



Patrick W. Beatty, Ph.D., DABT  
Scientific Advisor

Research and Scientific Affairs Department

1220 L Street, NW  
Washington, DC 20005-4070  
USA  
Telephone 202-682-8473  
Fax 202-682-8270  
Email beattyp@api.org  
www.api.org

NON-CONFIDENTIAL INFORMATION  
February 27, 2012

Dr. Ruth Lunn, Director  
Office of the RoC  
DNTP, NIEHS  
Room 2138 530 Davis Drive  
Morrisville NC 27560

Re: Public Comments on Nominations, National Toxicology Program Report on  
Carcinogens: Carbon Black

Dear Dr. Lunn:

The American Petroleum Institute (API) is the primary trade association for the oil and gas industry in the United States and its membership includes more than 400 companies engaged in all aspects of the oil and gas industry, including the exploration, production, refining, transportation and marketing of crude petroleum and petroleum products. API is pleased to submit comments on the nomination of Carbon Black for review as part of the 13<sup>th</sup> Report on Carcinogens (RoC).

API appreciates the NTP's request for comments from stakeholders and would like to avail ourselves of this opportunity to both comment directly and to urge NTP to carefully consider the comments from the International Carbon Black Association (ICBA) and the summary by the ICBA's Science Advisory Group of current data and ongoing research into the potential health effects of human exposure to carbon black.

API believes that the summary provided by the SAG of the ongoing efforts to update earlier occupational cohorts as well as collect new data supports the conclusion that nomination of carbon black for inclusion in the 13<sup>th</sup> RoC is premature. API also concludes that an examination of the currently available health effects data do not provide the basis for concern that a delay in placing Carbon black in the RoC process would result in an unacceptable risk of adverse health effects in either occupationally exposed individuals or the general population. These points are restated in more detail below supported by the detailed citations in the SAG summary.

**Studies in progress will provide a more robust data set for evaluation of carbon black health effects.**

Two epidemiological studies of occupational exposure to carbon black are currently underway. One is an update of the US study which earlier did not find evidence of an association between lung cancer exposure and carbon black. The update will include

an additional 7 years of vital status and individualized cumulative exposure estimates for each cohort member. The second study is designed to address the potential association between fine particle exposure and cardiac death. The original three cohort studies (UK, US and German) will be evaluated for a possible relationship between carbon black exposure and cardiac death. This outcome will also be included in the updates of the US and UK studies.

These current studies will provide additional years of follow up and or more detailed and estimates of cumulative exposure. The inclusion of data on cardiac death responds to new potential concerns regarding occupational exposure to particulates that were not included in recent evaluations by IARC or ACGIH. A delay to include data from these studies would allow a more rigorous and scientifically robust evaluation of the health effects of exposure to carbon black.

**Delay to allow inclusion of these new studies in the RoC evaluation process will not present an unacceptable risk of harm.**

Current occupational exposures to carbon black particulates are well below occupational standards and recommendations such as the OSHA PEL and the ACGIH TLV. (See the Table at the end of the SAG review.) Commercial use of carbon black is primarily in the synthetic rubber industry in the manufacture of tires, belts and hoses in which carbon black is mixed into a matrix from which the particulate material is no longer available. Similarly, in almost all other commercial uses of carbon black such as paints and toners carbon black is again present in a matrix. As reviewed in the ICBA SAG document numerous occupational epidemiology studies have not demonstrated an association between lung cancer and carbon black exposures.

Exposure of consumers or the general population at large to carbon black particulate should not occur (or at least be extremely limited) due to the entrained nature of the carbon black in a matrix such as rubber, plastic or paints.

Recent reviews of the health effects of carbon black do not support an unacceptable risk of adverse health effects at measured or anticipated ambient concentrations. The International Agency for the Review of Cancer (IARC) in its review of carbon black published in 2006 classified carbon black as a 2B (possibly carcinogenic to humans) based on the strength of evidence of lung cancer in rodents. IARC evaluated the human evidence for carcinogenicity as inadequate. The American Conference of Governmental Industrial Hygienists (ACGIH) in 2011 evaluated carbon black as a confirmed animal carcinogen with unknown relevance to humans. In 2011 Health Canada published the result of an evaluation of carbon black health effects and exposure levels concluding that carbon did not meet the criteria as either a high hazard to human health or a high potential for exposure.

The basis for classifying carbon black as an animal carcinogen is the occurrence of lung tumors in rodents exposed to carbon black as the free particulate. The tumors were restricted to animals experiencing “lung overload” in which the inhaled particulate exceeded the ability of lung clearance mechanisms to remove all of the inhaled material

resulting in inflammatory changes in the lungs. This effect is not restricted to carbon black but is also seen in other “inert” particulates such as titanium dioxide and talc. The existence of airborne concentrations of carbon black sufficient to cause a similar overload situation in humans is inconsistent with the many occupational exposure studies of carbon black manufacture or commercial use.

In summary, API requests that the consideration of carbon black in the RoC process be delayed until current studies can be peer reviewed and published.

If you have any questions or require additional information, please don't hesitate to contact me.

Sincerely,

[Redacted]

Patrick Beatty, PhD, DABT