PRE comments on Annex XV reports on Refractory Ceramic Fibres

PRE represents the European Refractory Producers covering 20,000 employees generating over 3 billion Euros. Following the German (re-)submission of two Annex XV reports on Aluminosilicate Refractory Ceramic Fibres and Zirconia Aluminosilicate Refractory Ceramic Fibres, PRE would like to make the following comments:

- Even though both Annex XV dossiers recognize that a registration dossier for this substance has been received, the CAS number (142844-00-6) and EINECS number (604-314-4) describing clearly the substance put on the market by the manufacturers, are not mentioned in the Annex XV dossier. This – again- creates confusion on the actual scope of the substance being proposed for inclusion on the candidate list.

- PRE does not agree to treat the two substances separately by submitting two separate Annex XV dossiers.

- Besides the CAS and EINECS numbers, other information provided in the registration dossier (such as exposure scenarios or limitations to substitution) is also neglected in the Annex XV dossier.

- Currently, Refractory Ceramic Fibre (RCF) is classified as a carcinogen 2 (under Directive 67/548) transferred to carcinogens 1b (under the CLP Regulation). This classification, established in 1997, is based on experiments which have afterwards shown to be using a particulate overload. Therefore, the current classification can no longer be supported.
  
  - Several new studies carried out after 1997 all support a re-classification.
  - In 2002, IARC already assigned RCF as a category 2b “possible carcinogen”.
  - The recent report by Mc Kay (2010) concludes that after another 10 years of the Epi-study there are still no health effects in humans detected. This is another argument confronting the German risk assessment methodology and indicates that and the German risk assessment and the current classification are based on questionable scientific grounds.
  - A study carried out by the Austrian Umweltbundesamt GmbH (Austrian Environment Institute) in 2010 also came to the conclusion that “A multi-stakeholder process, including representatives from science, policy and industry, is recommended for a data based, transparent and efficient re-evaluation.”
Based on this recent information, PRE strongly requests that no further regulatory action on RCF is taken forward before a new discussion and decision on the appropriate classification of RCF has taken place.

- The test-materials described in the two reports are dust samples which are obtained after grinding of the fibre. This grinding shortens the length of the fibre thereby changing its properties. It is estimated that the length of the test-material is hundred times shorter than the commercial fibres in the products! Due to their different shape the test samples do not have the same properties as the products sold on the market or during use and end-of-life stages. The results of these tests based on such samples are therefore only valid for the test itself, they cannot be extrapolated to the commercial fibres in the products.

- Consumer exposure to RCF fibrous dust could never be demonstrated (Schneider et al. (1996)). In addition, Refractory Ceramic Fibres can only be sold to professional users, as laid down in Directive 2001/41/EC. Rigorous occupational health regulations are applicable in the work space. Therefore, PRE does not see a need to prioritise RCF in the REACH authorisation process since REACH has as primary objective the protection of the environment and human health; worker protection is regulated through different pieces of legislation. These regulations have been proven adequate and practical for the protection of worker’s health and the environment.

- The reports mention that “… current product developments indicate that the upper temperature limit of AES [Alkaline-earth-silicate] wool products could be increased significantly”. This statement lacks any support and cannot be confirmed by the main producers of high temperature insulation wool including AES products. While the R&D efforts on these products continue, there is no indication for “significant” improvements in the foreseeable future.

- RCF possess many characteristics necessary for their downstream use, such as their long life-length, high temperature resistance, accurate temperature adjustment etc. As such, they are not substitutable. Since RCF have much better insulation properties than traditional refractories there is also a risk of higher energy consumption in the downstream process if they are to be banned. The important role that RCF play in resource and energy efficiency in modern furnaces and kilns is also highlighted in the ongoing study on the eco-design requirements for industrial and laboratory furnaces and ovens (www.eco-furnaces.org).

Both reports on RCF further contain a number of errors and omissions which are commented on separately by ECFIA, the European Association representing the High Temperature Insulation Wool Industry. These comments have been submitted to the ECHA separately and are fully supported by PRE.

In conclusion, based on (i) the insufficient quality of the Annex XV reports, (ii) the scientifically founded doubts on the current classification of RCF and (iii) the non-substitutable and exclusively professional uses of RCF, PRE requests that both Annex XV reports on RCF are withdrawn and RCF are not placed on the REACH candidate list. Furthermore PRE suggests that before any further steps are taken in the REACH process, a re-evaluation of the scientific findings (both new & old) should be organised to build a solid ground for future decisions.