

## CB4REACH Consortium

### Carbon Black SIEF Information Letter 4:

## Selection of Studies in the Carbon Black Dossier

As a consequence of the re-evaluation of carbon black (“**CB**”) to Group 2B (*possibly carcinogenic to humans*) by the International Agency for Research on Cancer (IARC) in 1996, the members of the Carbon Black REACH Consortium (“**Consortium**”) created a team of scientific advisors. This team consists of representatives of the member companies of the Consortium, as well as of respected scientists and consultants who are experts in occupational medicine, epidemiology, toxicology and industrial hygiene. At the same time, various organizations such as the American Conference of Industrial Hygienists (ACGIH) in the US and the Health and Safety Executive (HSE) in the UK began the development of new occupational exposure levels (“**OEL**”) for CB. The primary task of the scientific team was to recommend and monitor a research strategy and programme to address scientific and regulatory questions related to health and the environment and in particular, to address the question of possible carcinogenicity and where a health-based OEL should be set.

To meet these above objectives, a number of targeted studies were commissioned and performed. These studies addressed the following topics:

- I. Chemico-physical characterisation
- II. Toxicology
- III. Exposure
- IV. Epidemiology

The results of these studies are essential for the understanding of the critical health effects from CB exposure to CB production workers, downstream users and consumers. All studies were performed by leading scientists in the relevant fields located at well respected institutions and universities and were performed to high quality levels (Klimisch code 1/2). Relevant results of these studies were published in peer-reviewed journals with high scientific impact, and all of these studies were key studies for the REACH dossier.

It is important to note that the toxicology and epidemiology studies were essential to address the concerns over potential cancer risks to humans following the 1996 IARC evaluation. The industry wanted to have a better understanding of tumour response in animals. Without these studies, it would have been possible for IARC to later re-evaluate and reclassify CB from Group 2B to Group 2A, or even Group 1 just based on theoretical mechanistic grounds alone. This would have had serious implications for cancer classification in the EU and consequently, REACH. In fact, all of these member-funded studies were later used in an evaluation of CB by IARC (2006), where it was shown via the epidemiological studies that there was no increase in cancer with

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exposed workers. Furthermore, the lung cancer observed in the rat studies and the primary cause of the Group 2B evaluation was not due to any direct genotoxic action. As a consequence, IARC decided to keep CB in Group 2B after its 2006 re-evaluation.

The studies referred to in the cost audit report are all key studies for the REACH dossier. Based on the morbidity studies financed by the Consortium members, a DNEL of 2 mg/ m<sup>3</sup> inhalable was calculated and this is an essential part of the REACH dossier for CB which was prepared jointly by the members of the Consortium.

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