insulating material inside the pre-heating furnaces for rolling and extrusion operations and in the refining process inside the decoater or the swarf dryer. The risks for human health associated with RCF are well known and the appropriate countermeasures are in place. In many cases they are used as lining material in closed systems that do not require frequent maintenance intervention (e.g. every 5-7 years).
Concerning the alternative:
- No valid alternative has been found for temperatures above 900°C. AES materials are stable at temperatures below 900°C and in some cases they are used in the aluminum sector
- New materials like low cement castable may be used in the future but only few tests are available. Because of their characteristics (i.e. heavy material) they require an upgrade and a reengineering of the current system. |

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding the exemption request/coverage by other legislation:
Please see response to comment 2489, this section.
<table>
<thead>
<tr>
<th></th>
<th>2218</th>
<th>2013/09/16 08:58</th>
<th>Sandvik Wire &amp; Heating Technology, ZN der SMT Deutschland GmbH Company Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regarding the unclear substance identity:</strong></td>
<td></td>
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<td>See reply to comment 2272 in section I</td>
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<td><strong>Regarding your proposal of a different risk management option/other measures:</strong></td>
<td></td>
<td></td>
<td>See reply to comment 2169 in section I</td>
</tr>
</tbody>
</table>

There is no clear way to distinguish Alumino silicate RCF from Zirconia-Alumino silicate RCF and this can create confusion. In fact, both substances were included in the same registration dossier under REACH.

Based on the above information, AMAG does not support the prioritization of these substances at this stage.

Regarding the unclear substance identity:
See reply to comment 2272 in section I

Regarding your proposal of a different risk management option/other measures:
See reply to comment 2169 in section I

Kanthal is the heating brand within Sandvik. Our lightweight construction has become the norm in many industrial and special non-standard furnaces with the use of high temperature insulation wools (HTIW) up to furnace temperatures of 1550°C. Our products based on ASW are the main group of products for specific and extraordinary high temperature applications. The low thermal mass and respectively thermal conductivity of the ASW products used as furnace linings mean that you can build industrial furnaces which, depending on the type and mode of operation contribute significantly to energy saving, higher output and quality and better availability. Innovative products such as solar cells, non grain oriented steel, computer chips, special tools can be produced using ASW-products.

In the electrically heated furnaces, however, it is very expensive and time-consuming to combine ASW products, such as blankets or folding blocks, with electric heating elements. This has led to the product concept which we introduced to the market in 1978 under the trademark Fibrothal™ and Superthal™.

Today the Fibrothal and Superthal trademark covers a family of products consisting of vacuum-formed HTIW components, with or without electric heating elements.

Within Sandvik we convert yearly approx. 200 t ASW to vacuum-formed modules (Fibrothal). Since 1978, long before the classification and regulation took place, we try to reduce the exposure of our employees to fibre dust. Therefore we took the following measures to reduce the exposition towards dust:

1. Optimization of production processes to reduce exposure
2. Investments in ventilation systems
3. Research for alternatives to ASW in our product portfolio
4. Application trainings with customers and users

These actions were always adjusted following the Regulation at the time. We see that adequate regulation is in place since 1997 and...
wonder why the REACH authorization process should be set-up in addition. Health check’s on a regular basis of every employee actively handling ASW with possible exposure are realized. Within the 35 years of production at Walldorf (Germany), Hallstahammar (Sweden), Hosur (India) and Sakura (Japan), Sonora (USA) we had no indication of health impact on our employees. We have workers working since the beginning in 1978 with ASW in our facilities, without any concern. The ASW products are used in our processes for more than 35 years for the thermal process industry and until now no suitable replacement for this product has been found, despite extensive public and industrial research. So-called alternatives like AES wool suffer from its limited application range (Temperature and Atmosphere). This is investigated and tested in different field tests. The end use defines the process characteristics and therefore a safety factor especially for product limitations have to be taken into account to prevent from serious industrial and laboratory injuries. Most likely the production costs will be increase and therefore the European manufactures will have a location disadvantage against their Non-EU competitors. As we understand the REACH authorization process the target is substitution or alternatively a safe use of classified substances by keeping the competitiveness of the European industry. On our practical experience an authorization process would not lead to more substitution of ASW products than was not realized in the last 2 decades nor improve worker protection related to our uses of these products. So, where is the necessity for such a process?

<table>
<thead>
<tr>
<th>2216</th>
<th>2013/09/15 18:48</th>
<th>EIGA (European Industrial Gases Association) Industry or trade association Belgium</th>
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<tbody>
<tr>
<td></td>
<td>EIGA challenges the scoring for wide-dispersiveness of uses (number of sites X exposure) as being the highest score possible: 3*3=9. This score rates all sites with the highest rating for exposure. This evaluation does not correspond to the data from the Annex XV report summarised in the ECHA prioritisation document. There is clearly a difference of exposure for the workers at the 3 European manufacturers and those of the installation contractors with the workers of the operating furnaces (67% of the uses) and related applications (high temperature insulation: 5% of the uses). - The first group consists of a limited number of sites where the potential exposure could be higher than the OEL although it should be understood that the workers are working in controlled conditions and the RCF is mostly installed in furnaces as</td>
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</table>

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I
prefabricated articles, while the workers of the second group are at down-stream users site with negligible or no exposure because of controlled conditions, continuous process operations and low frequency of inspection. The numbers of workers of the first group is estimated in the prioritisation document at 2350 workers (850 +1500 workers) while the number of workers of the second group is estimated at 21 000, or a ratio in terms of workers of 6% and 94%. The rating for wide-dispersiveness of uses should be weighted taking into account the ratios of the two groups of workers (6% and 94%): Group of workers Nb. of sites Rating Nb. of sites Rating exposure % of workers Total 1: manuf., contractors “medium” 2 3 6 0.36 2. Furnaces operators “high” 3 1 94 2.82 Total score for wide-dispersiveness of uses: 0.36 + 2.82 = 3.18 or 3

Regarding low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

Regarding the priority assessment/scoring:
See reply to comment 2444 in section I

| 2213 | 2013/09/13 15:39 | NETZSCH Gerätebau GmbH Company Germany | We support the statement of Messrs Sandvik. The objections presented by Messrs. Sandvik against this possible admission procedure (authorization) of aluminosilicate wool (ASW) according REACH regulation (EG) No. 1907/2006 align with our experiences of many years. | See reply to comment 2218 |

| 2212 | 2013/09/13 10:28 | CERAMICA TRES ESTILOS, S.L. IS A COMPANY THAT MANUFACTURES A CERAMIC TILES. We are opposed to the inclusion of Al - Si RCF in annex XIV for the following reasons: • Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for the production of ceramic tiles. • No adequate substitutes are as yet available for these uses. • RCF products are indispensable for the fulfilment of the objectives of 2020 EU’s and industry’s increasing demand for resources and energy efficiency and associated CO2 reduction. • RCF replacement is not only technically difficult, but it also results in higher operating (energy, downtime, less flexibility) cost. • Our company competes in international markets with the manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization. • During the normal operation of RFC containing industrial | See reply to comment 2437 |
Sehr geehrte Damen und Herren,

Noch kritischer ist der Einsatz unter chemisch aggressiven Atmosphärenbestandteilen zu sehen. Dies gilt nicht nur für die genannten Beispiele aus der Petrochemie, diese gelten eher generell für alle wärmetechnischen Anlagen. Reine Luft-/Abgasatmosphären...

| 2201 | 2013/09/10 13:37 | Forschungsgemeinschaft Feuerfest e.V Other contributor Germany | The Forschungsgemeinschaft Feuerfest e.V. is a non-profit organisation which promotes and supports science and research in the fields of refractory material science and material engineering. 1. Identity of the “substance” and Al-RCF articles The recommendation of Al-RCF for an authorisation is not in line with the aim of article 55 of the REACH Regulation “to ensure a good functioning of the internal market” because 1. the chosen substance identity of Al-RCF in the Annex XV dossier (2011) and in the draft background document from ECHA (24th June 2013 and revision 31st July 2013) covers only a part of the Al-RCF on the European market and 2. more than 90% of Al-RCF which are placed on the European market are articles (modules, blankets, formed shapes,.....) and therefore importers of Al-RCF are not concerned by an authorisation. This leads to competitive advantages for Al-RCF importers and for European Al-RCF manufacturer in case the substance identity is not covered by the substance on the candidate list. 2. Information on alternatives “From 600 °C to approx. 900 °C, generally AES wool products can be used” and “Above 900°C und 1200°C the possibility for using AES wool products......” It is not possible to give a general statement on alternative materials! In high temperature processes above 600°C the choice and the combination of different refractory materials have to be evaluated and decided on very carefully to prevent from technical and environmental disasters! For a safe and failure-free operation of high temperature processes it is necessary to consider the |

| Regarding the description of uses: | See reply to comment 2272 in section I |
| Regarding the inter-substitutability with RCFs not identified as SVHC: | See reply to comment 2272 in section I |
| Regarding the use of the substance as an article: | See reply to comment 2292 in section I |
| Regarding addressing imported articles: | See reply to comment 2272 in section I |
| Regarding the non-availability of alternatives/information on alternatives in background document: | See reply to comment 2272 in section I |
| Regarding the existing threshold for RCFs: | See reply to comment 2272 in section I |
| Regarding the priority assessment/scoring: | See reply to comment 2444 in section I |
mechanical properties, the chemical resistance (e.g. possible interactions with the process media) and the thermal stability of refractories and high temperature insulation wools case by case.

3. Prioritisation

Scoring for Al-RCF is in-transparent and not traceable!

Inherent properties (IP)

SCOEL and DECOS classified Al-RCF as non-genotoxic. SCOEL (Scientific committee for occupational exposure limits) recommended a threshold at 0.3 f/ml in SCOEL/SUM/165 September 2011.

Score: 0 instead of 1

Volume (V)

Volume 24000t/yr (ECFIA)

- Al-RCF contain approx. 50 % "Shot" ("Shot" is harmless for human health)
- only 2 % (of the remaining 50 %) have WHO dimensions that meets the criteria "inhalable dust" and should be calculated.

Score 5 instead of 9

Uses - wide dispersiveness (WDU):

a) Site: high (user sites where Al-RCF articles are used)

Score 3

b) Release

Al-RCF is no consumer product and therefore only exposure to workers could occur who handle the materials actively.

- Manufacture:

o Only 3 companies in Europe produce Al-RCF.

The production of Al-RCF takes place under controlled conditions. The exposure is lower than the recommended threshold of 0.3 f/ml in most cases.

o Where higher exposure occur (above national OELs), experienced workers wear protective equipment (PSP).

- Downstream User:

o Exposure occurs only during the lining (mounting) and the breaking out of the Al-RCF.

o During the lifetime (often more than 10 years) of a thermal treatment device (e.g. furnace, kiln....) no exposure occurs. During lining and breaking out RMMs are state of the art to control workplace exposure. If exposure could occur the workers are protected with personal protection equipment. Controlled or insignificant exposure
Score 1 (the same result as in the 2nd prioritization by ECHA, May 2010) instead of 3
Overall score: 3*1 = 3
Total Score: 8
All in all, the facts presented above strongly support the cancellation of the prioritization of Al-RCF for Annex XIV!

<table>
<thead>
<tr>
<th>Company</th>
<th>Date/Time</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Spain</td>
<td>2013/09/06 14:09</td>
<td>We are opposed to the inclusion of Al-RCF in annex XIV for the following reasons: ● Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production, ● No adequate substitutes are as yet available for these uses. ● RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2. ● The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility). ● Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization. ● During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).</td>
</tr>
<tr>
<td>Germany</td>
<td>2013/09/04 08:43</td>
<td>Comment why not to include Aluminosilicate Refractory Ceramic Fibers in the authorization list History and technical background: MTU aircraft propulsion engines are using Aluminosilica Ceramic Fibers for thermal insulation since decades in operating aircrafts. These materials are chosen because they are high temperature resistant up to 1250°C and do show only little degradation of their specific thermal insulation properties over time. There is also evidence from long term engine use that material properties do not significantly change after soaking with condensation water or cleaning liquids and redrying during engine overhaul or engine operation. The insulations protect e.g. the Oil System from coking in a high temperature environment or protect components from being overheating and loosing the required mechanical properties needed.</td>
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</table>

See reply to comment 2437.
for safe operation. By using the specific heat transfer data and resulting material temperatures for analytical calculations in the design phase, they are part of the propulsion system type design. The ceramic fibers used are encapsulated in heat resistant sheet metal foils. The capsules are welded tight during the production process at the supplier except that there are tiny breather openings to prevent the insulation from collapsing or blowing up during heatup or cool down. The breather holes are covered by fine fabric and mesh and have a sheet metal cap to prevent fibers from escaping.

Certification: The aircraft engines containing such insulations are certified by FAA or EASA, are flying in numerous engine applications like PW2000 for Boeing 757, PW4000 for Boeing 777, V2500 for Airbus A319/320/321, GP7000 for Airbus A380 all around the globe and are overhauled in a worldwide aircraft engine industry. As soon as aircraft engines are certified by the FAA, EASA or other Airworthiness Authorities, the design of the engine is frozen and must not be changed without the official approval by the Airworthiness Authority. The type design testing prior to certification includes several engine tests with thermal instrumentation to control temperatures during operation and by this confirm the thermal models used during engine design. "Any" change to the so called "TYPE CERTIFICATE" needs to be approved by the Airworthiness Authorities and after that becomes part of the type design.

To get the approval for a change of a type design, data need to be provided to prove that the new design is at least as good as the old design or better with respect to the specific operational properties of the individual engines. As a basic rule a change must not negatively affect the Failure Modes which the Original Equipment Manufacturer (OEM) has foreseen in the risk analysis and must not introduce new failure modes.

Replacement of fibers not conforming to REACH: Current replacement materials that conform to REACH do not fulfill the temperate range of the Aluminosilicate fibers that are currently used. As the replacement insulation materials do have different material properties, the objective evidence needs to include test data and
analytical data for that material including wettening and redrying cycles which is hard to show. Therefore it is unacceptable to ban an insulation material from the industry that is part of an engine design that was certified according to international rules and did conform to legal requirements at time of design. Changes to the insulation material may cause a variety of changes in the technical behavior of a component like a change in the component temperature thus influencing the strength of a material which then may invalidate a component because FAR 21/FAR 33 or EASA part 21/EASA CSE regulations are no longer met. Showing compliance to the requirement that there is no negative effect to the engine compared to the current design and engine experience is hard to achieve. Engines that are currently being designed are using REACH conform insulation materials taking care of specific material properties. Why not include these materials into the Authorization List: The Aluminosilicate Fibers are in the REACH candidate list. To correspond to REACH regulations, customers are informed how to handle these materials and are getting respective data. Handling encapsulated aluminosilicate fibers during e.g. quality assurance, shipment, assembly and disassembly does not contain a health risk for people. In case that insulation packages are found damaged (cracked) during overhaul, protective means are to be taken according to the safety data sheet that is delivered to the customer along with the product.

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<th>Date</th>
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<th>Comment</th>
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</table>
| 2185       | 2013/09/03 17:02 | German Institute for Refractories and Ceramics Company Germany | Regarding the unclear substance identity: See reply to comment 2272 in section I  
Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I  
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I |
of any authorisation process should aim at a clear substance identity which covers all Al-RCFs on the European Market (manufactured in the EU and imported).

Comment on 2.3 Availability of information on alternatives

High temperature processes are very complex and customised, so a “case by case” evaluation of suitable refractory materials for each part of the process equipment has to be done from the beginning during construction planning/engineering.

Because of the very complex industrial applications it is not sufficient to see only the temperature demand when discussing possible alternatives or substitutes for Al-RCF-materials in the temperature range from 300 °C up to about 1400 °C. Mechanical properties and chemical resistance (e.g. interactions with the process media at working conditions) have the same importance as thermal stability. Their use is a guarantee for effective, safe and energy efficient industrial processes. Most often a combination of all kind of refractories are needed and used in an industrial application. The use of Al-RCF products can ensure the specific processability, thermal stability, corrosion resistance, mechanical flexibility and thermal shock resistance of i.e. furnace linings.

Because of the “case by case” situation a general use of AES products in the temperature range from 600°C to 900°C (1200°C) can not be recommended. The use of AES products depends on the particular process conditions. In the presence of atmospheres containing acids and condensable water vapour the lifetime of AES is significantly reduced. At 800°C AES-fibres already start to recrystallize and will get brittle.

Whether AES wool products can be applied has to be carefully evaluated on a case-by-case basis.

PRE - European Refractories Producers Federation Industry or trade association Belgium

PRE represents the European Refractory Producers covering nearly 20 000 employees and an annual turnover in 2012 of 3 billion Euro.

Substance ID

During the public consultations on the candidate listing in 2009, we have pointed out that the substance identification made in the Annex XV dossiers was not correct to identify the Refractory Ceramic Fibres sold on the market. The identifiers chosen to include Aluminosilicate RCF and Zirconia Aluminosilicate RCF on the Candidate List were designed specifically for samples used for animal testing, but not the commercial products. We requested that this matter should be rectified before prioritization could be considered. This lead in 2011 to the submission of two additional Annex XV dossiers, with a wider scope but still based on the aluminosilicate and zirconia

Regarding the unclear substance identity: See reply to comment 2272 in section I

Regarding the inter-substitutability with RCFs not identified as SVHC: See reply to comment 2272 in section I

Regarding the priority assessment/scoring: See reply to comment 2444 in section I

Regarding low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I
aluminosilicate RCF description which could be found in the testing samples. These additional entries to the candidate list did therefore not resolve fully the issue of the incorrect substance identification. As long as the substance ID is not correct, prioritisation cannot go forward.

Commercial RCFs, covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 are all covered by one single CAS number (142844-00-6), one single EU number (604-314-4) and one registration dossier. It is therefore possible to define the refractory ceramic fibres which are classified Carc. 1B under the CLP Regulation by one substance ID. We therefore request that the dossiers are corrected and consolidated into one candidate listing.

Intersubstitutability

There are certain RCFs (e.g. RCFs based on Chromia instead of Zirconia) which have the same application and user profile, which are covered by the same Index No. 650-017-00-8 of Annex VI of the CLP Regulation (classified as Carcinogen 1B) but which are not covered by the current substance ID of the substances on the candidate list and put forward for prioritisation, as they do not fulfil the condition a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges. Therefore, we repeat our position that prioritization cannot be considered until the substance ID is corrected, so until all substances placed on the market having the same application and covered by the same classification under CLP can be considered together.

Scoring

Based on the arguments provided below, we consider that the scoring given to Aluminosilicate RCF and Zirconia Aluminosilicate RCF is wrong and should be corrected.

Inherent properties: According to the general approach to prioritisation, a different scoring should be given for substances with different potencies to elicit health effects. Substances with carcinogenic properties where there is a threshold mode of action are to get a scoring of “0”. The Scientific Committee on Occupational Exposure Limits (SCOEL) classified RCF in 2011 as SCOEL Carcinogen group C: genotoxic carcinogens for which a practical threshold is supported. Therefore, the scoring for inherent properties is more correct to be “0” instead of “1”.

Volume: The scoring for the volumes is considered very high (> 10 000 t/yr) for aluminosilicate RCF. These figures are based on the
analysis of the joint registration dossier received. Here we would like to point out that the volume mentioned in the joint registration dossier submitted on RCF (CAS 142844-00-6):
- did not differentiate any volumes between zirconia aluminosilicate RCF and aluminosilicate RCF
- includes other RCFs than the ones covered on the candidate list (see comment above on substance ID)
- includes fibres and particles which have a length weighted geometric mean diameter less two standard geometric errors of more than 6 micrometers and therefore are not covered by the current substance ID (condition b of the substance ID).
We therefore consider that the volume scoring is overestimated.
In addition, the priority setting for volume is based on a substance-based assessment whereby every molecule of a substance has the same hazard profile so higher volume leads to higher prioritization. In the case of RCF, the hazard profile is based on the three dimensional shape and there is not a priori a correlation between the total volume and the hazard profile. In the case of fibres, the criterion for `volume` under REACH is not very appropriate and even misleading and any scoring for volume of fibres should be considered with much caution.

Uses – wide dispersiveness: With regard to the release of RCF, the following facts should be taken into account:
- Consumer exposure to RCF fibrous dust could never be demonstrated.
- RCFs are covered by Directive 2001/41/EC on restrictions on the marketing and use of certain dangerous substances and preparations, as regards substances classified as carcinogens, mutagens or substances toxic to reproduction. This means that RCF cannot be placed on the market for use by the general public.
- Exposure to airborne fibres only occur during the primary production (bulk wool and blanket) and downstream manipulation (manufacturing of secondary articles: paper, modules, vacuum formed shapes; installation, maintenance and removal of linings). During storage, transport and "in situ", fibre dust exposures are negligible if existing at all. Hence RCF dust exposures are a very specific workplace issue and can be controlled via proper workplace hygiene measures (including local exhaust ventilation) and personal protection equipment (e.g. respirators where appropriate).
We therefore conclude that RCF does not exhibit a 'wide-dispersive use' as defined in the different background documents used in the guidance on prioritisation and the maximum score of "9" is
| 2182 | 2013/09/02 16:55 | Company Austria | The production of substances and products by the German and European steel industry is mainly based on high-temperature processes. In the plants of the steel industry, such as coking plants, steel works, rolling mills and forging, refractory and insulation materials must be used, which make it possible to handle these processes safe and energy efficient. Different materials are used that have been developed specifically to the respective application processes to get there. Thus, for plants that are in direct contact with liquid pig iron / steel, such as steel converters, metallurgical vessels, blast furnaces and coke ovens in the brickwork, massive refractory materials are used. In addition to a number of other insulating materials at temperatures up to 1200 ° C, the iron and steel industry uses aluminum silicate wool in the temperature range above 1200 ° C. As a lightweight and flexible materials these contribute to a significant energy savings, which is not possible with other materials. This applies particularly for furnaces in the range of hot-rolling processes that require a low density of the insulation materials used. The density also has a direct influence on the static, to the dimensions of the equipment and the physical structure of the foundations. Another application of aluminum silicate wool is the use as gasket material of coke oven doors, where flexibility is required in conjunction with good sealing performance and durability. Substitute materials with comparable impermeability effect are not existing. Without alumina silicate wool increased emissions of pollutants leading to non-compliance of licensing rules would occur. Additionally increased burdens of employees and the environment would result. An additional advantage of alumina silicate wool is the low heat capacity and high thermal shock resistance, which enables a flexible application even with varying operation cycles. Under production conditions that are characterized by many successive heating and cooling processes, the expansion and shrinkage associated with the heating cooling and would lead to the destruction of alternative massive refractories. Alternative materials have been investigated, but so far no suitable material has been found, corresponding to the thermal and physical properties of aluminum silicate wool. |

See also replies to comments 2130 and 2138 in this section.

Regarding the description of uses:
See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

Regarding the exemption request/coverage by other legislation:
See reply to comment 2272 in section I

Regarding your proposal of a different risk management option/other measures:
See reply to comment 2272 in section I

Regarding the priority assessment/scoring:
See reply to comment 2272 in section I
mechanical requirements. With poorer insulation and higher energy consumption such materials may lead in addition to significantly reduced maintenance intervals associated with shutdowns and correspondingly higher costs with increased environmental pollution, energy consumption and CO2 emissions. The use of conventional refractory materials would lead to a technological step backwards and thus have a negative influence on the competitiveness of German and European steel industry.

