Refractory Ceramic Fibres

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Occupational Exposure to Refractory Ceramic Fibers (sic)

The report presents a very extensive analysis of evidence but seems to us to have jumped to precautionary conclusions e.g. that RCF could cause mesothelioma or lung cancer.

This publication summarises the toxicological information on refractory ceramic fibres (RCF) and proposes an occupational exposure standard. NIOSH proposes a recommended exposure limit (REL) for RCFs of 0.5 fibre per cubic centimetre (f/cm^3) of air as a time-weighted average (TWA) concentration for up to a 10-hr work shift during a 40-hr workweek. The HSE exposure standard set in 2004 was 1.0 f/cm^3.

RCFs are amorphous [non crystalline] synthetic fibres produced by the melting and blowing or spinning of calcined kaolin clay or a combination of alumina, silica, and other oxides. They are used in commercial applications requiring lightweight, high-heat insulation (e.g., furnace and kiln insulation).

In the United States, approximately 31,500 workers have the potential for occupational exposure to RCFs during distribution, handling, installation, and removal.

Evidence of health risks:
Epidemiologic studies have found no association between occupational exposure to airborne RCFs and an excess rate of pulmonary fibrosis or lung cancer. High exposures were present in the 1950s. RCF work has been associated with pleural plaques and decreased pulmonary function as well as short term effects such as membrane irritation. Pulmonary function decrements were only observed in RCF workers who also smoke(d).

Chronic animal inhalation studies have found increased rates of mesothelioma and lung cancer, [but these studies were complicated by the presence of large amounts of non fibrous material.]

Instillation studies (where a bolus of saline loaded with fibres is injected into the lung or lung cavity) have shown increased rates of lung cancer, [but almost any dust exposure in this fashion has a high probability of leading to such results.]

Under conditions of normal use, airborne fibres are of respirable dimensions. Most are of diameter less than 3µm and length > 10 µm.

Dissolution studies suggest that RCFs will dissolve in lung fluids, at approximately ten times the rate that the most soluble form of asbestos (chrysotile) will. In animals, the fibres with the slowest clearance [through a combination of dissolution and physical removal] from the lung were 5 to 20 µm in length and 0.5 µm diameter.

RCFs produce inflammation in lung tissues.

An estimate for the effectiveness of the REL suggests exposures below the REL should reduce the risk of lung cancer to between 0.073/1,000 and 1.2/1,000. At 0.2 f/cm^3 the risks of lung cancer are estimated at between 0.03/1,000 and 0.47/1,000. These estimates were made by extrapolation from rat experiments [1999]. Experience with asbestos suggests these would be underestimates. However, no attempt has been made to establish the relevance of these estimates to humans and they should be regarded as speculative. IARC 2002 classified RCFs as possibly carcinogenic to humans.

Exposure estimates were made of 10 f/cm^3 for RCF manufacturing process in the 1950s, and 0.05 to 2.6 f/cm^3 in RCF facilities in the middle to late 1970s. Work with RCFs is likely to include exposures to other respirable dusts, especially silica and asbestos.

The report goes into detail about how to control exposure.

Having concluded that the proposed exposure level is of uncertain effectiveness NIOSH recommends periodic health surveillance. Risk managers should be on the look-out for decreased pulmonary function, membrane irritation, recurrent dermatitis and pleural plaques. If biological signs are detected, then surveillance should be intensified. NIOSH fall short of stating that symptoms are a trigger for the need to improve control measures.

NIOSH provide a clear recommendation that RCF workers who smoke, should be offered assistance to quit smoking. In any case, smoking in the workplace should be prohibited.

Comment
There seems to be little doubt that occupational exposure to RCF is associated with increased risk of symptoms such as coughing and irritant dermatitis. In the interests of comfort, such signs would be useful as triggers for improved protection measures, but there is little evidence that they are sensitive or specific signs of other outcomes.

That RCF could aggravate the effects of smoking on lung capacity is confidently asserted by NIOSH. The evidence for this derives from what would usually be regarded as very few studies and, studies of indirect relevance.

NIOSH seem certain that the observed association with pleural plaques was a genuine one that was not explained by other exposures. That there is no epidemiological link between RCF exposure [over a 50 year time span] and any form of human lung cancer would tend to exclude any reasonable fear of 'dread disease' outcome in those with pleural plaques (unless they also had a history of asbestos exposure). It is asserted in this report that observation of RCF associated plaques would encourage the view that RCF exposure could lead to mesothelioma. The logic here is that plaques are evidence that RCF reaches the right part of the lung to cause mesothelioma. It would be informative to obtain an independent view of the plaques research.

Views on the carcinogenicity of RCF were formed with reference to animal experiments. NIOSH report in detail on the development of risk estimates from animal experiments and repeat in several places that the calculated risks could be underestimates by a factor of more than 1000, potentially making RCF far more carcinogenic than asbestos. In our view the designation "possibly carcinogenic to humans" is the right one even though studies of people have not found any risk. The uncertainties in this designation are very large. In our view the likelihood is biased towards an eventual resolution that RCF will be deemed not to be carcinogenic in the majority of formulations and doses that have been experienced to date.

A lifetime risk of 1 in 1000 is usually considered acceptable in NIOSH evaluations of exposure standards. An exposure level of 0.5 f/ml results in an estimated risk of cancer of about the right magnitude. In our view the risk estimation work has not been appropriately validated.