In the steel industry the protection of workers is of first priority, regardless if it is related to conventional refractory bricks, alumina silicate wool or other fiber materials. Aluminum silicate wool products are used under controlled conditions, such as described in the German TRGS 558 (Technische Regel für Gefahrstoffe 558. Tätigkeiten mit Hochtemperaturwolle = Technical Rule for Hazardous Substances 558, Activities involving high-temperature wool). Reports of occupational diseases related to aluminum silicate wool products are not available. The facts described above lead to the conclusion that the industry has reached a good performance in worker safety in combination with environment protection. Alumina silicate wools are not made for private end use, only for industrial high temperature processes. End products of the steel industry do not contain Alumina silicate wools. Therefore the inclusion into Annex XIV of the REACH Regulation does not improve worker safety and envoronment protection. It therefore does not make sense.

**RCF and Listing Criteria for Annex XIV:**

Comments for consideration by ECHA

By: L. Daniel Maxim and Ron Niebo

Everest Consulting Associates, Inc

Cranbury NJ 08512

posts@aol.com

(609) 655-7426

Sept. 1, 2013

The following comments are a summary of the comments and arguments laid out in the attached, formatted, and fully referenced MS Word document. Please refer to the complete Word document for more information. - Dr. Maxim.

Summary

These comments have been prepared by L. Daniel Maxim and Ron Niebo of Everest Consulting Associates (ECA) [Endnote 1], a firm that for the past twenty five years has conducted research on

**Regarding the description of uses:**

See reply to comment 2272 in section I

**Regarding the priority assessment/scoring:**

See reply to comment 2444 in section I

**Regarding low or controlled exposure/risk of RCFs:**

See reply to comment 2272 in section I

**Regarding the non-availability of alternatives/information on alternatives in background document:**

See reply to comment 2272 in section I

**Regarding the unclear substance identity:**

See reply to comment 2272 in section I
health and safety matters for various producers of High Temperature Insulating Wools (HTIW) and for their stewardship organizations; ECFIA in the European Union (EU) and the HTIW Coalition, in the United States. Alumino-Silicate Glass Wools (ASW), also termed Refractory Ceramic Fibres (RCF) [Endnote 2], are included among the products manufactured by ECFIA and HTIW Coalition members.

On the recommendation of the German Authorities, RCF was placed on the REACH Candidate List as a substance of very high concern (SVHC) and regulatory authorities are now deciding whether or not to place RCF on Annex XIV as a substance requiring authorisation. The European Chemicals Agency (ECHA) developed a draft background document (dated 24 June 2013) that proposes to prioritize RCF [Endnote 3] for its 5th recommendation of priority substances for inclusion in Annex XIV (list of substances subject to authorisation). For reasons discussed in these comments we believe that it is inappropriate to include RCF in Annex XIV.

ECHA has developed four broad criteria for prioritisation of substances which might require authorisation (ECHA 2010) and numerical scoring criteria to prioritize candidate materials. These comments examine RCF using the ECHA criteria. The ECHA Prioritisation Criteria include:
- Inherent Properties: Persistent, Bioaccumulative and Toxic (PBT) or very Persistent, very Bioaccumulative (vPvB) properties;
- Wide dispersive use;
- High volumes; and
- Additional considerations; such as (1) there is adequate control of risks, (2) uses can easily be replaced by another 'form' of the substance with a similar (or even worse) hazard profile, which is not on the candidate list [Endnote 4], or (3) uses have been identified, but the resulting releases are insignificant as such or insignificant compared to releases resulting from natural sources and/or uses not in the scope of the Authorisation Title of REACH.

In brief, we conclude that an appropriate numerical prioritization score for RCF totals 8 points, whereas ECHA concluded that the appropriate total scores for two related materials were 19 for Al-RCF and 17 for Zr-RCF, respectively as shown in Table 1. The reasons for our conclusions are detailed in this submittal.

Table 1. Comparison between the scores calculated by ECA and ECHA.

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<th>Category</th>
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<tr>
<td>Analysis AL-RCF</td>
<td>Zr-RCF</td>
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Specifically:

- **Inherent Properties**: RCFs are not PBT or vPvB substances, a fact acknowledged in the original German Government proposal to list RCF as a SVHC. Moreover, according to analyses by DECOS and SCOEL the mechanism of action by RCF is not genotoxic.

- **Wide dispersive use**: RCF applications do not result in wide dispersive use;
  - RCF is an industrial, not a consumer, product and available data indicate that even concentrations at the producer plant boundaries and landfills where RCF is disposed of are not detectable or very low. Thus, RCF exposure is confined to the workplace. The industry has a long-standing product stewardship program in place (for both RCF producers and their customers) designed, among other things, to reduce workplace exposure. The exposed cohort in Europe was estimated to be (at most) 25,000 workers—most of whom have only episodic exposure to RCF. Workplace fibre concentrations (exclusive of any use of personal protective equipment) have decreased over the years and now average (on an employee weighted basis) approximately 0.2 to 0.3 f/ml. In Europe, users are under legal obligation to search for substitutes for RCF. With the development of AES-Wools, RCF production in Europe has decreased substantially (approximately 50%) in the past 20 years. For all these reasons, we conclude that RCF does not meet any reasonable definition of a material with “wide dispersive use.” [Endnote 5]

- **Volume criterion**: RCFs fall under the ‘relatively high (100-1000 t/y category, with a volume score of 5 following ECHA criteria.

- **Additional considerations**:
  - RCF producers in Europe and users are minimizing the risk through the CARE/PSP Programme, which is in alignment with current strategies aimed at developing and maintaining health and safety at work [Endnote, 6];
  - RCF producers and their customers comply with either the manufacturers’ recommended exposure guideline or the regulatory occupational exposure limit, whichever is more stringent (see
In September 2011 the Scientific Committee on Occupational Exposure Limit Values (SCOEL) issued a recommendation for an 8-hour time weighted average (TWA) limit of 0.3 f/ml, which can be met using engineering controls and workplace practices in most jobs; measured average fibre concentrations of RCF have decreased substantially over the years, reflecting progress in the industry’s stewardship activities; RCF users are legally obliged to search for substitutes—and substitution has indeed taken place (see above); and the RCF industry has measured stack emissions and plant boundary fibre concentrations in studies conducted in both Europe and the United States and found that emissions and fence boundary fibre concentrations were either not detectable or de minimis. A similar study in Canada (overseen by the Canadian government) gave consistent results. Thus, the additional considerations noted in the fourth prioritisation criterion also support our contention that authorisation is not required.

ECHA has apparently recognized the need to evaluate aspects not directly addressed in the simple scoring system by introducing a second tier that addresses regulatory effectiveness (ECHA, 2010): “ECHA’s so far used prioritisation approach is a two-tiered procedure, in which in tier 1 the potential priority of a substance on the basis of the criteria of Article 58(3) was estimated before in tier 2 ‘regulatory effectiveness’ considerations have been taken into account, in order to conclude on the final priority that should be given to a substance for recommending it for inclusion in Annex XIV (see section 3.3). This second tier was introduced because situations may occur where inclusion in Annex XIV will require regulatory efforts but most likely will not result in benefits for human health or the environment, or where authorisation may hamper the use of other risk management instruments while not contributing significantly to achieving the risk reduction.

Therefore a second tier will in the same manner be used with the scoring algorithm as with the verbal-argumentative prioritisation. However, the regulatory effectiveness criteria used so far are rather specific examples that were derived from a limited number of existing cases and do clearly not cover all situations where
regulatory effectiveness aspects would need to be taken into account in order to arrive at a well founded conclusion as to whether to recommend a substance to Annex XIV.

Therefore, it has been decided that for tier II of the scoring based prioritisation approach all available information will be taken into account that is relevant for drawing a conclusion in the prioritisation process as to whether a substance should be prioritised and recommended for inclusion in Annex XIV.”

In thinking about possible risks posed by RCF, it is important to understand the available epidemiological data (Utell and Maxim, 2010). Simply put, the results of on-going epidemiological studies of occupationally exposed cohorts indicate that workers exposed to RCF have developed respiratory symptoms similar to that reported in other dust-exposed populations. These studies indicate some measureable effects (e.g., pleural plaques and decreases in certain spirometry results in which small changes were seen in the initial cross-sectional study but with follow-up the "aging curve" reverted to normal with the lower exposures) and otherwise no disease—no interstitial fibrosis, incremental lung cancer, and no mesothelioma—have been observed to date.

An independent analysis (IOM, 2011) performed for DG Employment, Social Affairs & Inclusion of the European Commission by the Institute of Medicine (IOM) addressed the health, socio-economic, and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work. RCF was among the materials included in this study. IOM evaluated the costs and benefits of imposing two distinct OELs for RCF, 1.0 f/ml and a more stringent level, 0.1 f/ml. They concluded that the likely risks related to occupational RCF exposure were quite small:

"The predicted number of deaths from past occupational exposure to RCF using our worst-case assumptions about potential risks is low (in 2010, no attributable deaths in manufacturing and two deaths in downstream users). The predicted number of deaths decreases in the future so that by 2050 there are no predicted deaths occurring as a result of RCF exposure at work. The number of incident lung cancers is similar to the estimated number of deaths. Introducing an OEL of either 0.1 or 1.0 f/ml has no important effect on the predicted cancer deaths or registrations from RCF.”

The IOM analysis did not address the benefits of authorisation
specifically, but it is clear from this conclusion that such benefits are likely to be small. In our judgment, the available data support the contention that these “tier 2” considerations indicate that risks are now adequately controlled. We remain convinced that RCF should not be required to be authorized under REACH, and hope these comments prove useful to ECHA.

Endnotes:
1 - ECA prepared a similar submittal for ECFIA that was submitted in December 2010. These comments provide more detail and update data originally submitted.

2 - The term ASW has been introduced in recent literature (incl. EN 1094), but we use “RCF” in this response as this is the description still present in most of the regulatory framework.

3 - ECHA actually included two materials, described and scored in two draft background documents; (a) Aluminosilicate Refractory Ceramic Fibres (Al-RCF) and (b) Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) as separate materials. Because these materials have similar chemical and physical properties and can be substitutes for each other, we believe that these should be treated as one material. The identification of the substance(s) is arguably inappropriate as discussed in a more detail in comments submitted to ECHA by ECFIA.

4 - Quoted from ECHA 2010.

5 - We are mindful of the quantitative criterion for wide-dispersive use outlined in ECHA (2010).

6 - See, for example, the UK HSE document “Leading Health and Safety at Work, Leadership Actions for Directors and Board Members” available online at http://www.hse.gov.uk/pubns/indg417.pdf.

zu empfehlen. Betone (auch auf CA6-Basis) und Steine sind frontseitig einsetzbar. Dabei muss aber in Kauf genommen werden, dass der Anlagenbetrieb aufgrund der höheren Dichte der Materialien als auch der niedrigeren Temperaturwechselbeständigkeit umgestellt werden muss. Zudem ist die Speicherenergie der Zustellung größer, was sich in einem sehr viel höheren Energiebedarf beim Aufheizen, höheren Betriebskosten und höheren CO2-Emissionen niederschlägt. Durch die schwere Zustellung müssen die Anlagen auch konstruktiv geändert werden. Die Energiebilanz der Anlagen wird somit insgesamt verschlechtert.


Wir sind der Auffassung, dass unter Beachtung der bestehenden gesetzlichen Rahmenbedingungen keine Gefährdung von diesen Stoffgruppen ausgeht und dass eine Einstufung in den Annex XIV auch im Sinne wirtschaftlicher und ökologischer Betrachtungen in
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<td>2172</td>
<td>2013/08/30 11:15</td>
<td>German Refractory Association Industry or trade association Germany</td>
<td>Additional comments to reference number 32d6def4-9fde-4185-be1a-df806c4f0dff Identity of the substance The substance identity of Aluminosilicate Refractory Fibres (AL-RCF) is wrong. The current substance identification of AL-RCF on the Candidate List (Annex XV-Dossier 2011) and in the draft background document covers only a part of the AL-RCFs on the European Market. There are several Al-RCFs on the market having compositions which are different from the ones defined in the Candidate List entry and in the draft background document. VDFFI already pointed out in its letter to ECHA (Mr. Jukka Malm 2010) and in its comments during the public consultation in 2009 and 2011 that we did not consider the substance identification made in Annex XV reports appropriate to identify the Refractory Ceramic Fibres. A clear substance identification should take place before any further regulatory action e.g. authorisation can be carried out. The chosen description of Al-RCF on the Candidate List and in the draft background document provides a law loophole for AL-RCF-Products.</td>
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<td>2169</td>
<td>2013/08/28 12:17</td>
<td>ECFIA Representing the High Temperature Insulation Industry Industry or trade association France</td>
<td>Overview This commentary raises two important questions relating to the recommended entry of RCF into Annex XIV. Firstly, the Annex XV dossiers do not describe the RCF products that are currently sold on the European market. We believe that the Annex XV dossiers contain information that does not correspond with the technical reality of RCF. The dossiers therefore require a significant improvement to ensure that the Candidate List accurately describes the “substance” presently on the European market. Secondly, we will discuss the prioritisation scoring, particularly regarding the evidence used to assess the potential risk to human health. We believe that the prioritisation score should be revised down. In the opinion of ECFIA, authorisation is not the most suitable approach to future regulation. We request that the “second tier (assessment of regulatory effectiveness)” approach be considered as the regulatory controls already in place are sufficient to protect human health. Moreover – in the event of a potential future authorisation requirement – we do believe that the arguments presented in this</td>
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comment would justify authorisation covering a wide range of applications on the basis of adequately controlled risk. In order to facilitate the review by the Rapporteurs and ECHA we have grouped the comments and additional information under the following headings:

- Substance identification
- Intersubstitutability and grouping
- Priority scoring
- Regulatory effectiveness and coherence

1. Substance Identification

The following comments refer to Section 1 of the existing Annex XV dossiers relating to RCF. Equal comments apply to both the Zirconia-Alumina-Silica/RCF and the Alumina-Silica/RCF dossiers. Section 1 needs revision in respect to the substance definition. The definition of RCF contained in the Annex XV dossiers does not correspond with the RCF materials currently sold in the European market. ECFIA fear that this misunderstanding, if continued through to authorisation, will result in an unclear description of which RCF’s require authorisation and which do not. We believe therefore that the Annex XV dossiers should first be updated and corrected recognizing the information provided in this document, prior to any further steps in the prioritisation process.

a) Which product form of RCF is the “substance”?

By way of introduction, it is necessary to comment on the nature of RCF as a substance. Chemically it is a high temperature glass and in its physical form it consists of fibres. This adds complexity to the consideration of RCF as a substance since its properties are determined both by its chemical formulation and by the fibrous form. Moreover, fibres are useful for their main purpose of high temperature insulation only when used collectively (i.e. after further processing into a useful product form or “article”). It follows that most RCF is transformed into blankets, furnace modules, boards and other products in order to apply them at the point of use. These products are all capable of releasing fibrous dust during active handling and manipulation in downstream operations, however in REACH terminology this will be dust released from “articles” (unintended release). Authorisation is designed as a control of substance use, not the use of articles. The Annex XV dossiers recognise that RCF is placed on the market in a variety of product forms but do not define the borderline between substance and articles. ECFIA believe that without an agreed clear understanding and

See reply to comment 2272 in section I

Regarding your proposal of a different risk management option/other measures:

You suggest ECHA to consider “alternative Risk Management Options” to Authorisation, such as Restriction or other measures.

Please note that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the approach described in the agreed general approach document.

In the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and therefore should be recommended for inclusion in this annex ECHA is not in the position to assess the pertinence of alternative regulatory risk management options for the substance or some of its particular uses.

In accordance with REACH Article 59 it is at the discretion of the Member States and the European Commission to decide for which substances Annex XV dossiers with proposals for identification as SVHC are subjected to the SVHC identification process. Ideally considerations on the most appropriate RMO should be discussed prior to proposing substances for inclusion to the Candidate List; while the decision to include substances in Annex XIV is taken by the Commission via the regulatory procedure with scrutiny under Article 133(4).

Regarding your request to carry out a risk management option (RMO) analysis:

The purpose of the RMO analysis is to clarify whether risk management activities are required for a substance and to identify the most appropriate instrument to address a concern. We fully agree that preparing an RMO analysis early in the process (i.e. before initiating the SVHC identification process) will promote early discussion and will help to get a
definition of which “physical” forms should be considered “substance”, there will be confusion on what shall be subject to future authorisation and authorisation will be very difficult to implement and enforce in a coherent way.

b) Chemical Composition
RCF is correctly stated to be a UVCB substance. The components that are intentionally included in commercial RCF products, sold by ECFIA members in Europe, are Zirconia, Chromia, Alumina and Silica. Two Annex XV dossiers have been submitted incorporating three of these components, the fourth, Chromia, has been overlooked.

The table attached to this submission gives the actual chemical analysis of RCF products on sale in Europe during July 2013 by the European manufacturers. The cells coloured yellow in this table are the intentional components. Other minor constituents are unintentional and arise from natural variations that occur in the raw materials used in production. All of the products in this table are included in the joint RCF registration 01-2119458050-50-XXXX (dossier ID: DISS-9fd75a2-3534-1e0f-e044-0014467d031), which uses CAS 142844-00-6 as a key part of its substance definition.

The issue of the inadequate substance definition in section 1 of the Annex XV dossiers appears to arise initially with the reference to RCF1, RCF 2, RCF 3 and RCF 4. These references refer to toxicology samples prepared for use in animal experiments during the 1980’s. They were specially prepared to provide respirable samples of RCF for rat experiments via various milling and separation steps. These samples were intended to be representative of the dust which may be released from RCF’s during use, but not the commercial products as such. They were, however, apparently misinterpreted as describing the full range of RCF’s sold commercially.

Possibly arising from this misinterpretation, a later paragraph states: “[Zr-Al-Si RCF]: Other oxides like potassium oxide (< 0.01 %), sodium oxide (< 0.3 %), magnesium oxide (0.01 %), calcium oxide (< 0.05 %), titanium oxide (0.04 %), iron oxide (< 0.05 %) and chromium oxide (< 0.01 %) are sometimes added to change the fibre properties.”

“[Al-Si RCF]: Other oxides like potassium oxide (< 0.01 %), sodium oxide (0.5 %), magnesium oxide (< 0.1 %), calcium oxide (< 0.1 %), titanium oxide (2 %), zirconium oxide (0.1 %), iron oxide (1 %) and chromium oxide (< 0.03 %) are sometimes incorporated to change the fibre properties.”

The table attached demonstrates that the commercial products do not contain such high levels of impurities.

common understanding on the action pursued. However, it should be noted that preparing and discussing an RMO analysis is not a legally required step in REACH in general or during any phase of the authorisation process as defined in Title VII of REACH but is a voluntary action.

Regarding the exemption request/coverage by other legislation:
See reply to comment 2361 in section III
not match the description given above in terms of the “other oxides” content. With the exception of Chromia, none of these oxides are intentional components of RCF and occur in varying quantities as a result of the natural origin of the raw materials. Chromia is added intentionally but at a level above 2.5% not <0.01% or <0.03% as stated.

c) Physical Properties
As a further result of the reliance on the specially prepared fibre samples to define RCF’s, Table 1 in the Annex XV dossiers purports to give the physical dimensions of typical RCF commercial products. The fibre dimensions shown in these tables refer to samples specially prepared for animal inhalation testing. The fibres covered by this definition in the Annex XV dossiers represent the finest fraction of a commercial product and, by weight, would represent only a very small part (ca. 2% w/w) of the product as placed on the market. For the purposes of substance identification, Table 1 should best be deleted as it does not correspond with the commercial "substance". Alternatively it should be relabelled to clarify that it represents a test sample used for the toxicology assessment and not the normal product as manufactured and used.

In summary the Annex XV dossiers fail to identify which product(s) delivered to the market constitute the RCF substance. At a more detailed level, both the chemical description and the physical description given do not match typical commercial products. ECFIA believe that the substance definition should first be brought in line with the technical reality if the Candidate List entries are intended to be used as the reference for inclusion on Annex XIV.

3. Intersubstitutability and Grouping
The inclusion of RCF in the Candidate List has been artificially divided into two entries, representing Zirconia-Alumina-Silica RCF and Alumina-Silica-RCF. This approach does not match the actual situation as explained above. ECFIA proposes both entries are merged so they correspond with the Registration dossier.

The various versions of RCF are manufactured in different factories and often have specific niche applications. However, for the most part the applications of Alumina-Silica-RCF, Zirconia-Alumina-Silica RCF and Chromia-Alumina-Silica-RCF’s overlap and these products are "intersubstitutable", often competing with each other for the same applications. All three versions have the same CMR classification. As not all variations are covered by the actual Candidate List entries, there will be a situation of unfair competition favouring those not covered.
ECFIA conclusively recommend that the Annex XV dossiers be combined into one entry and adopt the substance definition used in the REACH Registration dossier. This will immediately avoid future regulatory complications as the Annex XV dossier will match exactly the substances which are sold in the European Union. Additional RCF product variants such as Chrome RCF will automatically be included without the risk of oversight. This will reduce the burden on industry (and the authorities) in the event of future authorisation and will also prevent the unintended preferential treatment of one product over another through incomplete regulation.

4. Prioritisation Scoring

In July 2010, the ECHA published on their website the priority scoring to be adopted for RCF. The priority score at that time was 13. This result was discussed with ECFIA at a meeting in Helsinki as recently as March 2012.

In 2013, the background documents relating to the two RCF types identified for prioritisation give the following scores: 19 (Al-Si/RCF) and 17 (Zr-Al-Si/RCF), respectively. ECFIA are unable to understand why the priority scoring for RCF has increased, given that the registration file has not been changed. In this section ECFIA will demonstrate that the increased scoring level has no justification. The Zr version of RCF is a subset of the whole and so this may explain why it has been allocated a lower score relating to "Volume". However, in view of the arguments for intersubstitutability and grouping, ECFIA argues that a single priority score should be applied to all RCF types grouped together.

ECFIA wishes to comment on the exposure of workers reflected in the "Wide Dispersive Use (WDU)" score and also the "Inherent Properties" score. In this document we will set out the reasons why current scientific opinion would lead to these being rated 3 and 0 respectively. It is the opinion of ECFIA that the Registration file and the scientific references mentioned in this section only contain evidence to support a priority score for RCF of 12 (and possibly lower). ECFIA therefore proposes that the scoring be amended.

a) Inherent Properties – Threshold of Effect

The Annex XV dossiers give an assessment of the risk to the health of workers associated with exposure to RCF. It uses a methodology favoured by a working group in Germany but does not reflect the full range of scientific understanding or interpretation following a "weight of evidence" approach. ECFIA believes that the SCOEL report (SUM/165/RCF) gives a more
recent and more complete view of scientific opinion including the important epidemiological evidence based on a 25 year study of RCF workers in the USA.

ECFIA realises that the SCOEL report was published in September 2011 and so it is recent information that could not be taken into account in the preparation of the Annex XV dossiers. However, this new work, sponsored by the European Commission, should now be included in the assessment of RCF for entry into Annex XIV and potential future authorisation requests, especially as it sheds a different light on the threshold aspect.

SCOEL concluded that RCF displayed carcinogenic properties but with a practical threshold of exposure, below which no effect is noticed. This relates to the fundamental mechanism of carcinogenesis, which in the case of fibre such as RCF is by means of an inflammatory response, not by primary genotoxicity. In respect to the priority scoring this leads to an “Inherent Properties” score of 0. Combined with the evidence from the epidemiological studies, SCOEL conclude that workplace exposure at levels below 0.3 f/ml will have no harmful effect. By contrast, the German model in Annex XV assumes carcinogenicity without a minimum no effect threshold. The series of calculations carried out in this methodology lead to a “tolerated” exposure level in the workplace of 0.1 f/ml.

The German model ranks different fibres by means of the results of Intraperitoneal injection in rats (IP tests) to estimate the health risk to humans. This approach has been the subject of much debate in recent times and is not the subject of a scientific consensus. Potential errors arise both with the use of IP tests, which do not model inhalation into the lungs, and the use of rat data, which does not necessarily predict the response in humans. The IP data have been independently reviewed by the Austrian Environmental Agency and received a Klimisch score of 3. This means that the data was not generated and reported with sufficient scientific rigor to be considered reliable.

b) Wide Dispersive Use – Definition of “Significant Exposure”
As described above, SCOEL concluded, that RCF is a carcinogen that has “a no observed adverse effect level (NOAEL)”. In terms of workplace exposure, that NOAEL can be interpreted as an OEL of 0.3 f/ml – in contrast to the German model in Annex XV, which assumes carcinogenicity without an effect threshold, leading to a “tolerated” exposure level in the workplace of 0.1 f/ml.

The 3 to 1 difference, between SCOEL and the Annex XV dossiers, in
acceptable workplace exposures produces a large difference in the assessment of “significant exposure”. ECFIA believe that the findings of SCOEL should be used to make a new assessment of the worker exposure score which would be reduced from 3 “significant” to 1 “controlled”.

The most reliable evidence relating to human health is that generated by studies of the human working population. That data is reflected in the SCOEL report and drives their recommended OEL of 0.3 f/ml. Separately and independently, the EU sponsored IOM report (IOM Research Project: P937/99, Summary Report, May 2011) prepared as part of the SHEcan project also concluded, “...introducing an OEL of either 0.1 or 1 fibres/ml has no important effect on the predicted cancer deaths or registrations from RCF.” This supports the SCOEL view that 0.3 f/ml is a no observed adverse effect level (NOAEL) of exposure.

The findings of SCOEL and IOM provide a more recent and different view on the occupational exposure levels reported in Part 2 of the Annex XV dossiers. The findings of SCOEL and IOM imply a much smaller proportion of all occupational exposure readings to be at the “significant level”. The higher level of 1.0 f/ml mentioned by the IOM is in fact above 95% of all the reported measurements (which are reported “as measured” - not taking the effect of respiratory protection mandated at elevated exposure levels into account).

c) Wide Dispersive Use – Exposed Population

In the Annex XV dossiers it is suggested that the exposed population in Europe consists of a total of approximately 25000 workers. The following breakdown is provided:
- Primary production (ECFIA member companies): 750 employees (3.1%)
- Convertors: 850 employees (3.5%)
- Distributors/Agents: 250 (1%)
- Installation contractors: 1500 (6.2%)
- End users: 21000 employees (86.2%)

It is noteworthy that this estimate is based on data originally gathered and reported by ERM in 1995 as part of a regulatory impact assessment sponsored by the European Commission; two years prior to the EU adopting a carcinogen classification for RCF. In the subsequent 18 years, much RCF has been substituted by newer unclassified products such as AES fibres and the manufactured volumes have declined. More recently, the IOM’s SHEcan report set the total exposed population at 10000.

The reduction in the estimated RCF workforce is supported by the
fact that ECFIA members have closed a total of 4 European RCF manufacturing sites since 1995, consolidating the activities at the 4 remaining factories in France, UK and Germany, where more modern and productive equipment is installed. Overall, the RCF manufacturing volume has dropped by about 50% and, where technically feasible, has been replaced mainly by AES fibres. These can be made on the same equipment and so many former RCF workers now handle RCF part time and work with AES for the remainder of their time. This leads to a lower long term cumulative exposure to RCF and further reduces the risk to human health.

Based on the breakdown in Annex XV and the latest estimations from IOM, there are currently about 8600 employees working in the RCF "End User" category. End users (i.e. employees working in the vicinity of industrial thermal process equipment containing RCF insulation) typically experience little or no exposure to RCF during normal operations, except during maintenance activities when the RCF products are repaired. These exposures are infrequent and are referred to in Annex XV as "sporadic". Around 100 employees in the "Distributors/Agents" category are handling boxed/palletised products with a very low potential for any dust release. It follows that 1300 workers (in the Primary production, Converters and Installers categories) currently have actual contact and potential exposure to RCF dust. These would often only be exposed during a part of their work activity, which is carried out under controlled conditions (i.e. following the hierarchy of controls defined in EU regulation and the applicable RMMs recommended by industry).

It is very reasonable therefore to consider the worker exposure to RCF to be "controlled" as the potential to produce dust arises from only a small part of the volume distributed to the user sites, this volume has declined over time and appropriate risk management measures, including ventilation systems, are applied to control dust levels. ECFIA believes that the actual exposure situation as described above – including the potential dust release during the "article use" stage – does not qualify as "wide" or "dispersive". It follows that the total "WDU" score should be reconsidered accordingly.

5. Regulatory Effectiveness and Coherence
The issue of "intersubstitutability" driven by the inadequate substance definition raises immediate concerns in terms of the effectiveness of a potential authorisation process. Additional aspects falling under this heading are discussed in more detail in the following paragraphs.
ECFIA believe that the threshold effect reported by SCOEL combined with the evidence of the lack of health effects in workshops using current dust controls as well as the IOM conclusions in the SHEcan report imply that RCF is suited to the “second tier” or “Regulatory Effectiveness” approach as the improvements in workplace practices over the last 20 years have produced a situation where no additional health benefits will be produced by introducing authorisation. The risk associated with RCF is driven by the potential release of respirable fibres – as already stated above a small fraction of the product as manufactured and sold. Since this release can occur during direct processing and handling of most RCF based products, authorisation might not be the most effective risk management option (RMO) to improve worker protection as it can - by definition - only regulate at the “substance use” stage of a material. Based on the above, RCF materials imported from outside the EU in the form of articles would not be affected by authorisation while these would still have the potential of (unintended) release of fibrous dust during further processing steps, installation and removal. Hence the protection of workers involved in these processes would not be improved through an authorisation requirement while at the same time the EU-based manufacturers and “substance” users would be confronted with an additional regulatory burden. This competitive disadvantage is in contrast with one of the REACH principles as laid out in Art. 55 “The aim of this Title is to ensure the good functioning of the internal market [...]”. The “Carcinogens Directive” 2004/37/EC provides the framework for the existing substitution requirement and the applicable hierarchy of controls. The requirements laid out in this directive were adopted across all Member States in line with the EU Treaty. Most EU Member States already have established a specific workplace limit value for RCF dust, applicable at all workplaces – independent of the substance/article status of the material. A binding occupational exposure limit value (BOELV) – defining specific minimum requirements for RCF workplace dust controls across the EU – is currently under discussion at EU Commission level and will likely be implemented in the near future (via Annex III of Directive 2004/37/EC). The implementation of an adequate OEL appears to be a more effective RMO to reduce the potential worker risk associated with RCF dust exposure as it covers all stages of RCF product use. Moreover, once the BOELV is established, the existing regulations would justify a broad definition of exemptions from a potential future authorisation requirement following REACH Art. 58 (2).
6. Conclusion and suggestions for a way forward

Based on the detailed arguments presented above, ECFIA believes that RCF should at this stage not be recommended for authorisation for the following well founded reasons:
- The current Candidate List entries fail to adequately and correctly describe the product as registered in the EU – leading to a high level of uncertainty for all stakeholders (industry as well as regulators / enforcers).
- Intersubstitutability with RCF versions (with the same hazard profile) not covered by the present Candidate List entries has been demonstrated. This leads to an unjustified different treatment of the listed materials.
- The workplace risks associated with RCF dust exposures affect a small and declining cohort of professional workers who are adequately protected via applicable risk management measures; hence RCF should be a low priority for authorisation.
- The consideration of regulatory effectiveness criteria suggests that authorisation is not the most effective risk management option (RMO).

We therefore kindly request MSC and ECHA to consider the following steps in order to create a regulatory situation that provides clarity and transparency for all stakeholders. We’d be delighted to get actively involved where we can support the process steps described below:
1. To withdraw the recommendation to include RCF in Annex XIV
2. To carry out a risk management option analysis (RMOA) in cooperation with all stakeholders (given that a RMOA was not carried out as part of the CL process)
3. To submit one new Annex XV dossier in line with the identifiers used in the registration to establish an adequate Candidate List entry for RCF
4. Based on the outcome of the RMOA, to decide whether further regulatory controls are required and select the most appropriate option

Attachment: Table showing chemical analysis of RCF products in the European market

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<tr>
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<th>Name</th>
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<tr>
<td>2167</td>
<td>2013/08/27 20:13</td>
<td>Individual</td>
<td>Regarding the hazard property of RCFs: See reply to comment 2314 in section I</td>
</tr>
<tr>
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<td>Date/Time</td>
<td>Entity Type</td>
<td>Entity Name</td>
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<td>2166</td>
<td>2013/08/27 18:45</td>
<td>Individual</td>
<td>United States</td>
</tr>
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<td>2163</td>
<td>2013/08/22 12:21</td>
<td>Company</td>
<td>Keraben Spain</td>
</tr>
</tbody>
</table>
| 2160       | 2013/08/21 14:17 | SCHOTT AG Company | Germany         | Regarding the description of uses: See reply to comment 2272 in section I  
Regarding the non-availability of alternatives/information on alternatives in background document:  See reply to comment 2272 in section I  
Regarding low or controlled exposure/risk of RCFs: |
<table>
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<td>2155</td>
<td>2013/08/21 11:54</td>
<td>European Trade Union Confederation Trade union Belgium</td>
<td>Belgium</td>
<td>ETUC supports the recommendation to include Al-RCF in the REACH authorisation list. Al-RCF is included in the Trade Union Priority List for REACH authorisation: <a href="http://www.etuc.org/a/6023">http://www.etuc.org/a/6023</a></td>
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<td>2151</td>
<td>2013/08/16 11:42</td>
<td>KIND &amp; CO., Edelstahlwerk, KG Company Germany</td>
<td>Germany</td>
<td>We would like to refer to the consultation comments of: Wirtschaftsvereinigung Stahl/Stahlinstitut VDEh Aluminosilicate Refactory Ceramic Fibres (Al-RCF) b0127828-e4f9-4e21-a53e-1bc7c0ce8588 and the comments of EUROFER.</td>
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<tr>
<td>2148</td>
<td>2013/08/15 16:44</td>
<td>Rath GmbH Company Germany</td>
<td>Germany</td>
<td>Comments on ECHA Dossiers dated 24th June 2013 concerning Alumino silicate RCF and Zirconium-Alumino silicate RCF: 1. Alumino silicate RCF not a substance in the sense of Art. 3 No. 1 REACH Regulation (EC 1907/2006) Alumino silicate RCF may not be included in the REACH candidate list as Art. 57 REACH is not applicable. This regulation only applies to substances as defined by Art. 3 No. 1 REACH but not to articles as defined by Art. 3 No. 3 REACH. Fibres are not a substance according to the definition in Art. 3 No. 1 REACH. A substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. This definition obviously does not apply to fibres. They constitute an article, as they are objects which during production are given a special shape, surface or design which determines their function to a greater degree than does their chemical composition. Thus, a fibre is an article as defined by Art. 3 No. 3 REACH. According to the principle of legal certainty it is not permissible to interpret the REACH Regulation in an extensive manner as to treat fibres as a substance in the sense of Art. 3 No. 1 REACH. The wording of this legal definition is clear and does not leave room for any extensive interpretation. Alumino silicate RCF may not be treated as substances by way of qualification as so-called UVCB substances. The qualitative and quantitative composition of alumino silicate RCF is well-known (European Standard EN-1094-1). Thus, there is no room for the</td>
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<td>See replies to comments 2130 and 2143 in this section.</td>
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<td>Thank you for providing your opinion</td>
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<td>Regarding the status of RCFs as substance or article: See reply to comment 2292 in section I</td>
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<td>Regarding the hazard property of RCFs: See reply to comment 2314 in section I</td>
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application of the definition as UVCB substance. The three-dimensional structure of the fibres is not an argument for the opposite view as this structure is the result of the production process and thus is rather an argument for its character as an article. Furthermore, the character of alumino silicate RCF as a substance may not be derived from the listing in Annex I to the Directive 67/548/EEC on Dangerous Substances and Annex VI of the CLP-Regulation (EC 1272/2008). Art. 3 No. 1 REACH is now the decisive statute for the definition of a substance and in combination with Art. 57 REACH is now the relevant framework for the Candidate List. According to Art. 2 lit. a) Directive 67/548/EEC on Dangerous Substances, it would have been permissible to include articles as well. Fibres had even been expressly listed as an example for an article in EINECS:
“Articles should not be reported. Articles which undergo chemical surface reactions to increase their stiffness, strength, flame resistance or to improve their ion-exchanging capacity, chromatographic behavior, resilience, bacterial resistance, etc. while maintaining their bulk structure retain their status as articles. Fluids and particles are not considered articles regardless of shape or design, but rather mixtures or substances. Examples of articles include batteries, brake linings, chips, fabrics, fibres, filaments, films, flares, glass wool, leather, paper, pencils, rock wool, chromatographic supports and yarns. Components of articles and substances used in the finishing process of an article (e.g. dyes and fire retardants) can be reported if they have a separate commercial identity”
Reference:
Institute for Health and Consumer Protection European Chemicals Bureau; MANUAL OF DECISIONS FOR IMPLEMENTATION OF THE SIXTH AND SEVENTH AMENDMENTS TO DIRECTIVE 67/548/EEC ON DANGEROUS SUBSTANCES 2.3.2 Criteria; page 21ff
However, the Directive 67/548/EEC on Dangerous Substances with respect to any listing in the Candidate List has been superseded by Art. 3, 57 REACH. In consequence, alumino silicate RCF do not constitute substances which may be included in the REACH Candidate List but articles which are not covered by the relevant definition anymore.
2. The scientific basis for the classification of alumino silicate
RCF is insufficient. Several member states raised questions and pointed out uncertainties in the course of a discussion on re-classification of alumino silicate RCF in 2006. In fact, the classification is mainly based on very old data (and flawed animal studies) which cannot withstand the findings of more recent scientific research.

Meanwhile, there is scientific proof for the doubts mentioned above. In this context we cite the following studies:

a. 2010: Mc Kay et. al. "A long term study of pulmonary function among US refractory ceramic fibre workers (according to the findings of the author there is no scientific evidence for any connection between cancer and RCFs)."

b. 2010: Utell MJ & Maxim D. Refractory ceramic fiber (alumino silicate RCF) toxicity and epidemiology: A review. Inhalation Toxicology, 22(6), 500-521. (The mortality study has not shown any increase in death rate (all deaths), cancer deaths, or respiratory deaths.

c. 2010: UBA-Austria: Proposal for a scientific re-evaluation of Zirconia Aluminosilicate Refractory Ceramic Fibres and Aluminosilicate Refractory Ceramic Fibres; FINAL REPORT, 2010-07-02 (no significant excess mortality related to all deaths, all cancers, malignancies or diseases of the respiratory system was observed; pg. 7).

d. 2011: UBA-Austria: "Reliability assessment of selected references used for carcinogenic potency comparison of Zirconia Aluminosilicate Refractory Ceramic Fibres and Aluminosilicate Refractory Ceramic Fibres with Crocidolite; Vienna, 2011-01-11 (in this study, the selection of the specific references as the basis of the findings concerning carcinogenic potency has been explicitly criticized as insufficient).

3. As a consequence alumino silicate RCF has to be removed from the REACH Candidate List respectively from REACH/Substance regulatory system.

4. The same applies to zirconia-alumino silicate RCF respectively.

Comments submitted on alumino silicate RCF on ECHAs website apply comparably to zirconia alumino silicate RCF. Please refer to comments on: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/-/substance/4105/search/+term

2147 2013/08/15 Bundesverband BV Glas opposes the priorisation of aluminosilicate refractory

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<td>Glas e.V.</td>
<td>ceramic fibres and its inclusion in annex XIV REACH. Where the Al-RCF products are still used, substitution is not possible. Worker safety is ensured without further regulation beyond the existing rules. The priorisation with the consequence of authorisation would lead to negative impacts on energy saving and environmental protection.</td>
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<tr>
<td>2145</td>
<td>Bundesverband Glas e.V.</td>
<td>BV Glas opposes the priorisation of aluminosilicate refractory ceramic fibres and its inclusion in annex XIV REACH. Where the Al-RCF products are still used, substitution is not possible. Worker safety is ensured without further regulation beyond the existing rules. The priorisation with the consequence of authorisation would lead to negative impacts on energy saving and environmental protection.</td>
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Another application of alumino silicate refractory ceramic fibres is the use as gasket material of coke oven doors, where flexibility is required in conjunction with good sealing performance and durability. Substitutes were tested but materials with comparable impermeability effects were not found. Without alumino silicate refractory ceramic fibres increased emissions of pollutants leading to non-compliance of licensing rules would occur. Additionally increased burdens of employees and the environment would result. An additional advantage of alumino silicate refractory ceramic fibres is the low heat capacity and high thermal shock resistance, which enables a flexible application even with varying operation cycles. Under production conditions that are characterized by many successive heating and cooling processes, the expansion and shrinkage associated with the heating and cooling and would lead to the destruction of alternative massive refractories. Alternative materials have been investigated, but so far no suitable material has been found, corresponding to the thermal and mechanical requirements. With poorer insulation and higher energy consumption such materials may lead in addition to significantly reduced maintenance intervals associated with shutdowns and correspondingly higher costs with increased environmental pollution, energy consumption and CO2 emissions. The use of conventional refractory materials would lead to a technological step backwards and thus have a negative influence on the competitiveness of German and European steel industry. In the steel industry the protection of workers is of first priority, regardless if it is related to conventional refractory bricks, alumino silicate refractory ceramic fibres or other fiber materials. alumino silicate refractory ceramic fibre products are used under controlled conditions, such as described in the German TRGS 558 (Technische Regel für Gefahrstoffe 558, Tätigkeiten mit Hochtemperaturwolle = Technical Rule for Hazardous Substances 558, Activities involving high-temperature wool). Reports of occupational diseases related to alumino silicate refractory ceramic fibre products are not available. The facts described above lead to the conclusion that the industry has reached a good performance in worker safety in combination with environment protection. alumino silicate refractory ceramic fibres are not made for private end use, only for industrial high temperature processes. End products of the steel industry do not contain alumino silicate refractory ceramic fibres. Therefore the inclusion into Annex XIV of the REACH Regulation does not improve
worker safety and environment protection. It therefore does not make sense.


| 2140 | 2013/08/09 14:33 | Austrian Association for Building Materials and Ceramic Industries | Sehr geehrte Damen und Herren, der Fachverband der Stein- und keramischen Industrie Österreich als Vertreter großer Hersteller von (Zirconia-) Aluminiumsilikatwolle (Zi- Al-RCF) und von wichtigen Unternehmen mit energieintensiven Hochtemperaturprozessen fordert, dass die Priorisierung für eine Aufnahme auf die Autorisierungsliste (Anhang XIV REACH) zurückgenommen wird. Basis für diese Forderung sind qualitativ | **Regarding the description of uses:** See reply to comment 2272 in section I  
**Regarding the non-availability of alternatives/information on alternatives in background document:** See reply to comment 2272 in section I  
**Regarding low or controlled exposure/risk of RCFs:** See reply to comment 2272 in section I  
**Regarding the exemption request/coverage by other legislation:** See reply to comment 2361 in section III |
Austria
gute wissenschaftliche Argumente und jahrelange Erfahrungen aus
der industriellen Praxis.
Der Fachverband möchte vorab in Erinnerung rufen, dass die
produzierende Industrie (Zi-) Al-RCF als „Stoff“ vorsorglich im Sept.
2010 durch den Lead Registranden (Rath GmbH) registriert hat, weil
(Zi-) Al-RCF als „Stoff“ im Jahr 1997 in Annex 1 der „Directive
67/548/EEC on dangerous substances“ eingestuft wurde. Vorsorglich
deshalb, weil eine Vermarktung ohne ein Registrierungsdossier nach
Dezember 2010 nicht mehr möglich gewesen wäre. Die
Registrierung war also eine Vorsichtsmaßnahme der Industrie zur
weiteren Herstellung und zum Inverkehr- bringen gemäß REACH
Motto: „No Registration - No Market“
1. Argument: (Zi-) Al-RCF ist per REACH-Definition als
„Erzeugnis“ anzusehen und damit nicht Gegenstand der REACH-
Regulierung
Zum Zeitpunkt der Einstufung (1997) war die Unterscheidung
zwischen „STOFF“ und „ERZEUGNIS“ noch nicht ausschlaggebend für
eine weitere Betroffenheit durch REACH/CLP. Diese Kategorisierung
gewann erst später an Bedeutung, da „STOFFE“ unter REACH/CLP
behandelt aber „ERZEUGNISSE“ nicht erfasst werden.
Aufgrund des Herstellungsmechanismus lässt sich leicht erklären und
nachweisen, dass (Zi-) Al-RCF „Erzeugnisse“ sind. Diese rechtliche
Unklarheit, die sich aus einem (fehlerbehaftetem) Formalismus bei
der Einstufung in die „Directive 67/548/EEC on dangerous
substances“ ergeben hat, sollte geklärt werden, bevor weitere
Schritte im REACH-Prozess vollzogen werden.
Die Unterscheidung Stoff/Erzeugnis im Zusammenhang mit (Zi-) Al-
RCF ist offensichtlich nicht klar und bedarf in letzter Konsequenz
einer juristischen Klärung beim obersten Gerichtshof der EU (EUGH).

2. Argument: Falsche Einstufung
Bezüglich auf die Priorisierung zur Aufnahme in REACH
Anhang XIV auf Basis der vorliegenden Einstufung ist zu sagen, dass
die ursprüngliche Einstufung von Kategorie Karzinogen 2 nach
EU67/548 automatisch in CLP Kategorie Karzinogen 1b überführt
wurde, ohne weitere Prüfung „neuer wissenschaftlicher
Erkenntnisse“. Die Qualität der zugrundeliegenden
Tiersuchstudiens ist aufgrund ihres Alters und der Durchführung
sehr kritisch zu hinterfragen. Basis für die Einstufung 1997 war eine
Langzeit-Inhalationsstudie (RCC-Studie) aus den 1980er Jahren. Erst
nach der Einstufung im Jahr 1997 wurde festgestellt, dass diese
Studien mit fehlerhaften Proben durchgeführt wurden

Regarding the priority assessment/scoring:
See reply to comment 2444 in section I

Regarding low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I

Regarding the use of the substance as an
article:
See reply to comment 2292 in section I

Regarding the non-availability of
alternatives/information on alternatives in
background document:
See reply to comment 2272 in section I

Regarding addressing imported articles:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g.
energy efficiency, long service time,
disadvantage for EU industry:
See reply to comment 2272 in section I

Neuere Bewertungen und Studien stellen die Einstufung jedenfalls in Frage: sie bestätigen die Notwendigkeit einer neuen harmonisierten Einstufung der (Zi-) Al-RCF von Karzinogen cat 1b auf Karzinogen cat 2 gem. CLP. Damit ist die Empfehlung zur Aufnahme in Anhang XIV hinfällig und eine etwaige Gefährdung kann weiterhin in anderen bereits vorhandenen Gesetzgebungen (z.B. Arbeitnehmerschutz) geregelt werden.

3. Argument: begrenzte Verwendung (Zi-) Al-RCF werden industriell eingesetzt. Sie sind für die allgemeine Verwendung durch eine breite Öffentlichkeit längst nicht mehr zugelassen. Im Konsumentenbereich werden (Zi-)Al-RCF nicht mehr eingesetzt. Die Produkte werden von Spezialisten verarbeitet, die entsprechende Schutzmaßnahmen beachten. Hierbei ist vor allem
der Faserstaub zu bedenken, dem ein Arbeitnehmer ausschließlich beim Anbringen und Austausch der Dämmstoffe- nicht jedoch beim Betrieb von Industrieöfen bzw. industriellen Hochtemperaturanlagen - ausgesetzt sein könnte. Geeignete Arbeitnehmerschutzmaßnahmen stellen sicher, dass die hantierenden Personen maximal geschützt sind. In diesem Zusammenhang muss erwähnt werden, dass in mehr als 60 Jahren dokumentierter Verwendung noch kein einziger Fall einer Erkrankung des Menschen in Bezug auf (Zi-) Al-RCF gemeldet bzw. bekannt worden ist.

4. Argument: Sind Al-RCF eine Gefahr?

5. Argument: überschaubare gefährdende Mengen (Faserstaub)

6. Argument: Priorisierungs-Scoring fragwürdig
In den offiziellen Dossiers, die im Zuge der 5. Empfehlung der ECHA für die Priorisierung von (Zi-) Al-RCF entwickelt wurden, sind die Scoring-Resultate angeführt, die zu dieser Empfehlung geführt haben. Die Scoring-Resultate wie auch die Erklärungen im ECHA-Dossier sind für den Fachverband der Stein- und keramischen Industrie nicht nachvollziehbar, intransparent und entsprechen nicht den von ECHA selbst vorgegebenen Leitlinien. Der Fachverband der Steine- und keramischen Industrie hat die Leitlinien der ECHA vom May 2010, wissenschaftliche Erkenntnisse
und Praxiserfahrungen als Basis für eine eigene Bewertung (Scoring) zugrunde gelegt.
Für jede einzelne Kategorie des Scorings für (Zi-) Al-RCF kann unter Berücksichtigung der unter 1. – 5. Argument genannten Aspekte eine andere Bewertung sachlich argumentiert werden.
- Inherent properties: wissenschaftliche Gremien wie SCOEL 2010 oder DECOS 2011 stellen in ihrer Bewertung fest, dass RCF keine primär genotoxische Wirkung haben. Score von 1 auf 0
- Volume: das produzierte „Stoff“-Volumen (falls eine Faser als Stoff bezeichnet wird) wird in der Regel noch an der Produktionsstätte zu „Erzeugnissen“ verarbeitet. Der Stoff (Zi-) Al-RCF selbst kommt also hauptsächlich als Erzeugnis auf den Markt und liegt daher in geringem Volume als Stoff vor. Score von 9 auf max. 1
- Uses – wide dispersiveness:
  - Use at high number of sites: es gibt insgesamt 3 europäische Produktions-standorte
    Score von 3 auf 1 (small)
    Score von 3 auf 0
    Score von 9 auf 0
Die endgültige Bewertung fällt somit von Score 19 auf 1.
7. Argument: keine Möglichkeit der generellen Substitution (Substitution weitgehend umgesetzt)
In den Temperaturbereichen unter 900°C werden weitgehend (aber nicht in jedem Fall!) Substitute eingesetzt. Es hat sich aber gezeigt, dass bei höheren Temperaturen, sowie bei spezifischen chemischen und physikalischen Rahmenbedingungen, die Qualitäten der (Zi-) Al-RCF in Bezug auf Stabilität, Flexibilität, Langlebigkeit und Preis durch die Substitute nicht erreicht werden können. Deshalb sind diese
Produkte technisch, ökologisch und ökonomisch oft nicht geeignet. Der Einsatz der (Zi-) Al-RCF im Hochtemperaturbereich ist energieeffizient, CO2 -emissionsmindernd und nachhaltig - sowohl wirtschaftlich als auch ökologisch.

8. Argument: Wirtschaftlichkeit


Die Zulassungen werden nur begrenzt (fünf bis zehn Jahre) vergeben und die Erneuerung der Zulassung ist nicht garantiert. In der Folge ergeben sich Beeinträchtigungen in der Planungssicherheit für die Anwenderindustrie. Außerdem verringern diese immer wiederkehrenden massiven bürokratischen Kosten die Wirtschaftlichkeit in der Produktion. Dadurch besteht die Gefahr eines „occupational and environmental safety leakage“: die Produktion wird in Länder verlagert, in denen die Arbeitschutzbedingungen und Umweltauflagen nicht die EU-Standards erfüllen und so dem ursprünglichen Gedanken der Zulassung entgegen laufen. Das fertige Produkt kann dann billiger, ohne Zulassung, nach Europa importiert werden.

9. Argument: Auswirkung auf Klima- und Energiepolitik
Die Ziele der EU (z.B. EU 2020) in Bezug auf Klimaschutz und Energieeffizienz sind sehr klar und eindeutig verbindlich festgelegt. Eine flächendeckende Substitution von (Zi-) Al-RCF hätte weitreichende Auswirkungen auf den Energieverbrauch und die Ressourceneffizienz der Hochtemperaturprozesse. Es bedeutete einen Rückschritt in der technologischen Optimierung der Öfen und der Prozesse um Jahrzehnte, wenn die eingebauten Produkte nicht

Zusammenfassung

| 2138 | 2013/08/09 13:25 | Austrian Association for Steel and Mining Industry or trade association Austria | Our members in the steel and refractory industry use Alumininosilicate Refractory Ceramic Fibres (Al-RCF) and Zirconia Alumininosilicate Refractory Fibres (Zr-RCF) for various high-temperature industrial applications. Despite many efforts to find alternatives, for technical and economic reasons, for a number of applications no adequate substitutes are yet available. Our member firms are active in the search for alternatives to RCF and willing to use alternatives, where economically and technically feasible. But European regulators must bear in mind, that for most high-temperature applications, suitable alternatives are not yet available. For various reasons (see attached document) we believe that the authorisation process is not an effective tool to manage the risk and |

<p>|  |  |  | Regarding the description of uses: See reply to comment 2272 in section I |
|  |  |  | Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I |
|  |  |  | Regarding low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I |
|  |  |  | Regarding the socio-economic impact, e.g. |</p>
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| 2136   | 2013/08/09 | 13:17    | Austrian Non Ferrous Metals Association Industry or trade association Austria | Our members in the aluminium, copper, nickel alloys, tungsten, rare earth, vanadium and molybdenum sector use Alumininosilicate Refractory Ceramic Fibres (Al-RCF) and Zirconia Aluminosilicate Refractory Fibres (Zr-RCF) for various high-temperature industrial applications. Despite many efforts to find alternatives, for technical and economic reasons, for a number of applications no adequate substitutes are yet available. Our member firms are active in the search for alternatives to RCF and willing to use alternatives, where economically and technically feasible. But European regulators must bear in mind, that for most high-temperature applications, suitable alternatives are not yet available. For various reasons (see attached document) we believe that the authorisation process is not an effective tool to manage the risk and protect human health in industries like ours. RCF are used in our industrial applications under controlled conditions. Workers exposed to RCF articles have to comply with a set of strict rules. In our view, existing (workers protection) legislation sufficiently copes with the risks of workers being exposed to RCF and there is no need for further regulation. Subjecting RCF to the authorisation requirement under REACH would have a negative impact on the competitiveness of European industry, it would increase the energy consumption and CO2 emissions. | energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I
Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III |

See reply to comment 2272 in section I
Regarding the description of uses: See reply to comment 2272 in section I
Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I

Für die Stahlindustrie müssen wir jedoch seit Jahrzehnten sehr gut bewährte Artikel (Produkte) aus Aluminium Silikat Wolle einsetzen um für den Betreiber wirtschaftliche und damit wettbewerbsstaugliche Anlagen bereitstellen zu können. Der Anteil von Wärmebehandlungsanlagen für die Stahlindustrie macht im mehrjährigen Schnitt ca. 50 Prozent unseres Gesamtumsatzes aus. Nachfolgend betroffene Produkte aus der Sparte Stahl mit den maximalen Heizraumtemperaturen:

Wärmebehandlungsanlagen für Stahlband
- HICON/H2® - Haubenöfen für Bandbunde aus un- bis hochlegierten Stählen, bis 950°C
- HITT - Haubenöfen für GO Elektroband, bis 1200 °C
- HICON/H2® - Blankglühlinie für un- bis hochlegierte Stahlbänder, Bänder aus NiFe-Legierungen und Titan, bis 1200°C
- Kontinuierliche Galvanisierungs- und Glühlinien für legierte Stahlbänder, bis 1000°C
- Entkohlungs- und Finalglühlinien für GO- und NGO-Elektroband, bis 1200°C
- Presshärteöfen für Blechplatinen für die Autoindustrie, bis 1000°C
- HICON® - Blankvergütelinien für un- bis hochlegierte Stahlbänder, bis 1200°C

Wärmebehandlungsanlagen für Stahldraht
- HICON/H2® - Haubenöfen für Drahtbunde aus un- bis hochlegierten Stählen, bis 950°C

Wärmebehandlungsanlagen für Rohre und Stangen
- HICON® - Rollenherdöfen für Rohre und Stangen aus un- bis hochlegierten Stählen, bis 1000°C.

Diese Öfen werden in den eigenen Fertigungsstätten, bzw. bei spezialisierten Stahlbauunternehmen mit zugekauften Artikeln

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding low or controlled exposure/risk of RCFs:
See reply to comment 2272 in section I
(Produkten) aus Aluminium Silikat Wolle in energiesparender Leichtbauweise gefertigt. Unter Berücksichtigung des Arbeitnehmerschutzes wird von geschultem Personal die Wärmédämmung eingebracht. Als Leichtbauweise definiert EBNER Systeme aus einzelnen Mattenstreifen und Modulen (bestehend aus Mattenstreifen). Selbstverständlich arbeitet EBNER kontinuierlich an der Substitution der Produkte aus Aluminium Silikat Fasern (laut TRGS 619). Im Wesentlichen bestehen diese Substitutionsprodukte aus folgenden Materialien:
- AES-Wollen = Alkaline Earth Silicate Wools
- Faserfreie feuerfeste Erzeugnisse wie geformte Erzeugnisse (z.B. Steine, Platten) und ungeformte Erzeugnisse (z.B. Betone, Massen).


Ein weiterer kritischer Punkt beim Einsatz von feuerfesten Erzeugnissen ist, dass die Öfen nur mehr am Aufstellort, als Bestandteil der Montage, gemauert werden können. Die Zustellung am Fertigungsort unter kontrollierten Arbeitsbedingungen, ist anhand der zu großen Masse nicht mehr möglich. Die feuerfeste Ausmauerung würde im Gegensatz zur Aluminium Silikat Wolle beim Transport zu Schaden kommen.


Anmerken muss man auch, dass diese Einstufung bzw. die vielleicht

Zusammenfassung:
Der derzeitigen Pauschalalisierung der Anwendbarkeit von Substitutions-/produkten, kann EBNER nicht zustimmen. Unsere langjährigen Erfahrung (seit 1948) zeigt, dass bei jedem Einsatzfall auf die speziellen Ofengegebenheiten Rücksicht genommen werden muss, z. B. Beheizungsart, Ofenatmosphäre, stationärer oder beweglicher Ofen, Temperaturparameter.

Betrachtet man den folgenden Auszug aus der TRGS 619, ist eine weitere generelle Beschränkung des Einsatzes von Produkten aus Aluminium Silikat Wolle, für uns nicht nachvollziehbar:
- Die Prüfung einer Substitution ist im Rahmen einer Gesamtbetrachtung über den gesamten Lebenszyklus der möglichen Produkte durchzuführen und ist erfolgreich, wenn die Produkte:
- geringere gesundheitliche Risiken während des gesamten Lebenszyklus aufweisen, und
- die (technischen) Eigenschaften gleichwertig sind (Anwendungs-temperaturen, Wärmedämmegenschaften, Langzeitverhalten und Standzeit),
- die Umweltschutzkriterien vergleichbar sind (Rohstoffbedarf, Energie-verbrauch, CO2-Emissionen und Abfallmenge)
- die Wirtschaftlichkeitskriterien (Anschaffungs- und Betriebskosten) keine unverhältnismäßigen Nachteile ergeben (sozio-ökonomische Aspekte).

EBNER wird weiterhin aktiv mit den Herstellern von Hochtemperaturwolle und anderen feuerfesten Erzeugnissen nach Lösungsansätzen und sicheren Wärmédämmprodukten forschen. Wir sind aber davon überzeugt, dass Produkte aus Aluminium Silikat Wolle auch in Zukunft bei Wärmebehandlungsanlagen eingesetzt werden müssen.

| 2132 | 2013/08/07 15:15 | Company United Kingdom | Products may be used or should. EBNER remains actively involved with manufacturers of high-temperature wool and other fire-resistant materials in searching for solutions and safe thermal insulation products. We are convinced, however, that products from aluminum silicate wool will also be needed in the future in heat treatment installations. |
| 2130 | 2013/08/02 12:00 | EUROFER Industry or trade association Belgium | EUROFER CONTRIBUTION TO PUBLIC CONSULTATION: (Zr) ALUMINOSILICATE REFRACTORY CERAMIC FIBRES (RCF/ASW) In relation to the ECHA’s recommendation to prioritise (Zr) Aluminosilicate RCF for their inclusion in Annex XIV of REACH Regulation, EUROFER (The European Steel Association) would like to highlight the following points: Industrial use: In the steel industry, RCF/ASW are used for insulation and fire protection purposes in furnaces, heaters, lining for furnace doors and other high temperature applications (up to 1600°C). These materials are also used in a number of niche applications such as in high pressure steam mains on a blast furnace. Due to the nature of its use, only trained operators handle and work with these materials which are handled under high levels of control. Alternatives: Article 4 of Carcinogens and Mutagens Directive 2004/37/EC requires carcinogens and mutagens to be replaced by other substances which are non-dangerous or less dangerous to workers health and safety. Following these provisions, our members have been in the process of replacing RCF/ASW as far as technically and economically feasible. However, for a number of applications, these materials remain the best solution to date. Substitutes have been investigated but, in many cases no alternatives have been found with the same performance capable to withstand the high thermal and mechanical stresses experienced in the iron and steel production processes. The replacement of RCF/ASW for these applications would require the need to carry out more frequent maintenance programs, which would be detrimental for the competitiveness of the European Iron and Steel industry. In other cases, where alternatives can be used, it is the high price and the lack of availability from a quantitative point of view that would put the European steel industry in a commercial disadvantage in terms of competitiveness. RCF/ASW are the most energy efficient |
- | 2013/08/07 15:15 | Company United Kingdom | Regarding the description of uses: See reply to comment 2272 in section I |
- | 2013/08/02 12:00 | EUROFER Industry or trade association Belgium | Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I |
- | 2013/08/07 15:15 | Company United Kingdom | Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I |
- | 2013/08/07 15:15 | Company United Kingdom | Regarding the use of the substance as an article: See reply to comment 2292 in section I |
- | 2013/08/07 15:15 | Company United Kingdom | Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III |
insulation materials available to date.
The steel industry is an energy intensive sector in which the energy costs represent up to 40% of total operational costs depending on the segment of the value chain (source: Ecorys Study on European Energy-Intensive Industries - The Usefulness of Estimating Sectoral price Elasticities). RCF/ASW are the best solution not only to rationalise our energy use but also to meet the CO2 reduction and energy efficiency objectives envisaged in the Commission climate and energy targets for 2050. CO2 emissions reduction can be achieved through innovation, however, it is important to bear in mind that to reach these objectives a globally competitive European Steel industry is also a key element.
The above mentioned arguments are supported by a recently published study on Industrial and Laboratory Furnaces and Ovens carried out for the European Commission DG Enterprise in the context of the Ecodesign Directive which states that: 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. AES HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user’s business to be uncompetitive with non-EU competitors who would not need to comply with REACH authorisation obligations. If alumino-silicate wool (ASW/RCF) could not be used, EU energy consumption would increase very significantly.(Source: ERA Technology, Sustainable Industrial Policy – Building on the Eco-design Directive – Energy-Using Products Group Analysis /2, Lot 4: Industrial and Laboratory Furnaces and Ovens –, Tasks 1 – 7 Final Report, 2012). The final report can be found here: http://ecofurnace.org/documents.php
Risk Management: Suppliers provide information on the Safe Use to their customers securing in this way the safety instructions flow down the supply chain and that workers in the iron and steel industry handle RCF/ASW in a safe and professional way. In addition to this, workers protection is required when working with RCF/ASW. These materials are already regulated by the Chemicals Agents Directive 98/24/EC (CAD) and the Carcinogens Mutagens Directive 2004/37/EC which, at the same time, also promotes its substitution. Finally, a number of member states have also established national OELs in order to control the exposure. The European Steel Industry believes that RCF/ASW do not need further regulation as the existing legislation and the regulatory risk management measures in place
are sufficient to handle the risk and control the exposure in the workplace.
Most of the RCF/ASW are used as articles in the sense of REACH:
These materials are most often used in the industry in the form of articles (e.g. sheets, bricks, blankets, rolls, modules). While the whole production of RCF/ASW in the EU will be concerned by the Authorisation process, end-uses of the substance, once processed into shapes, would not be submitted to it, and those represent in our industry the vast majority of the volumes. So, to the contrary of what is said in the Draft background documents for (Zirconia) Aluminosilicate Refractory Ceramic Fibres of ECHA’s fifth Recommendation, the whole volume does not fall under Authorisation. This means that the Authorisation process is not the adequate tool to regulate the exposure situation of end-users and, is not an effective tool to manage the risk and protect the human health in industries like ours. EUROFER believes that more emphasis has to be put on the improvement of the existing risk management tools rather than imposing additional burdens that will be inefficient for the purpose of protecting the human health and the environment.
Scoring: The volumes used to estimate the use of RCF/ASW in the annex XV dossier and in the scoring approach are based on their manufacture and imports. The considerations about the volumes of RCF/ASW used as bulk versus articles also mean that the score attributed to the volume criteria is largely overestimated with respect to the factual amounts of RCF’s potentially concerned by Authorisation and effectively in-use in this industry. Therefore, the global score of this substance should be much lower to reflect this situation, meaning that these substances would likely not be prioritised vs. other substances.
Consequences of non-availability: Installations using RCF/ASW as a thermal insulation material have a service life between 10 and 30 years, the replacement of these materials by other solutions in existing installations is not a straight forward issue and would require an important economical investment for industry. In addition to this, and as mentioned before, for many applications RCF/ASW remain as one of the best solutions to achieve the EU climate and energy targets. 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
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<td>2128</td>
<td>2013/08/02</td>
<td>09:43</td>
<td>MARAZZI IBERIA SAU Company</td>
<td>Spain</td>
<td>We are opposed to the inclusion of Al-Si RCF in annex XIV for the following reasons:</td>
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<td>See reply to comment 2437 in this section.</td>
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<td>2013/08/01</td>
<td>13:40</td>
<td>REY GRES., S.L. Company</td>
<td>Spain</td>
<td>We are manufacturers of ceramic tiles, with more than 100 employees, and we are opposed to the inclusion of (Zr-)</td>
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<td>2013/07/31</td>
<td>16:22</td>
<td>Company</td>
<td>Spain</td>
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See reply to comment 2437 in this section.
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| 2123 | 2013/07/31 12:05 | Industry or trade association
Spain | The Spanish ceramic tiles sector
The Spanish ceramics sector has a special significance for the Spanish economy because:
- It is an industry of Spanish origin and capital, leading the world in technology, quality, prestige and design.
- It is the second largest European producer and the world’s third largest exporter.
- It constitutes an industrial cluster with a huge economic, social and labour impact in a small geographical space (the ceramic district of the province of Castellón).
- Despite the difficulties, it is an industry that is still competitive. Shows it both its ability to export to all over the world, despite the increased competition and the penalty in logistical costs of their products, such as the fact that imports only cover 7% national consumption.
- Therefore the ceramic industry presents itself as a clear example of seated industry originating in Europe able to compete successfully in a global market and create wealth and employment in your environment.
- The main economic figures are (2012):
  - Companies: 162
  - Production (Mill. m²): 402
  - Total sales (Mill. €): 2,656
  - Domestic sales (Mill. €): 575
  - Export sales (Mill. €): 2,081
  - Import sales (Mill. €): 59,7
  - Trade surplus (Mill. €): 1,812
  - Direct employment: 14,400
ASCER (Spanish Ceramic Tile Manufacturer’s Association) represents 142 companies which produce more than 95 per cent of total Spanish production.
We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons:

See reply to comment 2437 in this section.
| 2121 | 2013/07/31 10:55 | Company Spain | The main activity of Azulev, S.A.U. is the design, development, production and commercialization of ceramic tile and special pieces. Currently we have 251 workers.

At Azulev we are committed to caring for the environment. Proof of this is our "Integrated Environmental Authorisation" This authorisation is in addition to certification under the 14001:2004 "Environmental Management System" standard, which is evidence of Azulev’s commitment to the environment.

Through the "Integrated Environmental Authorisation", Azulev guarantees the use of less contaminating technologies in the different phases of the production process. Using these reduces the impact on the atmosphere, water and soil to a minimum and means we produce less waste.

At Azulev we are continuing to move forward with our Total Quality objective. The ISO 9001:2008 certification on the "Quality Management System", and ISO 14001:2004 certification on the "Environmental Management System", have been added to the system for quality management and respect for the environment, based on customer satisfaction through continuous improvement of processes. This work philosophy coincides 100% with Azulev’s | See reply to comment 2437 in this section. |
customer services policy.

We are opposed to the inclusion of Al-Si RCF in annex XIV for the following reasons:

• Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.

• No adequate substitutes are as yet available for these uses.

• RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2.

• The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).

• Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.

• During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).

| 2119 | 2013/07/31 09:31 | Company Spain | Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production | Regarding the description of uses: See reply to comment 2272 in section I |
| 2116 | 2013/07/30 17:00 | cerlat s.a. Company Spain | we are a tile factory We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons: • Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production. • No adequate substitutes are as yet available for these uses. • RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy | See reply to comment 2437 in this section. |
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| 2114| 2013/07/30 | AZULIBER 1 S.L. PRODUCTION OF FLOOR TILES WORKERS:160 | We are opposed to the inclusion of (Zr-)Al-Si RCF in annex XIV for the following reasons:
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- No adequate substitutes are as yet available for these uses.
- RCF products are indispensable for meeting the EU's 2020 goals an industry's growing demand for resource and energy efficiency and the associated reduction of CO2.
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| 2113| 2013/07/30 | ROSAGRES SLU, 150 EMPLOYES, CERAMIC TILES | We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons:
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See reply to comment 2437 in this section.
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- No adequate substitutes are as yet available for these uses.
- RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO₂.
- The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).
- Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.
- During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).

<table>
<thead>
<tr>
<th>2110</th>
<th>2013/07/30 12:29</th>
<th>Company Spain</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>STN Cerámica makes up today a sound group of companies which produces and markets the most advanced ceramic products. Our industrial activity in STN Cerámica began 30 years ago when Cerámica Nulense was born. Its production started with 32 workers in an area of 60,000 sqm in order to produce ceramic biscuit. Thanks to both this period of time passed by and to a non stop investment, STN Cerámica has moved into a firm which spreads out over an area of 200,000 sqm, with 70,000 sqm of buildings and 225 professionals capable of producing 34,000,000 sqm ceramic products a year. Over the recent years, STN Cerámica has renewed its producing processes. We have gone through a gradual and constant investment that has culminated with the incorporation in september of 2010 of the digital printing technology named “Styljet” that nowadays covers all of our production lines. As a result we obtain an outstanding quality product which is acknowledged all over the world because of its design and competitiveness. Nowadays STN Cerámica is one of the most modern factories in the world and one of the largest in Spain. STN Cerámica commercial power covers 120 countries with special presence in all spanish territory. All this effort gaining quality gave as a result that STN Cerámica received the ISO 9001:2000 Quality Certificate in 2007. It is for us a plesure to launch you this catalogue where you</td>
<td>See reply to comment 2437 in this section.</td>
</tr>
</tbody>
</table>
will no doubt be able to find a wide range of ceramic products on tiling and paving, manufactured in porcelain and red body, glazed and coloured body as well as a differential product those thicked tiles. On the other hand you will be able to find a large assortment of sizes, from those slightly lengthen to big formats.

We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons: Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.

No adequate substitutes are as yet available for these uses. RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO2.

The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility).

Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.

During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).

| 2106 | 2013/07/22 00:07 | Verband der Deutschen Feuerfest-Industrie e. V. / German Refractory Association Industry or trade association Germany | The production capacity/output of the members of the German Refractory Association (VDFFT) represent about 70% of the refractory products manufactured in Germany and about 25% of the European refractory production.

One main goal of the authorisation process for the substitution of Alumino-silicate Refractory Ceramic Fibres (Al-RCF) with less hazardous substances, cannot be met, because about 90% of the manufactured AL-RCF are placed on the marketed as articles (e.g. in the form of blankets, modules, formed shapes, papers, etc.). Downstream users are using almost exclusively these Al-RCF articles.

The authorisation aimed at will primarily serve the promotion of the non-European manufacturers and will stimulate the import of AL-RCF as articles into the EU. This will lead to a competitive advantage for companies which are importing AL-RCF articles and will significantly impair the competitiveness of the European AL-RCF manufacturers, |

| 2106 | 2013/07/22 00:07 | Verband der Deutschen Feuerfest-Industrie e. V. / German Refractory Association Industry or trade association Germany | Regarding the description of uses:
See reply to comment 2272 in section I |

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I |

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I |

Regarding the use of the substance as an article:
See reply to comment 2292 in section I |
Technical information on alternative substances/materials presented in your draft background document ("Draft background document for Aluminosilicate refractory Ceramic Fibres") is basically not correct! A general statement on feasible alternative substances/materials cannot be made since the end-use applications are highly complex with respect to governing technical parameters, i.e. mechanical, chemical and thermal parameters. Whether a possible alternative substance/material can be used, depends on a large number of various technical properties of the materials, e.g. density, resilience, thermal shock resistance, etc. Of similar or even higher importance is the fact, that the alternative materials will not only have to withstand the plain application temperature, but additional severe physical and chemical conditions, e.g. imposed by the combustion chamber atmosphere, and many more! (See also "Technical Rules for Hazardous Substances; TRGS 619"; http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-619.html).

Whether an alternative substance/material can be applied, has to be carefully evaluated on a case by case basis, as is perfectly reflected in the common praxis for applying the substitution requirement of the Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. This case-by-case approach is also fully supported by the results of the study „Technical feasibility and economic efficiency of alternatives for replacing refractory ceramic fibers“ ("Aluminosilicate Refractory Ceramic Fibres and Zirconia Aluminosilicate Refractory Ceramic Fibres (RCFs)"), initiated by the German Federal Institute for Occupational Safety and Health (BAuA), which has been sufficiently discussed during a meeting with BAuA, BIPRO (Study holder) and technical experts on 21. June 2013. All things considered, the German Refractory association strongly requests to stop the authorisation process because:

- Authorisation is not the right way to achieve the substitution of Al-RCF.
- Regulations are already in place since many years.
- Substitution of Al-RCF by other refractories has already been done whenever possible.
below is strictly on the basis of scientific results. This comment is solely subjected towards aspects of alternative substances.

I disagree with the draft background for Aluminosilicate Refractory Ceramic Fibres because clause 2.3. of the document does not meet the requirements as stated in Article 55 of the REACH regulation. In there it is stated that "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." The content of clause 2.3 of the background document is neither a prudent nor a fair evaluation of alternative substances. To ensure a proper installation of any thermal treatment device (furnace, reactors etc.) it is indispensable to consider the three major properties of refractory material. As there are mechanical properties, chemical resistance (possible interactions with the process media at working conditions) and the thermal stability. If no evaluation of all three properties takes place prior to installation, a safe and failure-free operation is impossible. Incidents caused by improper selection of refractory materials not only cause financial damage but also escalate the endangerment for occupational health. Clause 2.3 of the said draft background document only reflects the thermal stability. Following the clause word by word could cause serious incidents in the future (i.e. fires).

Specific appraisals on clause 2.3 of draft background document for Aluminosilicate Refractory Ceramic Fibres

Quote: "From 600 °C to approx. 900 °C, generally AES wool products can be used"

According to a FOGi study, funded by the German ministry of economy, for AES wool products the resilience is significantly reduced at 800°C. That means AES-fibres already start to recrystallize and get brittle under ambient atmospheric conditions. The said publication gives a strong incidence that acid containing atmospheres will reduce the lifetime of AES wool products significantly even in their typical temperature range of application. AES wool products are even not stable in acid condition at room temperature. This is the reason why they are less bio-persistent. In any case it is indispensable to check carefully the individual process conditions before it is decided to install AES wool products.

Quote: "Above 900 °C to max. 1200 °C, the possibility for using AES..."
wool products may be reduced owing to technological constraints.”
As already said for the temperature range from 600 to 900 °C: The higher working temperatures affect more severely the AES wool products and the corrosion is more drastic. Under dry and neutral atmospheric conditions AES wool products may be applied up to 1150°C. This may already change dramatically if the process gas is particle loaded. In further the specific chemical composition of AES wool products may cause chemical and mineralogical interactions with other refractory materials that lead to severe damage of the latter (e.g. spinel formation in burner bricks that causes a volume increase and hence a destruction of the bricks). In any case it is indispensable to check carefully the individual process before it is decided to install AES wool products.
Quote: “On the other hand current product developments indicate that the upper temperature limit of AES wool products could be increased significantly”
Within the ternary system CaO, MgO and SiO2 the technical capabilities are limited to SiO2-rich formulations. In case of higher CaO and MgO additions AES wool products may get more thermally stable but also hygroscopic and therefore not stable under typical conditions of ambient humidity at room temperature. Therefore without leaving the said ternary system AES wool products that have a higher thermal stability cannot be produced. If further oxides are added to the formulation the bio-persistence has to be carefully checked again. By observing the ternary system of CaO, MgO and SiO2, it appears to be impossible to develop AES wool products with a higher application temperature than 1150°C.
Quote: “Non-fibrous substitutes are refractory materials such as calcium silicate or vermiculite panels and mouldings, thermal insulation bricks and concretes, lightweight refractory bricks and concretes, thermal insulation refractory compounds and other non-fibrous products that meet the application requirements as substitute products.”
All mentioned non-fibrous products cannot be compared with Aluminosilicate Refractory Ceramic Fibres - products in that general way, because e.g. the thermal and mechanical properties are completely different. In general all said materials are mechanically weak and behave brittle. Therefore they show no comparable thermal shock resistance. In further they typically show a higher heat capacity than AL-RCFs what makes them uneconomic in periodic working furnaces. In further all mentioned product types have a higher thermal conductivity and are too heavy for economic
high temperature process constructions. For every single furnace or reactor it has to be carefully checked if alternative fibre-free materials could replace Al-RCFs. It is extremely dangerous to oversimplify this item.

Quote: "ultra high temperature microporous insulation material (Microtherm Super A)"

In general microporous materials are an interesting alternative if only the thermal conductivity is considered that is solely comparable to those of high temperature insulation wool products (HTIW). On the other hand these materials behave even more brittle than other fibre-free insulating refractory products. Again the ambient service condition of the furnace or reactor is highly important due to chemical and tribo-mechanical attack. The cited Product, Microtherm Super A, is clearly not an ultra high temperature insulation material. The producer states: "can handle up to 1200°C". This is not an ultra high temperature and at these conditions it might be applied in small laboratory furnaces as back-up-insulation (the material turns brittle and fragile after the first heat-up and therefore is defective at the hot face of an industrial furnace). Under industrial conditions the service temperature for these kinds of microporous materials is limited to 1000°C if no reactive atmosphere is present. In further Microtherm Super A is moisture-sensitive and very expensive. In further it is questionable if it is permissible that specific brand names are included in this draft.

Concluding remarks
Industrial furnaces, reactors etc. are tailor made devices that fulfil the distinct tasks as required by the user. They are typically optimized in function and economic aspects. It is impossible to compare devices even if they are constructed for the same purpose because they are unique technical solutions. This was one of the major outcomes of the Eco-Design Lot 4 discussions in which I participated as a refractory expert. The same result is expected and already discussed for a study that was assigned by the German BAUA and conducted by BIPRO in which the substitution of Aluminosilicate Refractory Ceramic Fibres – products by alternative products is evaluated. Therefore many technical properties have to be considered for various unique high temperature processes where specific refractory materials have to be used in terms of health & safety for employees as well as environmental and economic aspects. An across-the-board substitution advice regardless of the individual design of a distinct industrial furnace, reactor etc. may cause severe incidents.
ERA has carried out an eco-design study for the European Commission DG ENTR on industrial and laboratory furnaces and ovens. Industrial furnaces use Aluminosilicate Refractory Ceramic Fibres (Al-RCF) for thermal insulation and have resulted in very large decreases in energy consumption and also significantly lower greenhouse gas emissions. In the course of the study, it became apparent that furnace manufacturers were very concerned that the need for authorisation to use this material in niche applications would be very costly and would make manufacturing in the EU uneconomic in comparison with their non-EU competitors. Furthermore, the evidence on which the classification of this substance as a CMR appeared to be based on unrealistic testing and in reality, there is no evidence that it is a CMR. The final report from this study is available at http://www.eco-furnace.org/documents.php which describes the uses of this substance and applications where no alternatives exist. It also refers to national maximum exposure limits that exist. If a mandatory EU exposure limit existed then authorisation would not be required, and should be considered as an alternative option.

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

Regarding the hazard property of RCFs:
See reply to comment 2314 in section I

### II - Transitional arrangements. Comments on the proposed dates:

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Submitted by (name, Organisation/MSC A)</th>
<th>Comment</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>2475</td>
<td>2013/09/23 19:41</td>
<td>Industry or trade association, Belgium</td>
<td>See attachment, section IV (common paper with Zr-RCF, previously submitted under the Zr-RCF draft recommendation)</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>2472</td>
<td>2013/09/23 19:28</td>
<td>ChemSec, International NGO, Sweden</td>
<td>It is assumed that the Commission Regulation including the substances of this 5th Recommendation in Annex XIV would enter into force only in February 2015. Keeping the proposed application date would mean an application date by November 2016 with an extra 18 months to sunset the</td>
<td>Regarding shorter sunset and application dates: ECHA made its proposals for the latest application dates on the basis of discussions by the stakeholder expert group that was following the Guidance for including</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>Organization</td>
<td>Scenario Description</td>
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| 2459       | 2013/09/23 17:49 | Aerospace Industries Association, Industry or trade association, United States | **Aerospace Industries Association, Industry or trade association, United States**

Al-RCF is a critical substance that introduces serious safety and economic viability concerns if unavailable. Currently offered Al-RCF alternatives are limited and not suitable for all aerospace applications. In one specific aerospace application, smoke was generated, which was an unacceptable result. Other proposed alternatives have proven deficient in strength, friction, thermal protection, and fibre sizing (treatment) properties. Metallic replacements are heavier and do not provide comparable thermal insulation characteristics. Additional time is needed by the aerospace industry to continue to seek suitable alternatives for each application. Where potential alternatives have been identified, the evaluation, qualification and certification will take an additional five to ten years to complete, as extensive validation and certification for these systems is required by the United States Federal Aviation Administration (FAA) and the European Aviation Safety Agency (EASA). Implementation following certification takes several additional years. Developing alternatives for maintenance of legacy, out-of-production products is even more challenging, since the original design basis and requirements may not be fully understood or readily available.

Given the critical need for ongoing uses of Al-RCFs, the AIA asks for consideration of the industry’s challenges as downstream users and establish application and sunset dates that are a minimum of five years after the chromate authorization dates in order to minimize the impact and allow industry to apply the lessons learned from the prior authorization applications to the process for Al-RCFs.

**Regarding the request to prolong the sunset date to further develop alternatives:**
Please note that the sunset date does not need to consider the timeframe in which it may be possible to substitute the substance in question in its uses.

**Regarding the burden of authorisation on certain industry sectors/prolong LADs:**
See reply to comment 2272 in section I.
<table>
<thead>
<tr>
<th>Comment ID</th>
<th>Date/Time</th>
<th>Organization/Address</th>
<th>Text</th>
<th>Reference to Other Comments</th>
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<tbody>
<tr>
<td>2452</td>
<td>2013/09/23 17:21</td>
<td>Industry or trade association, Belgium</td>
<td>please see comments in joint SEMI/ESIA response attached</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>2409</td>
<td>2013/09/23 13:28</td>
<td>ASD, Industry or trade association, Belgium</td>
<td>See attachment</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>2400</td>
<td>2013/09/23 12:53</td>
<td>Glencore Nikkelverk AS former Xstrata Nikkelverk AS, Company, Norway</td>
<td>A latest application date of 21 months after inclusion in Annex XIV of the RCFs is most presumably unachievable considering the technical challenges we as a company will have to solve. We also see organisational challenges if we join a consortia for the Authorisation process. This will be even more complicated given the lack of a separate CSR for each of the substances.</td>
<td>Regarding the burden of authorisation on certain industry sectors/prolong LADs: See reply to comment 2272 in section I.</td>
</tr>
<tr>
<td>2394</td>
<td>2013/09/23 12:31</td>
<td>Industry or trade association, Netherlands</td>
<td>I agree with the position of CerameUnie</td>
<td>See reply to comment 2361 in sections I, III and IV.</td>
</tr>
<tr>
<td>2386</td>
<td>2013/09/23 11:48</td>
<td>Company, Liechtenstein</td>
<td>Adequate regulation exists since many years, therefore we have looked for substitutes for a long period of time (ongoing), in many areas of our product-portfolio without success. We need long term planning periods because of the safety of our business and that of our customers (dental laboratories). Products of AlSi RCF are proven to be safe in the application.</td>
<td>Regarding the request to prolong the sunset date to further develop alternatives: See reply to comment 2459 in section II.</td>
</tr>
<tr>
<td>2366</td>
<td>2013/09/22 23:47</td>
<td>Deutsche Gesellschaft für Arbeitshygiene DGAH, National NGO, Germany</td>
<td>these proposed time Frames do only make sense, if not only the Arguments provided by the German BAuA will be validated looking also in the available Date provided by others.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2358</td>
<td>2013/09/20 22:32</td>
<td>Carbolite Limited, Company, United Kingdom</td>
<td>We have a range of 480 products that rely on the use of RCF material within the thermal insulation construction. If we would no longer be able to use these materials we would have to redevelop all these products. This range of products has been developed over many years of business and you could imagine would take a significant time to redevelop to use alternative materials. They would have to be redeveloped because there are no direct alternative materials to the range of materials made using RCF. We have been carrying out evaluation work on the AES alternatives available on the market place now from various suppliers. We can state that none of these are direct alternatives. We would have to make design changes to our product to be able to utilize the alternative AES materials and for some products it would change the technical specification of the product because the alternatives are not a direct equivalent. All redeveloped product would have to be tested for safety and performance. This would be very onerous for our business. We have our own forming process where we create our own formed shaped</td>
<td>Regarding the request to prolong the sunset date to further develop alternatives: See reply to comment 2459 in section II.</td>
</tr>
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</table>
parts in RCF materials. In some cases these formed parts also hold wire heating elements in place. It would take considerable time and investment for us to develop a forming process that could use the alternative AES materials, and of course that development may not be successful.

<table>
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<tr>
<th>Timestamp</th>
<th>Company, Poland</th>
<th>Action</th>
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<tr>
<td>2351 19:32</td>
<td>We suggest to postpone the date of inclusion of Al-RCF in Appendix XIV by 3 years to get time to develop relevant substitute. Current technology of our suppliers didn't achieve the refractory substitute with working temperature of 1300 C degrees, enough flexible to insulate the shells before pre-hat and pouring.</td>
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<tr>
<th>Timestamp</th>
<th>ADS Group Limited, Industry or trade association, United Kingdom</th>
<th>Action</th>
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<tr>
<td>2335 15:55</td>
<td>Aerospace would caution against blanket assumptions for validation of aerospace alternatives. Rigorous qualification testing is required based on engine application, hardware requirements, customer contracts and Airworthiness requirements set by the regulatory authorities. Should the EU Commission accept the ECHA recommendation then our industry would require an extended sunset date to allow sufficient time to present an application for Authorisation. The Authorisation process is not well understood, nor is it guaranteed and for a crucial product that has no viable alternatives. As a result we are extremely concerned and consider it essential that we are allowed to receive feedback from current Authorisation applications prior to pursuing yet another. An extensive Authorisation period would, however, still be required to allow us to collect the extensive empirical data to understand the long-term capability of any alternative material, and products, and how they interact with the surrounding environment. We note that failing to gain an Authorisation would be catastrophic for any aviation business intending to continue operations in the EU. From the point at which a viable alternative first becomes identified, extensive empirical data will be required to establish flight safety and airworthiness - this typically would take 10 years. As a result, Aerospace would therefore request a sunset date beyond 2025.</td>
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<tr>
<th>Timestamp</th>
<th>Refratechnik Cement GmbH, Company, Germany</th>
<th>Action</th>
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<tbody>
<tr>
<td>2332 15:43</td>
<td>Cement refractory applications are long term and high investment installations. Only parts of an installation are repaired during the lifetime of the total installation depending on the applications and individual conditions. Long term planning reliability is an important factor in the decision for cement investments. As a consequence we would need long term application dates (&gt; 30 years).</td>
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<tr>
<th>Timestamp</th>
<th>Salzgitter Flachstahl</th>
<th>Action</th>
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<tr>
<td>2320 15:43</td>
<td>see attached dokument</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>Time</td>
<td>Author</td>
<td>Comment</td>
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<tr>
<td>14:26</td>
<td>160 (200) GmbH, Company, Germany</td>
<td>Please, see document attached.</td>
</tr>
<tr>
<td>2314</td>
<td>2013/09/20 13:11 Wirtschaftskammer Österreich (WKO), Other contributor, Austria</td>
<td>The lifetime of kilns using (zirconia) aluminosilicate RCF is up to 30 years. Due to the high investment costs and the fact that most kilns are individually custom designed it is not possible to change to a different (and less energy efficient) kiln before the proposed sunset date.</td>
</tr>
<tr>
<td>2306</td>
<td>2013/09/20 12:09 Bundesverband Keramische Industrie e.V., Industry or trade association, Germany</td>
<td>The anticipated timeframe to successfully switch to alternate viable &amp; verified substances would be unlikely given the EASA &amp; other regulatory airworthiness approvals required in such a short timeframe.</td>
</tr>
<tr>
<td>2304</td>
<td>2013/09/20 12:06 Company, United Kingdom</td>
<td>Substitutions have been checked in some furnaces of heat/treatment and rolling mills (Isolation and expansion gaps). Additional some covering of maschine parts (Sparks, slag). In sectors/production sites where substitutions are possible they have been realized: some heat treatment furnaces and some covering applications. Result of substitution analysis: We had especially problems with the stability of replacement material in the temperature range above 1.200 degrees celsius. Facilities for high temperature processes have long service life times (between 10 to more than 20 years) (e.g. forging furnaces). The time scale for the analysis of alternatives lies in the same range as the service life time. The availability of facilities has to be ensured. Therefore Application date(s) and Sunset date(s) must be in a range of at least 20 years.</td>
</tr>
<tr>
<td>2300</td>
<td>2013/09/20 11:21 European Aluminium Association AISBL, Industry or trade association, Belgium</td>
<td>Facilities for high temperature processes have long service life times. Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are used in industrial</td>
</tr>
<tr>
<td>2297</td>
<td>2013/09/20 Company, Germany</td>
<td>Facilities for high temperature processes have long service life times. Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are used in industrial</td>
</tr>
<tr>
<td>Comment</td>
<td>Date/Time</td>
<td>Author</td>
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<td>10:59</td>
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<tr>
<td>2292</td>
<td>2013/09/20 10:29</td>
<td>CEMBUREAU, Industry or trade association, Belgium</td>
</tr>
<tr>
<td>2274</td>
<td>2013/09/19 16:24</td>
<td>Pruna Betreiber GmbH, Company, Germany</td>
</tr>
<tr>
<td>2272</td>
<td>2013/09/19 15:30</td>
<td>Group of associations, consortia and companies in the metals industry, Industry or trade association, Belgium</td>
</tr>
<tr>
<td>2270</td>
<td>2013/09/19 15:24</td>
<td>ThyssenKrupp Steel Europe AG, Company, Germany</td>
</tr>
</tbody>
</table>

**Industry:**
See reply to comment 2272 in section I

**Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:**
See reply to comment 2272 in section I

**Regarding the burden of authorisation on certain industry sectors/prolong LADs:**
See reply to this comment in section I.
Beside the temperature resistance other physical properties are essential for the use of those Ceramic Fibres. Depending on the physical strain the fibres have to be renewed after 12 or more years, in extreme situations lifetime can be much shorter.

<table>
<thead>
<tr>
<th>Comment ID</th>
<th>Date/Time</th>
<th>Author</th>
<th>Text</th>
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<tbody>
<tr>
<td>2254</td>
<td>2013/09/19 12:36</td>
<td>Sweden, Member State</td>
<td>We agree with the proposed dates.</td>
</tr>
<tr>
<td>2251</td>
<td>2013/09/18 15:55</td>
<td>CECOF, Industry or trade association, Germany</td>
<td>Facilities for high temperature processes have long service life times (between 10 to more than 20 years) The time scale for the analysis of alternatives lies in the same range as the service life time. The availability of facilities has to be ensured. Therefore Application date(s) and Sunset date(s) must be in a range of at least 20 years.</td>
</tr>
<tr>
<td>2247</td>
<td>2013/09/18 16:43</td>
<td>VDMA - FV TPT, Industry or trade association, Germany</td>
<td>Facilities for high temperature processes have long service life times (between 10 to more than 20 years) The time scale for the analysis of alternatives lies in the same range as the service life time. The availability of facilities has to be ensured. Therefore Application date(s) and Sunset date(s) must be in a range of at least 20 years.</td>
</tr>
<tr>
<td>2243</td>
<td>2013/09/18 15:55</td>
<td>CECOF, Industry or trade association, Germany</td>
<td>Facilities for high temperature processes have long service life times (between 10 to more than 20 years) The time scale for the analysis of alternatives lies in the same range as the service life time. The availability of facilities has to be ensured. Therefore Application date(s) and Sunset date(s) must be in a range of at least 20 years.</td>
</tr>
<tr>
<td>2182</td>
<td>2013/09/02 16:55</td>
<td>Company Austria</td>
<td>Substitutions have been checked according to TRGS 619 (Substitute materials for aluminium silicate wool products) In sectors/production sites where substitutions are possible they have been realized.</td>
</tr>
</tbody>
</table>

Regarding low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I

Regarding the burden of authorisation on certain industry sectors/ prolong LADs: See reply to comment 2272 in section I

Regarding the description of uses: See reply to comment 2272 in section I

Regarding the non-availability of
| Heat treatment furnaces (use of fire-resistant concrete or CaSi plates); burner for heating up (concrete for insulation); further examples are ladle covers, tundish or isostatically pressed products. Result of substitution analysis: specific requirement of materials and processes have to be taken into account: heat treatment furnaces: the time for heating up and cooling down becomes much longer when using the alternatives, costs for alternatives are much higher (25-30 times), operating costs become higher when using alternatives because of longer stand still times, steel construction of furnace has to be larger because of the higher weight of the concrete / CaSi plates compared to RCF’s. burner for heating up: steel construction of burner has to be larger because of the higher weight of the concrete compared to the RCF’s. Steel treatment ladles: Good insulation is an important part of the layered refractory lining in a ladle. The steel shell has to be protected from high temperatures coming from the liquid steel inside the ladle. If the insulation does not work properly there is a risk of the steel shell being deformed, added maintenance for the shell, loss of containment, and disruption of operations. RCF/ASW-Carton material with a temperature resistance of up to 1250° C, has been one of the best choices for this application in the past. Up to now, a biosoluble version of this type of material has not been able to achieve the same resistance against the combined high thermal and compressive loads. The main alternative is currently a vermiculite-based brick, but it has a higher thermal conductivity. Ladle Covers: In the case of ladle covers and roofs for ladle preheaters, easy installable KONIBLOCK fibre bricks are a popular choice. However, especially in the case of ladle covers where there is a minimal distance to the liquid steel and slag, a layer of high-alumina mix is recommended to protect such biosoluble materials from disintegration. Alternatively, lining with high insulating castables can be performed. Tundish: In regard to the achievable sequence length and process safety, tundish insulation is of major importance to prevent heat loss. An appropriate insulation design results in slower heating up of the steel shell and efficient tundish use. RCF/ASW boards are well established for this application because they are quick and easy to install. However, biosoluble fibre materials can also be considered for the tundish application because typical temperatures in the installation area are below the application temperature of biosoluble fibre materials. Isostatically pressed products: thermal insulations and preformed gaskets for isostatically pressed products, used in the steel continuous casting process, are characterized by their high-temperature stability, low thermal conductivity, and required flexibility. Traditionally, RCF/ASW has been the alternatives/information on alternatives in background document: See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2169 in section I
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Author/Entity</th>
<th>Response</th>
<th>Comment/Relevant Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2151</td>
<td>2013/08/16 11:42</td>
<td>KIND &amp; CO., Edelstahlwerk, KG Company Germany</td>
<td>We have repeatedly checked the possibilities of substitution also through several discussions with other companies of the forging industry in the committees of experts within professional association. There are no alternative materials applicable to our furnaces.</td>
<td>Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>2143</td>
<td>2013/08/14 15:19</td>
<td>Wirtschaftsvereinigung Stahl/Stahl Institut VDEh Industry or trade association Germany</td>
<td>High temperature process facilities have long service life times in ranges up to more than 20 years. The time scale for the analysis of alternatives lies in the same range as the service life time. The availability of facilities has to be ensured. Therefore Application date(s) and Sunset date(s) must be in a range of at least 20 years.</td>
<td>Regarding the burden of authorisation on certain industry sectors/prolong LADs: See reply to comment 2272 in section I Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>2140</td>
<td>2013/08/09 14:33</td>
<td>Austrian Association for Building Materials and Ceramic Industries Industry or trade association Austria</td>
<td>Der Fachverband Steine-Keramik stricht heraus, dass die Investitionszyklen innerhalb der Branche ausnehmend lang sind und der Zulassungsprozess entsprechende Planungsunsicherheiten auslösen würde wenn die Sunset-dates mit 18 Monaten festgelegt werden. Der Übergangszeitraum muss wesentlich länger sein, um eventuelle Änderungen vernünftig berücksichtigen zu können</td>
<td>Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>ID</td>
<td>Date/Time</td>
<td>Organization</td>
<td>Message</td>
<td>Relevant Section</td>
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<tr>
<td>2138</td>
<td>2013/08/09 13:25</td>
<td>Austrian Association for Steel and Mining Industry or trade association Austria</td>
<td>RCF are used in many high temperature applications in various key industry segments. High temperature processes are often unique, using highly customised equipment with 10-30 years of service life. In order enable long term investment planning long periods are necessary.</td>
<td>Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>2136</td>
<td>2013/08/09 13:17</td>
<td>Austrian Non Ferrous Metals Association Industry or trade association Austria</td>
<td>RCF are used in many high temperature applications in various key industry segments. High temperature processes are often unique, using highly customised equipment with 10-30 years of service life. In order enable long term investment planning long periods are necessary.</td>
<td>See reply to comment 2138 in this section.</td>
</tr>
<tr>
<td>2127</td>
<td>2013/08/01 13:</td>
<td>REY GRES., S.L. Company Spain</td>
<td>We are opposed to the inclusion of (Zr-) Al/Si RCF in annex XIV for the following reasons:  • Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production.  • No adequate substitutes are as yet available for these uses.  • RCF products are indispensable for meeting the EU ´s 2020 goals and industry ’s growing demand for resource and energy efficiency and the associated reduction of CO2.  • The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibiltiy).  • Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization.  • During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).</td>
<td>See reply to comment 2437 in section I.</td>
</tr>
<tr>
<td>2119</td>
<td>2013/07/31 09:31</td>
<td>Company Spain</td>
<td>No adequate substitutes are as yet available for these uses</td>
<td>Regarding the non-availability of alternatives/information on alternatives in</td>
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<td></td>
<td></td>
<td>background document:</td>
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<td></td>
<td>See reply to comment 2272 in section I</td>
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</tbody>
</table>
### III - Comments on uses that should be exempted from authorisation, including reasons for that:

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Submitted by (name, Organisation/MSCA)</th>
<th>Comment</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>2480</td>
<td>2013/09/23 20:28</td>
<td>European Automobile Manufacturers' Association – ACEA, Industry or trade association, Belgium</td>
<td>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, please see also attachment under point IV.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
</tr>
<tr>
<td>2475</td>
<td>2013/09/23 19:41</td>
<td>Industry or trade association, Belgium</td>
<td>See attachment, section IV (common paper with Zr-RCF, previously submitted under the Zr-RCF draft recommendation)</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>2472</td>
<td>2013/09/23 19:28</td>
<td>ChemSec, International NGO, Sweden</td>
<td>ChemSec supports the proposal of ECHA to not allow any exemptions.</td>
<td>Thank you for providing your opinion.</td>
</tr>
</tbody>
</table>
| 2465 | 2013/09/23 18:30 | AIR LIQUIDE, Company, France                                                                         | At least an exemption should be granted for existing units, for the following additional reasons:  
- SMR units provide directly H2, CO or syngas (H2/CO mixture) to a client (refinery, chemicals industry,...) through pipes.  
One important consequence of a SMR shutdown is the simultaneous shutdown of the downstream processes at our clients' sites.  
Programming the replacement of the insulation of all our units before a sunset date poses major contractual problems, technical coordination issues and impacts not just the hydrogen industry but many other downstream industrial activities.  
- Also, the storage capacities of the authorized landfills susceptible to accept the amount of RCFs from all involved industries may pose problems. The product being low density, we believe that we are talking about several tens of thousands cubic meters needed for the disposal of all RCFs in all industries and corresponding CO2 impact for transportation to the landfills.  
- demolition works correspond to the highest exposure of the personnel to RCFs. This replacement would add an unnecessary risk to the workers. | Regarding exemption request for existing units: Please note that for substances in Annex XIV the authorisation requirement applies for uses as such or in mixtures (above the relevant concentration limits). Use of articles (produced in the EU / imported) containing Annex XIV substances is not subject to authorisation (still articles' service life and waste stage need normally to be covered in applications for the use of incorporation of the substance into an article). Therefore, in case RCFs are included in Annex XIV, articles containing the RCFs which were produced before the sunset date (or which are imported) will be still possible to use after the sunset date, without authorisation. As long as authorisation is granted to a company (or up their supply chain) for incorporating an Annex XIV substance into an article, production of such articles can continue also after the sunset date. |
<table>
<thead>
<tr>
<th>2452</th>
<th>2013/09/23 17:21</th>
<th>Industry or trade association, Belgium</th>
<th>please see comments in joint SEMI/ESIA response attached</th>
<th>See reply to this comment in section I.</th>
</tr>
</thead>
</table>

| 2445 | 2013/09/23 16:47 | SSAB EMEA AB, Company, Sweden | Background<br>SSAB is a leading manufacturer of high strength and quenched steels, with production in Sweden and the United States. In Sweden the three major production sites are Luleå, Borlänge and Oxelösund. With our high strength steels, constructions became lighter, stronger or more durable. This way the customer does not need so much steel compared to regular steel.<br>Substitute of RCF-fibres<br>At SSAB EMEA in Sweden (hereafter named SSAB) a large scale programme for substitution of Zr-RCF(Zirconia Aluminosilicate Refractory Ceramic Fibres, also known as RCF) and Al-RCF(Aluminosilicate Refractory Ceramic Fibres, also known as ASW) fibers been made. Sometimes the change have been made to AES(AluminoEarthSilicate)-fibers and sometimes to dense castables(named “gjutmassa” in Sweden) or ceramic refractory. This substitution work started as soon as the new classification where known, and is still going on.<br>When changing system completely from fibre to dense castables or refractory bricks, the density change is huge and therefore the technology around also will have to change, for examples engines need to have higher capacity and whole constructions will have to be bigger to carry the sometimes 10 times heavier insulation construction. This has been a great development work together with investment. On the places where fiber is still needed, the use are normally of the AES-type of fibre. This type of fibre has often a shorter life time and need to be changed more often. When replacing the old AES with new one, there has most often been a change from the amorphous form to some of the crystalline forms of silica. This means that extra precautionary measures need to be made also when replacing the used AES fibre. <br>After all this development work and together with huge investments SSAB still need Zr-RCF or Al-RCF on two specific types of places in the production plants namely in the slab heating furnaces (named “ämnesugn” in Swedish) and in the blast furnace hot stoves (named “varmapparat” in Swedish). SSAB have two slab heating furnaces in Borlänge and two in Oxelösund. SSAB have totally three blast furnaces, one in Luleå and two in Oxelösund, with 3-4 blast furnace hot stoves | Regarding the description of uses:<br>See reply to comment 2272 in section I |<br>Regarding the non-availability of alternatives/information on alternatives in background document:<br>See reply to comment 2272 in section I |<br>Regarding low or controlled exposure/risk of RCFs:<br>See reply to comment 2272 in section I |<br>Regarding the exemption request/coverage by other legislation:<br>See reply to comment 2361 in section III |
connected to each blast furnace. Below some detailed information about why these fibres are needed and to witch amount.

The slab heating furnaces in Oxelösund
These slab heating furnaces are of the type called a pusher furnace, which means that the slabs are pushed on rails through the oven. The temperature in the oven go up to 1400°C. In Oxelösund the rails are made out of pipes which are cooled with water. There are longitudinal pipes with supportive transversal pipes in the oven. Where these two types of pipes are meet there is a need for a slide face between them and bellow there is a pole to support. This place where the pipes are meet is called a cross. The cross need to be insulated in order to work correctly. The best insulation today are Zr-RCF or Al-RCF. This is a common technique for these types of ovens. The yearly need is approximately 1000 kg. See also additional information in attached confidential document.

The slab heating furnaces in Borlänge
The slab heating furnaces in Borlänge are of a type called walking furnace, the temperature in these two ovens are above 1400°C. Due to changes in the temperature each oven has two zones with so called expansion joints (to take up the movement that will occur during the temperature changes). In these expansion joints the fiber is changed when need occur. Each year approximately 70 kg of Zr-RCF or Al-RCF is needed to be changed in these two ovens together. In this temperature interval the AES type of fiber does not stand the stress of the heat in combination with the movement. If the AES fiber type where to be used then there will be a great risk that it will scrimp/melt and create heat leakage with another direct risk for the safety of workers near the ovens as well as damaging vital parts of the oven and create stop in the production.

Blast furnace hot stoves in Luleå and Oxelösund
The purpose of the blast furnace hot stoves are to heat the air before using the air in the blast furnace. The hotter air the better efficiency of the blast furnace. 100°C increase of the air blast give a reduction of the coke need in the blast furnace by 10 kg coke per produced tone of crude iron, and at the same time a reduction of the emitted amount of CO2 corresponding to the coke reduction.

The blast furnace hot stoves, consists of a burner shaft and a checker work shaft with lots of fire-clay bricks. It works like a heat exchanger. First you heat the bricks in the checker work shaft by burning and then you stop burning and let air come through the system. This is why a blast furnace need 3-4 blast furnace hot stoves. When the checker work
shaft is properly heated then the burners are shut down and air is led up through the checker work shaft and then down through the burner shaft and off to the blast furnace. The flame temperature is between 1400-1500°C. The burner shaft is the place with the highest temperature changes, with a fluctuation up to approximately 400°C. These fluctuations create an expansion and a contraction in the oven. The oven is coated with fire-clay bricks and a mantle of steel, between these layers there is isolating bricks who are to take up the movement. The continuous expansions and contractions in the oven creates a grinding effect on the isolating bricks. Over time this usually create hot spots in the oven and to fix these hot spots, SSAB use a filling like a paste with Zr-RCF or Al-RCF fibers in. A hole is drilled in the mantle, then the paste is pushed in to the right place, afterwards the hole is sealed. The fibres are in place until the fire-clay bricks in the blast furnace hot stoves will be changed completely. The material needs to withstand a temperature up to 1400°C especially in the lower part of the burner shaft where cracks can occur in the fire-clay bricks. By using this method the lifetime of the hot-blast cupolas can be extended by several years.

Although, SSAB are well aware of the classification of the Zr-RCF and Al-RCF fibers, so at the moment a test is going on at one place with another paste with unclassed AES fibres. But it is too early to know the outcome of this test.

If SSAB can't substitute the RCF in above mentioned use, the approximate amount needed would be about 0-300 kg fibre per year.

Removing and replacing fibres at SSAB
The work to remove and replace fibres at SSAB are often a co-operation between SSAB employees and different external experts. This type of job is often done during the summer standstill period and in project form. SSAB run the projects and also have their own experts in the occupational health department. External experts from waste companies as well as experts from insulating and refractory ceramics installation companies are mostly present in this kind of work as well as other external companies depending on the work ahead. SSAB might seem like a big company in Sweden, but in comparison with other Iron- and Steel producing companies around the world SSAB are small and therefore can't afford to have own experts in every field of work.

Occupational health and fibre counting analysis
At SSAB the respect for fibres are high and the Swedish workplace regulations are followed. Employees that came in contact or are at risk in getting in contact with fibres will have to be tested for lung function and undergo other specified medical examinations before being allowed

| Table |
to work with fibres. During close contact removal of fibres the workers use protection hoods with fresh air or regular dust masks and disposable work wear depending on the fibre release. When removing old fibres it does not matter if it is AES wool that had undergone changes from amorphous form to different crystalline forms or if it is a RCF type of fibre. Both types are treated extremely carefully and put away in plastic bags or sucked away by a sucking machine or lorry (which are design to suck fibres). The disposal is made by waste experts and the fibres are taken care of at deposits that are permitted to receive such waste.

Fibres have also been measured both before removing and during the removing work. If we are not sure about what type of fibre there are in some places we carry out an analysis. In Oxelösund and Borlänge there have been approximately 17 different determination of airborne fibre number concentrations over the past 10 years both during production and during removal and replacing with new wool. The fibre air analyses help SSAB confirm that the efforts made had the right effect.

Alternatives to Zr-RCF and Al-RCF in the SSAB use

When fibres are needed there are today two alternatives PCW (polycrystalline wool) and AES:
The PCW withstand a much higher temperature than RCF but are the same type of fibre like Zr-RCF and Al-RCF, but are not classed today because the sold amount of this fibre are so low. PWC is not cost effective because the price is ten times higher than the regular RCF. The AES alternative does not have the right properties to tolerate the temperatures along with the movements that occur on the uses described above.

Conclusions

Today the alternatives are poor but the work to substitute will continue.

Over the past ten years the work of substitute the Zr-RCF and Al-RCF to AES fibres have resulted in a total need of the relatively small amount of 1200-1500 kg Zr-RCF and Al-RCF fibre per year, for SSAB EMEA in Sweden, within the EU.
The Zr-RCF and Al-RCF are only used when every other possibility is ruled out.

Proposals

SSAB propose that the use of Zr-RCF and Al-RCF in steel slab heating processes and in blast furnace hot stoves should be exempted.

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2444 2013/09/23 16:45 Company, Switzerland EIGA requests that the following use should be exempted:

"Use of RCF for the insulation of high temperature furnaces (above 900°C) in a reducing atmosphere for a long continuous operation", for the following reasons:

See response to comment 2216 in this section.
Existing Community legislation properly controls the risks to human health and the environment from the use of the substance arising from the intrinsic properties of the substance and the existing Community legislation also imposes minimum requirements for the control of risks of the use.

- The legislation in question is the Carcinogen & Mutagen Directive (2004/37/EU) which is currently under review to be updated and for which a Community-wide OEL specific to RCF is currently being proposed (0.1-0.3 f/ml as per ACSH Opinion Document 2011/2012 adopted on 05/12/2012).

- There is a strong case to validate that RCF is a threshold carcinogen and therefore can be adequately controlled by the appropriate OEL
  - SCOEL (2011) Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic fibres - SCOEL/SUM/165
    - "...concluded that the genotoxic effects observed in the different studies are secondary so that RCFs are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported";
    - Which builds on comments from 2010 SCOEL “for these compounds a true ("perfect") threshold is associated with a clearly founded NOAEL”.
  - This is also quoted in the IOM (Institute of Occupational Medicine) Research Project: P937/14 from May 2011, who was acting as a consultant for the European Commission.
  - Also the conclusion of the Health Council of the Netherlands supports the presence of a threshold for RCF
    - "Overall, the Committee considers the induction of chronic inflammation as the most plausible mechanism of carcinogenic action of RCFs. This would imply a threshold mechanism of action. In addition, it is unlikely that RCFs possess stochastic genotoxic properties via direct production or reactive oxygen species, due to the very low iron content. However, the Committee emphasizes that the relevance of genotoxicity testing for fibres is limited due to a lack of in vitro assays suitable for fibres.”
    - This report can be downloaded from www.healthcouncil.nl
Existing industry practice and RMM’s (risk management measures) in SMR operations are already adequately managing exposure to RCF’s to ensure it is well below the lowest proposed OEL (0.1-0.3 f/ml) as evidenced by actual measured exposure data (see attached document – section 2) which demonstrates insignificant ambient pollution.

Keep in mind that such SMR’s are operated continuously 24/7 which further minimises opportunity for exposure during normal operation unlike in some other RCF uses where they are batch operated and where the regular temperature cycling also reduces their lifetime and increases frequency of maintenance.

Furthermore the number of workers exposed is very low due to the low frequency of maintenance (typically 3-5 years) and the long technical life of the furnaces (30 years)

During minor maintenance, operators always wear full body protective clothing such as disposable overalls, gloves, protective glasses or goggles and high quality particle filters.

For new build and major maintenance, this work is always undertaken by specialist contractors. In order to minimise RCF exposure outside the furnace the SMR building is held at a slightly negative pressure and air (plus any particulates/fibres) withdrawn from the building via appropriate filters.

- The operating temperature of SMR’s is higher than for many other RCF uses and there is no available, proven substitute for furnaces operating at these temperatures and, in particular, in such a reducing atmosphere – see below for more details
- For the specific kind of SMR’s described in these comments it is estimated that there are less than 100 in operation by EIGA member companies today and during normal maintenance operations less than 100 tonnes pa of RCF is being handled. The combination of the unique challenges represented by these SMR’s and the very low volumes involved during in-situ maintenance make this case an obvious choice for exemption.

Furnace doors seals, furnace panel insulation, heaters insulation, and some high temperature tubes insulation among others. Due to its thermal stability and flexibility intervention over the insulation lining is very limited. These materials has already been substitute in many uses wherever was possible and technically and economically viable. They used to be covered by other materials (reflective metallic sheets) and manipulation, if needed, is carried out by trained personal, specially for very high temperature uses where the silica might have suffer a
<table>
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<th>Timestamp</th>
<th>Author</th>
<th>Comment</th>
<th>Response</th>
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<tbody>
<tr>
<td>2409 2013/09/23 13:28</td>
<td>ASD, Industry or trade association, Belgium</td>
<td>partial recrystallization. A limited exposure in practice is supported by the measurements which shown actual figures between 0.1 and 0.01 fibers/cm³. To improve and ensure the application of the current Risk Management Tools is more adequate. We should not forget that in many cases these substances are eventually used as articles. Therefore the authorisation process is not the more suitable tools. IN parallel, it should not be forgotten that regardless of whatever authorization, these materials fall under the classification and labeling regulation. In Spain the Instituto Nacional Seguridad e Higiene en el Trabajo (INSHT), with in their technical files NTP 641 and 642 fix an exposure limit of 0,5 fibers/cm³ for these kind of fibers. <a href="http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasTecnicas/NTP/Ficheros/601a700/ntp_641.pdf">http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasTecnicas/NTP/Ficheros/601a700/ntp_641.pdf</a> <a href="http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasTecnicas/NTP/Ficheros/601a700/ntp_642.pdf">http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasTecnicas/NTP/Ficheros/601a700/ntp_642.pdf</a></td>
<td>See reply to comment 2292 in section I.</td>
</tr>
<tr>
<td>2403 2013/09/23 13:14</td>
<td>Individual, Spain</td>
<td>We are opposed to the inclusion of (Zr-) Al-Si RCF in annex XIV for the following reasons: • Because of its unique combination of desired characteristics, RCF is still needed in many high temperature applications, especially as furnace linings for ceramic tiles production. • No adequate substitutes are as yet available for these uses. • RCF products are indispensable for meeting the EU’s 2020 goals and industry’s growing demand for resource and energy efficiency and the associated reduction of CO₂. • The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility). • Our company competes in international markets with manufacturers from other countries (China, Iran, Turkey, Brazil, Mexico, etc.) where the use of RFC has no need of authorization. • During the normal operation of RCF containing industrial equipment, exposure of operators is highly unlikely. Adequate control – only small group of trained and adequately equipped workers are exposed. Exposure to workers operating RCF containing process equipment negligible (typically below LOD).</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>2394 2013/09/23 12:31</td>
<td>Industry or trade association, Netherlands</td>
<td>I agree with the position of CerameUnie</td>
<td>See replies to comment 2361 in sections I, III and IV.</td>
</tr>
</tbody>
</table>
| 2386 | 2013/09/23 11:48 | Company, Liechtenstein | If authorisation is necessary then professional and industrial use in furnaces having a process temperature > 900°C should be exempted. This covers dental furnaces for use in the dental practice and dental laboratory. This is because every furnace is unique according to the needs in a specific application. Beside temperature limitations there are also chemical corrosion and physical limitations (i.e. thermal shock resistance) to be taken account of. This is mandatory to achieve a safe process and avoid damage. Changes in the thermal insulation may also lead to alterations in the temperature regimes in the firing chamber. These changes may have a detrimental but undetected effect on the end product (dental restoration for placement in patient’s mouth). The professional use of AlSi/RCF products in laboratory and dental furnaces should be exempted to maintain the safety for workers and the business. | Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III
Regarding the burden of authorisation on certain industry sectors/prolong LADs: See reply to comment 2272 in section I |
| 2361 | 2013/09/21 13:33 | Cerame-Unie - The European Ceramic Industry Association, Industry or trade association, Belgium | The use of RCF is already well regulated. At first, a restriction applies under Directive 2001/41/EC, limiting the use to industrial applications only. Furthermore, as regards industrial applications, the risk is properly controlled. National OELs (occupational emission limit) exist for RCF and a European binding OEL for RCF under the Carcinogens and Mutagens Directive is currently under discussion as part of the overall review of this Directive. A binding OEL for RCF is expected by the end of 2014, i.e. before authorisation would start. We therefore believe the criteria mentioned in REACH article 58 (2) are met as concerns the use of aluminosilicate RCF in the production of articles used for the ceramic industry. In addition, this binding OEL will be applicable throughout the supply chain and cover all types of RCF covered by CAS number (142844-00-6) and EU number (604-314-4). As mentioned before, the current two dossiers put forward for prioritisation do not cover this full scope. Cerame-Unie welcomes the SVHC-Roadmap which was published in 2013 and advocates a RMO (Risk Management Options) assessment before substances are proposed for the candidate list. As such assessment was not carried out in 2009 or 2011, we strongly recommend a proper RMO assessment for these materials before any further action is taken in respect of authorisation. An authorization process will not bring an added-value in terms of environment or human health but will have a negative impact on the energy efficiency of the ceramic industry and hence the competitiveness of this industry. This is in conflict with the aim of REACH to enhance competitiveness and the aim of authorisation to ensure the good functioning of the internal market. | Regarding the exemption request/coverage by other legislation: Information on the low level of risk associated to a use or related to the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use, as well as the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. Please note that according to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses |
or categories of uses ‘provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled’.

ECHA considers the following elements when deciding whether to include an exemption of a use of a substance in its recommendation:
- There is existing EU legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question, compared to the REACH definitions in accordance with Art. 3(24). Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- This EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to, e.g. by referring to the classification criteria or the Annex XIII criteria;
- This EU legislation imposes minimum requirements for the control of risks of the use. Legislation setting only the aim of imposing measures or not clearly specifying the actual type and
<table>
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<tr>
<th>Date/Time</th>
<th>Company/Industry/Trade Association</th>
<th>Location</th>
<th>Description</th>
<th>Relevance and Context</th>
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<tbody>
<tr>
<td>2358 22:32</td>
<td>Carbolite Limited, Company, United Kingdom</td>
<td></td>
<td>Uses that should be exempted are use of RCF materials as thermal insulation; specifically for use in laboratory and industrial ovens and furnaces. There are already occupational exposure limits for these RCF materials that are used to control the use of the materials in the workplace. We work with the materials in our work place and have control measures in place with regular check to ensure our workers are protected. Once the materials are installed in the products the exposure to the material by the end users of our products is minimal i.e. they are not working with the material directly – they are contained in the products.</td>
<td>Article 58(2) exemption response: See reply to comment 2169 in section I</td>
</tr>
<tr>
<td>2351 19:32</td>
<td>Company, Poland</td>
<td></td>
<td>Production of equiax, investment castings for aerospace engines (including blades, vanes) made out of supper alloys for insulation, wrapping process.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
</tr>
<tr>
<td>2335 15:55</td>
<td>ADS Group Limited, Industry or trade association, United Kingdom</td>
<td></td>
<td>The thermal and electrical insulation and fire burn-through protection offered by RCF on products that experience a wide range of atmospheric and usage conditions throughout their significant lifecycle is essential for the aerospace industry to meet stringent Airworthiness requirements. Many areas of the components surrounded by RCF-containing products are inaccessible and difficult to inspect for damage following product delivery without disassembly. These product areas are expected to last for the anticipated product lifespan, i.e. in excess of 40 years. RCF-containing products are used in the fabrication of thermal insulating blankets that provide the required significant thermal gradient between</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
</tr>
</tbody>
</table>
high temperature structural components and lower temperature-capable containment structures, rigid fire burn-through protection components to meet aerospace fire containment requirements, flexible electrical insulating wrappings on critical electrical wires in high temperature exposure applications as well as providing structural reliability for high temperature composites. All of these applications are dependent upon several unique characteristics of the RCF. The thermal and acoustical insulating properties of a RCF are due to its high aspect ratio that makes it difficult to pack tightly resulting in a bulk material with large amount of space or air between fibres or filaments yielding a product that is a thermal insulator and acoustical damper. The high melting points of the composition in RCF make them highly resistant to fires and they do not outgas toxic materials. RCF are electrically insulating and can be formed into tubing making them an excellent insulator for electrical wiring, especially for high temperature, severe environments commonly encountered by the aerospace industry. Finally, the high temperature strength retention capability and chemical stability of RCF make them an excellent candidate for ceramic and metal composite reinforcement. As a result, the industry needs to have qualified materials and processes that have a high degree of compatibility with previously used materials. Aviation materials are highly-engineered, low-volume products. For most high temperature RCF applications, in particular as a safety thermal barrier in aircraft, no known equivalent material or product currently exists. These applications, and others, in the Aerospace sector should be exempted as was highlighted during the public consultation of the Candidate Listing phase for these products. It should be stressed that exposure to the general public of RCF’s does not occur from our usages.

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<th>Date</th>
<th>Time</th>
<th>Company, Germany</th>
<th>Description</th>
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<tbody>
<tr>
<td>2332 2013/09/20 15:43</td>
<td></td>
<td>Refratechnik Cement GmbH, Company, Germany</td>
<td>Based on our practical experience and ongoing substitution tests the limit for AES products is at 900-1000°C and even lower under specific physical and chemical conditions in an application.</td>
</tr>
</tbody>
</table>

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

2327 2013/09/20 15:31 | Company, Germany | In accordance with EIGA comments also LINDE requests that the following use should be exempted: “Use of RCF for the insulation of high temperature furnaces (above 900°C) in a reducing atmosphere for a long continuous operation”, for the reasons as explained by EIGA. It is important to understand that real tests/trials under real operating conditions showed, that there is no adequate or proven substitution material available - this statement is done knowing that other

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2216 in this section.

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I
documents based on theoretical data and assumptions explain that such alternative materials would be already available, again this is not the case (also not for AES or SLA-92 or others) based on LINDE experiences.

As also explained by EIGA, existing industry practice and RMM’s (risk management measures) in SMR operations are already adequately managing exposure to RCF’s to ensure it is well below the lowest proposed OEL (0.1-0.3 f/ml.

| 2323 | 2013/09/20 15:22 | Company, Germany | Application: Transfer rollers and roller changing system in the hot and cold milling steel production, > 1300°C.

We will inform that in applications for transfer rollers in the hot and cold milling steel production worldwide the ASW based insulation boards are used up to 1300°C process temperature combined with a very heavy load.

In this application an ASW based Material is necessary for technical reasons.

There is no commercial and technical alternative material available on the market yet – beside asbestos.

This means a serious technical and commercial disadvantage of producers and end users in the EU.

In former times asbestos rollers were used whole over the world and are still used in countries were asbestos is actually allowed.

If ASW material gets prohibited there exists the danger for changing back to asbestos material.

There is also a danger that the ASW based Materials for transfer roller applications and high temperature insulation are produced outside of the regulation district and delivered back as an article into EU. Finally this would be a serious discrimination and distortion of competition of European producers and steelworks.

Also a movement of labor and steel industry could be a worst case scenario.

Our actual tonnage is round about 600 to/a (confidential). Worldwide of course few times more

| 2320 | 2013/09/20 14:26 | Salzgitter Flachstahl GmbH, Company, | see attached dokument

Regarding the non-availability of alternatives/information on alternatives in background document:
See reply to comment 2272 in section I

Regarding the perception of authorisation being a ban of the substance:
See reply to comment 2292 in section I

Regarding addressing imported articles:
See reply to comment 2272 in section I

Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:
See reply to comment 2272 in section I

See reply to this comment in section I.
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<th>Comment</th>
<th>Date/Time</th>
<th>Entity</th>
<th>Description</th>
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<tbody>
<tr>
<td>2314</td>
<td>2013/09/20 13:11</td>
<td>Wirtschaftskammer Österreich (WKÖ), Other contributor, Austria</td>
<td>Please, see document attached.</td>
</tr>
<tr>
<td>2308</td>
<td>2013/09/20 12:25</td>
<td>centrotherm photovoltaics AG, Company, Germany</td>
<td>All special lab and industrial furnace application above 1000°C should be exempted from authorization. Based on our practical experience worker protection is realized through existing regulation since many years and the use is adequately controlled. Beyond worker protection competitiveness for the European producers and users for our products should be kept by using ASW products to ensure employment in these areas.</td>
</tr>
<tr>
<td>2306</td>
<td>2013/09/20 12:09</td>
<td>Bundesverband Keramische Industrie e.V., Industry or trade association, Germany</td>
<td>(Zirconia) Aluminosilicate RCF based articles are used in ceramic installations as insulating material in the kilns. During kiln operation, exposure to workers is insignificant. The majority of ceramic kilns are continuously working tunnel kilns or roller kilns. Therefore exposure is strictly limited to defined moments during inspection/maintenance and demolition. Due to the specific industrial nature of these activities this is carried out by trained operators under highly controlled conditions. The zirconia aluminosilicate RCF which is ‘used’ in the ceramic industry in the sense that articles consisting of these fibres are a part of the kiln furniture i.e. they cover the walls and/or roof of the kiln (furnace). These articles can be sheets, bricks, blankets, rolls, modules. The ceramic industry is a customer for these articles, not a downstream user according to the REACH definition.</td>
</tr>
</tbody>
</table>
| 2304    | 2013/09/20 12:06 | Company, United Kingdom | 2 aerospace uses and 1 industrial use:  
(1) RCF used as heatshield material due to its insulant properties in solenoid valves for use in aircraft engine air bleed system controls.  
(2) RCF used as heat protection insulator (no known validated alternative) used in the Crash-Survivable Memory Unit (CSMU), commonly referred to as a “black box” in the Eurofighter Typhoon fighter aircraft used by multinational Ministries of Defence, including UK, Austria, Germany, Spain, Italy, Saudi Arabia & Oman. Due to airworthiness implications concerning any aerospace alternatives |
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<th>Organization</th>
<th>Actions/Remarks</th>
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| 2301       | 2013/09/20 11:26 | Deutsche Edelstahlwerke GmbH, Company, Germany | Applications in high temperature processes at temperatures higher than 900 - 1200 degrees C (at 900 degrees C the uses of alumina silicate wool is dependent on the conditions such as control strategies and flexibility seals).

Furnaces (insulating material and flexibility seals) for rolling mill and forging.

Insulating and sealing material at the ladle with molten steel.

Sealing material at the cast iron mould (continuous casting).

Application: production of steel and other high-temperature processes.

Steel produced in the described facilities is used in the following fields: automotive, aviation, medical, wind turbine gearbox.

All industrial uses where alumina silicate wool is used in the production under controlled conditions should be exempted from authorisation. The end products do not content alumina silicate wools, so there is no risk for the consumer or of pollution of the environment. |

| 2292       | 2013/09/20 10:29 | CEMBUREAU, Industry or trade association, Belgium | See attachment |

| 2265       | 2013/09/19 14:24 | Refratechnik Steel GmbH, Company, Germany | Based on our practical experience and ongoing substitution tests the limit for AES products is at around 900°C and even lower under specific physical and chemical conditions in an application. These applications should be exempted from authorisation as a minimum to prevent from bureaucratic costs without improving workers |

**See reply to comment 2459 in section II**

**Regarding the burden of authorisation on certain industry sectors/prolong LADs:**
See reply to comment 2272 in section I

**See reply to this comment in section I.**

**See reply to comment 2361 in section III**

**Regarding the exemption request/coverage by other legislation:**

*See reply to comment 2361 in section III*
The documentation used in this public consultation didn’t use CAS numbers for substance identification. Using CAS numbers is an essential support for users to identify whether the material they use is within the inclusion in the authorisation list or not.

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<th>Comment</th>
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<th>Issue</th>
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<tr>
<td>2251</td>
<td>2013/09/18 15:55</td>
<td>CECOF, Industry or trade association, Germany</td>
<td>ITPE in high temperature processes at temperatures higher than 600 degrees C the use of RCF/ASW is a need base on energy saving and CO2 reduction reasons. A combination of process and design parameters result in an unmanageable variety of possibilities and therefore a general clustering of ITPE is not possible. (ErP) Material produced in the described high-temperature ITPE is used in the following fields: e. g. automotive and automotive supplier, energy, wind power station and other re-newable energy equipment, heat treatment of products made of steel, nonferrous metals, ceramics, porcelain, glass, other high-end applications. All industrial processes where RCF/ASW products are used under controlled conditions, based on existing regulation (Art 58.2) should be exempted from authorisation. The end products do not content RCF/ASW, so there is no risk for the consumer.</td>
</tr>
<tr>
<td>2248</td>
<td>2013/09/18 17:21</td>
<td>Company, Germany</td>
<td>The use of RCF for temperatures more than 1050 °C should be exempted from authorization.</td>
</tr>
<tr>
<td>2247</td>
<td>2013/09/18 16:43</td>
<td>VDMA - FV TPT, Industry or trade association, Germany</td>
<td>ITPE in high temperature processes at temperatures higher than 600 degrees C the use of RCF/ASW is a need base on energy saving and CO2 reduction reasons. A combination of process and design parameters result in an unmanageable variety of possibilities and therefore a general clustering of ITPE is not possible. (ErP) Material produced in the described high-temperature ITPE is used in the following fields: e. g. automotive and automotive supplier, energy, wind power station and other re-newable energy equipment, heat treatment of products</td>
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Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I

Regarding the unclear substance identity: See reply to comment 2272 in section I

Article 58(2) exemption response
Please see response to comment 2489, Section I.

Regarding the socio-economic impact, e. g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I

Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I

Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III

See response to comment 2251 in this section
made of steel, nonferrous metals, ceramics, porcelain, glass, other high-end applications. All industrial processes where RCF/ASW products are used under controlled conditions, based on existing regulation (Art 58.2) should be exempted from authorisation. The end products do not contain RCF/ASW, so there is no risk for the consumer.

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<tr>
<td>2243</td>
<td>2013/09/18 15:55</td>
<td>CECOF, Industry or trade association, Germany</td>
<td>ITPE in high temperature processes at temperatures higher than 600 degrees C the use of RCF/ASW is a need base on energy saving and CO2 reduction reasons. A combination of process and design parameters result in an unmanageable variety of possibilities and therefore a general clustering of ITPE is not possible. (ErP) Material produced in the described high-temperature ITPE is used in the following fields: e.g. automotive and automotive supplier, energy, wind power station and other re-newable energy equipment, heat treatment of products made of steel, nonferrous metals, ceramics, porcelain, glass, other high-end applications. All industrial processes where RCF/ASW products are used under controlled conditions, based on existing regulation (Art 58.2) should be exempted from authorisation. The end products do not contain RCF/ASW, so there is no risk for the consumer. See response to comment 2251 in this section</td>
</tr>
<tr>
<td>2239</td>
<td>2013/09/18 13:52</td>
<td>Glass Alliance Europe, Industry or trade association, Belgium</td>
<td>The use of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) is essential in the European glass industry in certain insulation applications, allowing for energy savings and environment protection. Major efforts have been made over the last decade to substitute RCF products wherever possible. Substitute materials have been investigated in glass furnaces applications. Glass manufacturers have already implemented the use of alternative materials for certain applications, where technically and economically feasible, for many years. Nevertheless, substitute materials are still not available for all applications. To date, no appropriate materials have been found that can withstand the required combination performance of the high thermal, chemical and mechanical stress experienced in the high temperature glass melting process and at the same time giving appropriate insulation performance. (please see arguments developed in the attached file) Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>2235</td>
<td>2013/09/17 17:35</td>
<td>Nordenhamer Zinkhütte GmbH, Company, Germany</td>
<td>The use as heat isolation material in the roasting section should be exempted. Arguments see our general comment above. Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
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<tr>
<td>ID</td>
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<tr>
<td>2222</td>
<td>2013/09/16 14:09</td>
<td>Selas-Linde Company Germany</td>
<td>see general comments!</td>
</tr>
<tr>
<td>2218</td>
<td>2013/09/16 08:58</td>
<td>Sandvik Wire &amp; Heating Technology, ZN der SMT Deutschland GmbH Company Germany</td>
<td>Exempted from authorization: All special lab and industrial furnace application above 800°C should be exempted from authorization to ensure safe use of the equipment and to prevent from worker protection issues resulting from so-called substitutes. Based on our practical experience worker protection is realized through existing regulation since many years and the use is adequately controlled. Beyond worker protection competitiveness for the European producers and users for our products should be kept by using ASW products to ensure employment in these areas.</td>
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<tr>
<td>2216</td>
<td>2013/09/15 18:48</td>
<td>EIGA (European Industrial Gases Association) Industry or trade association Belgium</td>
<td>EIGA requests that the following use should be exempted: &quot;Use of RCF for the insulation of high temperature furnaces (above 900°C) in a reducing atmosphere for a long continuous operation&quot;, for the following reasons: - Existing Community legislation properly controls the risks to human health and the environment from the use of the substance arising from the intrinsic properties of the substance and the existing Community legislation also imposes minimum requirements for the control of risks of the use. o The legislation in question is the Carcinogen &amp; Mutagen Directive (2004/37/EU) which is currently under review to be updated and for which a Community-wide OEL specific to RCF is currently being proposed (0.1-0.3 f/ml as per ACSH Opinion Document 2011/2012 adopted on 05/12/2012). - There is a strong case to validate that RCF is a threshold carcinogen and therefore can be adequately controlled by the appropriate OEL o SCOEL (2011) Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic fibres - SCOEL/SUM/165 &quot;...concluded that the genotoxic effects observed in the different studies are secondary so that RCFs are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported&quot;; o Which builds on comments from 2010 SCOEL &quot;for these compounds a true (&quot;perfect&quot;) threshold is associated with a clearly founded NOAEL&quot;. o This is also quoted in the IOM (Institute of Occupational Medicine) Research Project: P937/14 from May 2011, who was acting as</td>
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a consultant for the European Commission. Also the conclusion of the Health Council of the Netherlands supports the presence of a threshold for RCFs. The conclusion of the Health Council of the Netherlands, 2011; publication no. 2011/29. “Overall, the Committee considers the induction of chronic inflammation as the most plausible mechanism of carcinogenic action of RCFs. This would imply a threshold mechanism of action. In addition, it is unlikely that RCFs possess stochastic genotoxic properties via direct production or reactive oxygen species, due to the very low iron content. However, the Committee emphasizes that the relevance of genotoxicity testing for fibres is limited due to a lack of in vitro assays suitable for fibres.”

This report can be downloaded from www.healthcouncil.nl.

Existing industry practice and RMM’s (risk management measures) in SMR operations are already adequately managing exposure to RCF’s to ensure it is well below the lowest proposed OEL (0.1-0.3 f/ml) as evidenced by actual measured exposure data (see attached document –section 2) which demonstrates insignificant ambient pollution.

Keep in mind that such SMR’s are operated continuously 24/7 which further minimises opportunity for exposure during normal operation unlike in some other RCF uses where they are batch operated and where the regular temperature cycling also reduces their lifetime and increases frequency of maintenance.

Furthermore the number of workers exposed is very low due to the low frequency of maintenance (typically 3-5 years) and the long technical life of the furnaces (30 years).

During minor maintenance, operators always wear full body protective clothing such as disposable overalls, gloves, protective glasses or goggles and high quality particle filters.

For new build and major maintenance, this work is always undertaken by specialist contractors. In order to minimise RCF exposure outside the furnace the SMR building is held at a slightly negative pressure and air (plus any particulates/fibres) withdrawn from the building via appropriate filters.

The operating temperature of SMR’s is higher than for many other RCF uses and there is no available, proven substitute for furnaces operating at these temperatures and, in particular, in such a reducing atmosphere – see below for more details.

For the specific kind of SMR’s described in these comments it is
estimated that there are less than 100 in operation by EIGA member companies today and during normal maintenance operations less than 100 tonnes pa of RCF is being handled. The combination of the unique challenges represented by these SMR’s and the very low volumes involved during in-situ maintenance make this case an obvious choice for exemption.

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<th>Regarding the description of uses:</th>
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<tr>
<td>2201</td>
<td>2013/09/10 13:37</td>
<td>Forschungsgemeinschaft Feuerfest e.V Other contributor Germany</td>
<td>Uses &gt; 900°C</td>
<td>See reply to comment 2361 in section III</td>
</tr>
<tr>
<td>2189</td>
<td>2013/09/04 08:43</td>
<td>Company Germany</td>
<td>Use in closed technical devices in aeroengines (heatprotector, sealing, etc.)</td>
<td>See reply to comment 2361 in section III</td>
</tr>
<tr>
<td>2187</td>
<td>2013/09/03 18:11</td>
<td>RIEDHAMMER GmbH Company Germany</td>
<td>RIEDHAMMER engineers, delivers and brings in operation heat treatment plants for the industrial application fields of ceramic sintering, baking carbon products and powder metals sintering. The working temperature range is starting at 550 °C up to 1850°C. The kiln plants and furnaces are nearly all customized. More than 85% are exported. Unfortunately there is never ever only the temperature as a parameter that specifies the applicable lining of the kiln or furnace. In all above mentioned operations also chemical reactions between atmosphere and product and lining material are taking place. Sometimes these reactions are also time or cycle time related. The selection of the right lining materials and concepts are relevant for the later success of process and the operation of the plant. RIEDHAMMER during the last 3 years intensively tried to substitute Al-RCF products with AES wool products. In all applications (5) AES could not succeed. AES wool failed even far below 800°C application temperature due to atmosphere conditions and chemical corrosion. AES only achieved 13%-27% of lifetime compared to Al-RCF, means that the lining of these production plants has to be replaced within 2 years to 3 years instead of 10 to 15 years. The results were in all cases economical disasters for the customer and us. As a consequence of these bad experiences we have to use mandatory Al-RCF for the above mentioned applications. RIEDHAMMER is employing about 125 people and generates about 50</td>
<td>See reply to comment 2272 in section I</td>
</tr>
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</table>

Regarding the exemption request/coverage by other legislation:
See reply to comment 2361 in section III
Mio Euro turnovers from the above mentioned application fields. Al-RCF products are part of nearly each of this application in a design and functional relevant content. A usual lead time for the plants is 6–7 month. All our competitors are located outside Europe and will ultimately benefit if we need to extend delivery due to additional bureaucratic measures.

| 2185 | 2013/09/03 17:02 | German Institute for Refractories and Ceramics Company Germany | High temperature processes above 900°C. A wrong choice of insulating refractory material could result in serious consequences concerning the insulating conditions during the process. If insulating properties changes because of the false material use, temperature at the outer shell could rise and hot spots and break outs could be a consequence. In worst case situations fires or explosions could occur and as a consequence it could result in human health and environmental risks. |
| 2182 | 2013/09/02 16:55 | Company Austria | Both, the steel and refractory industry, use Aluminosilicate Refractory Ceramic Fibres (Al-RCF) and Zirconia Aluminosilicate Refractory Fibres (Zr-RCF) (both, Al-RCF and Zr-RCF, are hereinafter referred as RCF) for various high-temperature industrial applications. High-temperature applications are those in the temperature range of above 1100°C and up to about 1600°C. In the steel industry Zr-Al-RCF are used for high-temperature applications in heat treatment furnaces. For temperature applications below 1100°C, steel industry has replaced almost all RCF by biodegradable ceramic fibres. In the hot dip galvanizing furnaces also Al-RCF are used for temperature applications up to around 1350°C. The advantage of RCF fibres is that they demonstrate high-temperature and thermal shock resistance as well as low thermal conductivity. Due to its unique combination of desired characteristics, RCF are still the best solution in many high temperature applications. For a number of applications, no adequate substitutes are yet available despite recent developments of alternative fibres materials (see below at “substitution”). The uses of RCF covered include inter alia the lining of metallurgical vessels as well as the insulation, gasket and fire-protection applications in the steel industry (steel treatment ladles, ladle covers, tundish, isostatically pressed products, etc.). We do not use RCF as such, but in most cases we use them in form of mats and blankets, which are both regarded as articles under the REACH Regulation. Suppliers of such mats and blankets containing RCF are predominantly European manufacturers of RCF. |

<p>| 2185 | 2013/09/03 17:02 | German Institute for Refractories and Ceramics Company Germany | Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III |
| 2182 | 2013/09/02 16:55 | Company Austria | Regarding the description of uses: See reply to comment 2272 in section I Regarding low or controlled exposure/risk of RCFs: See reply to comment 2272 in section I Regarding the use of the substance as an article: See reply to comment 2292 in section I Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III |</p>
<table>
<thead>
<tr>
<th>Comment ID</th>
<th>Date/Time</th>
<th>Entity Type</th>
<th>Entity Name / Details</th>
<th>Text</th>
<th>Response</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>2151</td>
<td>2013/08/16 11:42</td>
<td>KIND &amp; Co., Edelstahlwerk, KG Company</td>
<td>Germany</td>
<td>Our furnaces work with temperatures up to 1280 degrees Celsius. The currently known alternative isolating wools are not suitable for that purpose. Our furnaces apply to charge operating (Batch-furnaces). Besides heating, the furnaces are suited with cooling functions, which are necessary for heat-treatment of our steel-qualities. It is not possible to obtain the cooling function by using other isolating materials, like refractory materials, because they are not resistant enough to thermal shocks.</td>
<td>Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I.</td>
<td></td>
</tr>
<tr>
<td>2143</td>
<td>2013/08/14 15:19</td>
<td>Wirtschaftsvereinigung Stahl/Stahlinstitut VDEh</td>
<td>Industry or trade association</td>
<td>Germany</td>
<td>All industrial uses where alumino silicate refractory ceramic fibre is used in the production under controlled conditions should be exempted from authorisation. The end products do not contain alumino silicate refractory ceramic fibre, so there is no risk for pollution of the environment.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III.</td>
</tr>
<tr>
<td>2142</td>
<td>2013/08/12 18:03</td>
<td>Company</td>
<td>Germany</td>
<td>Prozeßtemperaturen &gt; 900°C, da grundsätzlich immer geprüft wird, ob Ersatzmaterialien verwendet werden können.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III.</td>
<td></td>
</tr>
<tr>
<td>2140</td>
<td>2013/08/09 14:33</td>
<td>Austrian Association for Building Materials and Ceramic Industries</td>
<td>Industry or trade</td>
<td>Verwendungen für alle industriellen Hochtemperaturprozesse, da die verfügbaren Substitute nicht die gleichen notwendigen Eigenschaften wie (Zr-) Al-RCF haben. Da mehr als 90% als RCF-Erzeugnis auf den Markt kommt, sind deren</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III.</td>
<td></td>
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<tr>
<td>ID</td>
<td>Date</td>
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</tr>
<tr>
<td>2138</td>
<td>2013/08/09 13:25</td>
<td>Austrian Association for Steel and Mining Industry or trade association Austria</td>
<td>Anwendungen ebenfalls auszunehmen.</td>
<td>All uses for industrial high temperature applications should be exempted.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
<td></td>
</tr>
<tr>
<td>2136</td>
<td>2013/08/09 13:17</td>
<td>Austrian Non Ferrous Metals Association Industry or trade association Austria</td>
<td>Anwendungen ebenfalls auszunehmen.</td>
<td>All uses for industrial high temperature applications should be exempted.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
<td></td>
</tr>
<tr>
<td>2133</td>
<td>2013/08/09 11:26</td>
<td>EBNER Industrieofenbau GmbH Company Austria</td>
<td>Heat treatment facilities used for high temperature applications above 850°C should be excepted from the registration requirements. See general comments for reasoning.</td>
<td>Heat treatment facilities used for high temperature applications above 850°C should be excepted from the registration requirements. See general comments for reasoning.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
<td></td>
</tr>
<tr>
<td>2132</td>
<td>2013/08/07 15:15</td>
<td>Company United Kingdom</td>
<td>High tempreature insulation in the metallurgical and mineral processing industries, provided that the fibres are fully contained within a structure. Aluminosilicate fibres are used widely in the metallurgical industries for high-temperature, low thermal mass, high-efficiency insulation. There is no effective alternative at temperatures above 900°C.</td>
<td>High tempreature insulation in the metallurgical and mineral processing industries, provided that the fibres are fully contained within a structure. Aluminosilicate fibres are used widely in the metallurgical industries for high-temperature, low thermal mass, high-efficiency insulation. There is no effective alternative at temperatures above 900°C.</td>
<td>Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III</td>
<td></td>
</tr>
<tr>
<td>2119</td>
<td>2013/07/31 09:31</td>
<td>Company Spain</td>
<td>RCF products are indispensable for meeting the EU ‘s 2020 goals and industry ‘s growing demand for resource and energy efficiency and the associated reduction of CO2</td>
<td>RCF products are indispensable for meeting the EU ‘s 2020 goals and industry ‘s growing demand for resource and energy efficiency and the associated reduction of CO2</td>
<td>Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:</td>
<td></td>
</tr>
<tr>
<td>ID</td>
<td>Date</td>
<td>Name</td>
<td>Text</td>
<td>See reply to comment 2272 in section I</td>
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| 2104| 2013/07/19 | University of Applied Science Dept. of Materials Ceramics and Glass Engineering Academic institution Germany | Exemptions shall be made for all high temperature furnaces and thermal loaded devices that operate above 900°C. Particularly with regard to a German FOGi Study, funded by the German ministry of economics, other alternative materials especially AES-wool-products start to embrittle at higher than the mentioned temperature. They are susceptible to thermal shock and gas jet induced erosional wear (particle loaded or even not particle loaded). In further AES-wool-products are in many cases too sensitive to chemical attack. Fiber-free alternatives as well suffer from low mechanical strength, brittle behavior, low thermal shock resistance and are as well susceptible to erosional wear. | Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III  
Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I                                                                                                                                                                                                                       |
| 2101| 2013/07/02 | ERA Technology Ltd Company United Kingdom | Manufacture of industrial furnaces and thermoprocess equipment in compliance with an agreed EU mandatory exposure limit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Regarding the exemption request/coverage by other legislation: See reply to comment 2361 in section III.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
### IV - Comments on uses for which review periods should be included in Annex XIV, including reasons for that:

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Submitted by</th>
<th>Comment</th>
<th>Response</th>
</tr>
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<tbody>
<tr>
<td>2475</td>
<td>2013/09/23</td>
<td>Industry or trade association, Belgium</td>
<td>See attachment, section IV (common paper with Zr-RCF, previously submitted under the Zr-RCF draft recommendation)</td>
<td>See reply to this comment in section I.</td>
</tr>
<tr>
<td>2472</td>
<td>2013/09/23</td>
<td>ChemSec, International NGO, Sweden</td>
<td>ChemSec supports the proposal of ECHA to not allow any review periods.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2465</td>
<td>2013/09/23</td>
<td>AIR LIQUIDE, Company, France</td>
<td>AL supports the EIGA comment asking for a long review period. A long term visibility is required to install a new product and the current absence of toxicological data on new fibrous materials proposed as substitutes is hindering their possible use. As explained by EIGA, we further need a positive testing period for both the material and its anchoring system to be convinced that a substitution is viable and does not threaten the safety of our personnel or the reliability of the supply to our clients. Should a product become widely recognized as potentially applicable, then its production capacities should match the demand; if all sites concerned are substituting their insulation material, it may create a demand much higher than the production capacities and prevent a smooth substitution within the required timeframe.</td>
<td>See reply to comment 2216 in this section.</td>
</tr>
<tr>
<td>2452</td>
<td>2013/09/23</td>
<td>Industry or trade association, Belgium</td>
<td>please see comments in joint SEMI/ESIA response attached</td>
<td>See reply to this comment in section I.</td>
</tr>
</tbody>
</table>
| 2444 | 2013/09/23  | Company, Switzerland                        | Should the use of RCFs products for the insulation of high temperature processes (i.e. furnaces) be subject to Authorization, a review period shall be long enough to provide additional information on potential substitutes proven for the specific use:  
- high temperature processes (furnaces) have a long technical life (30 years), are continuously operated under long term contracts (10 to 20 years), | Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I  
Regarding the review periods: Thank you for your comment. |
exposures are far below the minimum OEL (0.1 f/ml), with limited period for shutdowns planned in coincidence with the shutdown of downstream users of the products.

- the downstream activities and the corresponding contractual issues do not allow the replacement of a lining on all furnaces at the same time. A test period on one site is required to demonstrate the long term suitability of any substitute to minimize the risks for the whole downstream industry. Only after a clear evidence of the suitability has been proven on one furnace by long enough operation, the replacement of the insulating material can be programmed for the other furnaces in accordance with downstream users requirements.

- any short term lab or pilot testing can only give trends about the suitability of a potential substitute, but cannot prove the long term viability of the product.
- the demonstration of the absence of any toxicological risk must have been made.

Please note that several products are currently presented as potential substitutes but without any toxicological study and sometimes with recommendations to consider them as RCFs for health protection (high temperature insulation wools).
- there is no means to accelerate an in situ test at elevated temperatures in a furnace in operation.
- a slow degradation of the insulating material and its mechanical properties will result in:
  - An increase the susceptibility of particles emissions due to erosion by the flue gas.
  - additional heat losses, higher energy consumption and CO2 emissions;
  - a negative impact on the capital and operating costs;
- notwithstanding the environmental impact, the contractual conditions do not allow the operator of the high temperature furnace the possibility to recover such costs during the lifetime of existing contracts
  - an additional negative environmental effect when being demolished and replaced by the original lining, with an unneeded additional exposure of the workers.
  - a potential risk of mechanical failure, falling off from the walls, risks for the personnel and unplanned shutdown of the furnace and of downstream activities.

Therefore a minimum review period of 10 years is necessary, bearing in mind
that the exposure is low, limited and well below the SCOEL recommendation to the few persons carrying out maintenance works at long intervals for a limited time of exposure, and that the long term suitability must be clearly demonstrated both in terms of insulating and mechanical performances, and in terms of absence of health risks (from substitutes and from the high temperature process).

<table>
<thead>
<tr>
<th>Comment ID</th>
<th>Date/Time</th>
<th>Origin</th>
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<tbody>
<tr>
<td>2409</td>
<td>2013/09/23 13:28</td>
<td>ASD, Industry or trade association, Belgium</td>
<td>See attachment</td>
</tr>
<tr>
<td>2394</td>
<td>2013/09/23 12:31</td>
<td>Industry or trade association, Netherlands</td>
<td>I agree with the position of CerameUnie</td>
</tr>
<tr>
<td>2386</td>
<td>2013/09/23 11:48</td>
<td>Company, Liechtenstein</td>
<td>For a responsible acting company like Ivoclar the existing regulation was and will be followed, there is no need or advantage in forwarding AISi-RCF on Annex XIV!</td>
</tr>
<tr>
<td>2361</td>
<td>2013/09/21 13:33</td>
<td>Cerame-Unie - The European Ceramic Industry Association, Industry or trade association, Belgium</td>
<td>The average lifetime of ceramic kilns using aluminosilicate RCF is up to 30 years. Due to the high investment costs and the fact that most kilns are individually custom designed it is not possible to change to a different (and possibly less energy efficient) kiln before the kiln has been written off. An extended review period is therefore necessary.</td>
</tr>
<tr>
<td>2351</td>
<td>2013/09/20 19:32</td>
<td>Company, Poland</td>
<td>Production of equiax, investment castings for aerospace engines (including blades, vanes) made out of supper alloys for insulation, wrapping process.</td>
</tr>
<tr>
<td>2335</td>
<td>2013/09/20 15:55</td>
<td>ADS Group Limited, Industry or trade association, United Kingdom</td>
<td>Review periods for uses in the aerospace and defence sector should be based upon the Authorisation application and the associated research timescales to produce the technical justification for substitution, as noted above and in the attached paper.</td>
</tr>
<tr>
<td>2332</td>
<td>2013/09/20 15:43</td>
<td>Refratechnik Cement GmbH, Company, Germany</td>
<td>Based on already existing regulation concerning (Zirconia-) Alumino silicate fibers Refratechnik Cement is forced to search for substitution materials and technologies since many years and we will do so in the future.</td>
</tr>
<tr>
<td>2327</td>
<td>2013/09/20 15:31</td>
<td>Company, Germany</td>
<td>LINDE fully agrees again with EIGA’s comment that a minimum review period of 10 years is necessary, since: - exposure is low, limited and well below the SCOEL recommendation to few persons, - long term suitability must be demonstrated</td>
</tr>
<tr>
<td>2320</td>
<td>2013/09/20 14:26</td>
<td>Salzgitter Flachstahl GmbH, Company,</td>
<td>see attached dokument</td>
</tr>
<tr>
<td>ID</td>
<td>Date</td>
<td>Time</td>
<td>Entity</td>
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</tr>
<tr>
<td>2314</td>
<td>2013/09/20 13:11</td>
<td>Wirtschaftskammer Österreich (WKÖ), Other contributor, Austria</td>
<td>Please, see document attached.</td>
</tr>
<tr>
<td>2306</td>
<td>2013/09/20 12:09</td>
<td>Bundesverband Keramische Industrie e.V., Industry or trade association, Germany</td>
<td>Substitution of zirconia aluminosilicate RCF has taken place where possible, however, there are a number of uses where this is not the case. The German rule on hazardous materials (TRGS) 619 gives advice where substitution is an appropriate way. But for most applications is no substitute available with the same properties as RCF. In the reply to comments on the proposed candidate listing of 2009 and 2011 a number of alternatives are mentioned. It should be noted that these substitutes does not have the same performance when it comes to energy efficiency of the kiln. In this regard we refer to the study on Industrial and Laboratory Furnaces and Ovens carried out for the European Commission DG Enterprise in the context of the Ecodesign Directive which states that: Alumino-silicate RCF products, better described as alurno-silicate wools, are one of the most energy efficient insulation materials available with, in many applications, no alternatives that have the same performance. As HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user’s business to be uncompetitive with non-EU competitors who would not need to comply with REACH authorisation obligations. If alumino-silicate wool (ASW/RCF) could not be used, EU energy consumption would increase very significantly. The final report can be found here: <a href="http://eco-furnace.org/documents.php">http://eco-furnace.org/documents.php</a>. The use of RCF is already well regulated, a restriction applies under Directive 2001/41/EC, limiting the use to industrial applications. In addition, national OELs (occupational emission limit) exist and a European OEL under the Carcinogens and Mutagens Directive is currently under discussion as part of the overall review of this Directive. An authorization process will have an impact on the energy efficiency of the ceramic industry and hence the competitiveness of this industry, without having an added-value in terms of environment or human health.</td>
</tr>
<tr>
<td>2304</td>
<td>2013/09/20 12:06</td>
<td>Company, United Kingdom</td>
<td>No comment</td>
</tr>
<tr>
<td>2301</td>
<td>2013/09/20 11:26</td>
<td>Deutsche Edelstahlwerke GmbH, Company, Germany</td>
<td>Reference to Comments on the proposed dates: The service life-time of the facilities should be considered. Therefore the review periods should be about 20 years.</td>
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<tr>
<td>Comment ID</td>
<td>Date/Time</td>
<td>Organization</td>
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</table>
| 2300       | 2013/09/20 11:21 | European Aluminium Association AISBL, Industry or trade association, Belgium | The review period should be in line with technology cycles. RCF are often used in closed systems maintained every 5-7 years. 
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I |
| 2297       | 2013/09/20 10:59 | Company, Germany | Industrial furnaces in the steel industry can be 50 years old and surely some will still be in use for the next 50 years. Depending on the physical strain the fibres have to be renewed e.g. after 12 or more years. Therefore the reviewing period should reflect this timetable. 
Regarding the review periods: See reply to comment 2444 in section IV 
Regarding exemption request for existing units: See reply to comment 2465 in section III 
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I |
| 2292       | 2013/09/20 10:29 | CEMBUREAU, Industry or trade association, Belgium | See attachment 
Regarding the review periods: See reply to this comment in section I. |
| 2274       | 2013/09/19 16:24 | Pruna Betreiber GmbH, Company, Germany | As described in “Transitional arrangements” coke ovens can be in use for decades. A realistic plan for the coke oven battery means production for the next 60 years. Depending on the physical strain the fibres have to be renewed 
Regarding the review periods: See reply to comment 2444 in section IV |
<table>
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<th>ID</th>
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<th>Organization</th>
<th>Comment</th>
<th>Action</th>
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</thead>
</table>
| 2270 | 2013/09/19 15:24 | ThyssenKrupp Steel Europe AG, Company, Germany | As described in “Transitional arrangements” industrial furnaces in the steel industry can be 50 years old and surely some will still be in use for the next 50 years. Depending on the physical strain the fibres have to be renewed e.g. after 12 or more years. Therefore the reviewing period should reflect this timetable. | Regarding exemption request for existing units:  
See reply to comment 2465 in section III  
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:  
See reply to comment 2272 in section I |
| 2265 | 2013/09/19 14:24 | Refratechnik Steel GmbH, Company, Germany | Based on already existing regulation concerning (Zirconia-) Alumino silicate fibers Refratechnik Steel is forced to search for substitution materials and technologies since years and we will do so in the future. In our view, there is no need for an additional regulation like the REACH process (e.g. authorisation). REACH is a burden (cost &admin) for global competitiveness for EU-manufacturers and constructors. | Thank you for this information. |
| 2251 | 2013/09/18 15:55 | CECOF, Industry or trade association, Germany | See Comments on the proposed dates  
The service life-time of the facilities should be considered. Therefore the review periods should be > 20 years. | Regarding exemption request for existing units:  
See reply to comment 2465 in section III  
Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry:  
See reply to comment 2272 in section I |
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<th>Date/Time</th>
<th>Sender</th>
<th>Role</th>
<th>Message</th>
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<tbody>
<tr>
<td>2247</td>
<td>2013/09/18 16:43</td>
<td>VDMA - FV TPT, Industry or trade association, Germany</td>
<td>See Comments on the proposed dates</td>
<td>The service life-time of the facilities should be considered. Therefore the review periods should be &gt; 20 years.</td>
</tr>
<tr>
<td>2243</td>
<td>2013/09/18 15:55</td>
<td>CECOF, Industry or trade association, Germany</td>
<td>See Comments on the proposed dates</td>
<td>The service life-time of the facilities should be considered. Therefore the review periods should be &gt; 20 years.</td>
</tr>
<tr>
<td>2219</td>
<td>2013/09/16 10:22</td>
<td>Individual Austria</td>
<td></td>
<td>The review period should be in line with technology cycles. RCF are often used in closed systems maintained every 5-7 years.</td>
</tr>
<tr>
<td>2216</td>
<td>2013/09/15 18:48</td>
<td>EIGA (European Industrial Gases Association)</td>
<td>Should the use of RCFs products for the insulation of high temperature processes (i.e. furnaces) be subject to Authorization, a review period shall be long enough to provide additional information on potential substitutes proven for the specific use:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Industry or trade association, Belgium</td>
<td>- high temperature processes (furnaces) have a long technical life (30 years), are continuously operated under long term contracts (10 to 20 years), exposures are far below the minimum OEL (0.1 f/ml), with limited period for shutdowns planned in coincidence with the shutdown of downstream users of the products.</td>
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<td>- the downstream activities and the corresponding contractual issues do not allow the replacement of a lining on all furnaces at the same time. A test</td>
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</table>
period on one site is required to demonstrate the long term suitability of any
substitute to minimize the risks for the whole downstream industry. Only after
a clear evidence of the suitability has been proven on one furnace by long
enough operation, the replacement of the insulating material can be
programmed for the other furnaces in accordance with downstream users
requirements.
- any short term lab or pilot testing can only give trends about the suitability of
a potential substitute, but cannot prove the long term viability of the product.
- the demonstration of the absence of any toxicological risk must have been
made.
Please note that several products are currently presented as potential
substitutes but without any toxicological study and sometimes with
recommendations to consider them as RCFs for health protection (high
temperature insulation wools).
- there is no means to accelerate an in situ test at elevated temperatures in a
furnace in operation.
- a slow degradation of the insulating material and its mechanical properties
will result in:
  - An increase the susceptibility of particles emissions due to erosion by
    the flue gas.
  - additional heat losses, higher energy consumption and CO2
    emissions;
  - a negative impact on the capital and operating costs;
- notwithstanding the environmental impact, the contractual conditions do not
allow the operator of the high temperature furnace the possibility to recover
such costs during the lifetime of existing contracts
- an additional negative environmental effect when being demolished
and replaced by the original lining, with an unneeded additional exposure of
the workers.
- a potential risk of mechanical failure, falling off from the walls, risks
for the personnel and unplanned shutdown of the furnace and of downstream
activities.
Therefore a minimum review period of 10 years is necessary, bearing in mind
that the exposure is low, limited and well below the SCOEL recommendation to
the few persons carrying out maintenance works at long intervals for a limited
time of exposure, and that the long term suitability must be clearly
demonstrated both in terms of insulating and mechanical performances, and in
terms of absence of health risks (from substitutes and from the high
temperature process).

| 2182 | 2013/09/02 16:55 | Company Austria | See also comments on section "Comments on the proposed dates". The service
life-time of the facilities should be considered. Therefore the review periods
should be at least 20 years. |
<p>| See reply to comment 2272 in section I | | | See reply to comment 2444 in section IV |
| | | | |</p>
<table>
<thead>
<tr>
<th>ID</th>
<th>Date/Time</th>
<th>Company/Association</th>
<th>Comment</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2151</td>
<td>2013/08/16 11:42</td>
<td>KIND &amp; CO., Edelstahlwerk, KG Company Germany</td>
<td>We would appreciate the review periods to be more than 10 years, because of the long durability of these furnaces-insulations.</td>
<td>Regarding the socio-economic impact, e.g. energy efficiency, long service time, disadvantage for EU industry: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>2143</td>
<td>2013/08/14 15:19</td>
<td>Wirtschaftsvereinigung Stahl/Stahlinstitut VDEh Industry or trade association Germany</td>
<td>The service life-time of the facilities should be considered. If an inclusion of alumino silicate refractory ceramic fibre into Annex XIV is really seen as necessary the review periods should be in a range of 20 years or more.</td>
<td>Regarding the review periods: See reply to comment 2444 in section IV</td>
</tr>
<tr>
<td>2140</td>
<td>2013/08/09 14:33</td>
<td>Austrian Association for Building Materials and Ceramic Industries Industry or trade association Germany</td>
<td>Der Fachverband Steine-Keramik unterstützt den derzeitigen Ansatz keine review Perioden einzuführen.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2138</td>
<td>2013/08/09 13:25</td>
<td>Austrian Association for Steel and Mining Industry or trade association Austria</td>
<td>Due to the fact, that different applications have different operating conditions, we cannot give a general answer to this question.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2136</td>
<td>2013/08/09 13:17</td>
<td>Austrian Non Ferrous Metals Association Industry or trade association Austria</td>
<td>Due to the fact, that different applications have different operating conditions, we cannot give a general answer to this question.</td>
<td>Thank you for providing your opinion.</td>
</tr>
<tr>
<td>2119</td>
<td>2013/07/31 09:31</td>
<td>Company Spain</td>
<td>The replacement of RCF is not only technically difficult but would also result in increased operation costs (energy, downtime, reduced flexibility)</td>
<td>Regarding the non-availability of alternatives/information on alternatives in background document: See reply to comment 2272 in section I</td>
</tr>
<tr>
<td>2101</td>
<td>2013/07/02 13:19</td>
<td>ERA Technology Ltd BehalfOfAnOrganisation Company United Kingdom</td>
<td>Due to the large amount of research already carried out, it is very unlikely that a suitable and competitive alternative will be developed so the review period should be as long as possible.</td>
<td>Regarding the review periods: See reply to comment 2444 in section IV</td>
</tr>
</tbody>
</table>