

EURACOAL Position Paper

on Silica and the Carcinogens Directive

Carcinogens Directive

Directive 2004/37/EC on the protection of workers from the risks related to exposure to **carcinogens or mutagens** at work, under the framework directive on health and safety at work (89/391/EEC), sets exposure limit values and preventive measures to reduce the risks to workers who might be exposed to cancer-causing substances (carcinogens) and substances that change genetic material leading to cell mutations (mutagens – also likely to be carcinogens).

The Carcinogens Directive obliges employers to **reduce or replace** the use of carcinogens and mutagens, as far as is technically possible, and to **prevent and reduce exposure** by deploying closed systems, where technically possible. In any event, exposure must not exceed limits set out in Annex III of the directive: protective clothing and respiratory personal protective equipment must be worn in clearly demarked areas to strictly minimise exposure.

Where carcinogens or mutagens are present in the workplace, they must be of limited quantity, clearly labelled and warning signs displayed. The health of exposed workers must be monitored, cases of cancer notified and records kept for 40 years. PAHs present in coal soot, coal tar or coal pitch are identified as carcinogens, although only benzene, vinyl chloride monomer and hardwood dusts are subject to occupational exposure limits.

Silica: a carcinogen?

Proposed revisions to the Carcinogens Directive may address other substances, including respirable crystalline silica dust (α -quartz and cristobalite). There is a high percentage of quartz (*i.e.* silica or silicon dioxide – SiO₂) in coal ash, so any such revision could have important consequences for the coal mining and electricity generation sectors. Typically, 40% or more of the mineral matter in coal is silica and the fraction found in coal dust is often 3%-7%, but this varies with coal quality and mine operations. Occupational exposure limits for coal dust mean that the levels of respirable silica at mines are proportionally lower.

The Commission funds and takes advice from the International Agency for Research on Cancer (IARC) in Lyon, part of the UN World Health Organisation. IARC *Monographs on the Evaluation of Carcinogenic Risks to Humans* are authoritative references prepared by expert working groups – the Carcinogens Directive reflects hazard evaluations published in Volume 68, “Silica, some silicates, coal dust and *para*-aramid fibrils” (IARC, 1997). The working group concluded that crystalline silica inhaled in the form of quartz or cristobalite dust from occupational sources is carcinogenic to humans (Group 1), although their evaluation was qualified because of inconclusive evidence, and that

amorphous silica is not classifiable as to its carcinogenicity to humans (Group 3). In the case of coal dust, the working group concluded that it cannot be classified as to its carcinogenicity to humans (Group 3) since there was inadequate evidence in humans and animal experiments. The German MAK committee's evaluation of coal mine dust reached the same conclusion (MAK, 2012). In practice, it has been the risk of coalworker's pneumoconiosis or "black lung" disease that has led to lower occupational exposure limits for coal dust.

In December 2011, IARC published a new assessment in Monograph Volume 100 "Part C: Arsenic, metals, fibres, and dusts" (IARC, 2012). It confirms the Group 1 classification for crystalline silica, without qualification, and postulates that lung cancer may follow inflammation, "*which results in macrophage activation, and the sustained release of chemokines and cytokines*". The mechanism described by IARC is the same pathogenetic mechanism of silicosis. Coal dust is not covered in the new report, although reported studies at coal mines and coal-fired power plants show low concentrations of respirable crystalline silica when compared with other industries where the presence of silica dust increases the risk of silicosis.

Occupational exposure limits for silica

For a number of years, the Commission has considered whether a respirable crystalline silica exposure limit should be established at EU level. Any new exposure limit could be enforced under the Carcinogens Directive or the Chemical Agents Directive (98/24/EC).

Having reviewed the scientific literature, the independent Scientific Committee on Occupational Exposure Limits (SCOEL, set up under Commission Decision 95/320/EC) recommended a very low exposure limit of 0.05 mg/m³ **to prevent silicosis** (SCOEL/SUM/94, November 2003). The Committee concluded that there was an increased risk of lung cancer in persons with silicosis, but not in employees without silicosis who were nevertheless exposed to silica dust.

Social Partner consultations on amendments to the Carcinogens Directive took place in 2004 and 2007, and then, in 2009, the Commission engaged a contractor to undertake a scoping study to examine 25 substances including silica (SHEcan project led by the Institute of Occupational Medicine in Edinburgh). Unofficial reports suggest that the SHEcan final report will recommend an occupational exposure limit for respirable crystalline silica for inclusion in a revised Carcinogens Directive. It will be important for the Commission to ensure that any biases or weaknesses in this scoping study are quantified before taking any decisions because the study's methodology has been subject to some criticism (Erren and Morfeld, 2011). Moreover, the relevance of exposure thresholds in relation to the prevention of silicosis and lung cancer should be addressed (Mundt *et al*, 2011). The Working Party on Chemicals of the tripartite Advisory Committee for Safety and Health at Work (ACSHW, under Council Decision 2003/C 218/01) will meet on 21-22 March 2012 to discuss the

inclusion of respirable crystalline silica and other substances with the aim of agreeing an Advisory Committee opinion by the end of 2012. A Commission proposal could then follow in 2013.

Separately, industrial mineral producers have notified the Commission of a classification for silica under the CLP Regulation on classification, labelling and packaging of substances and mixtures (EC 1272/2008): STOT RE 1 (specific target organ systemic toxicant with repeated exposure), if the respirable fraction is $\geq 10\%$; STOT RE 2, if the respirable fraction is 1-10%; and no classification if $< 1\%$. There is currently no harmonised classification for silica at the EU level (managed by the European Chemicals Agency) and silica is not included in the REACH Regulation on chemicals and their safe use (EC 1907/2006).

EURACOAL position on silica

EURACOAL notes the European Social Dialogue “Agreement on Workers’ Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing It” (OJ 2006/C 279/02 and NePSI, the European Network for Silica). Monitoring and reporting of dust exposure and workers’ health in the coal industry follows similar good practices, which together with training helps to reduce the risks of pneumoconiosis and other diseases linked with dust inhalation.

EURACOAL notes that the risk of lung cancer is increased in persons with silicosis and apparently not in employees without silicosis but exposed to silica dust, so the focus should be on reducing the risk of silicosis. Moreover, **no excess risk of lung cancer is observed among coal mineworkers**, so again the focus should be on preventing pneumoconiosis.

EURACOAL supports the February 2012 position of the EU Industry Silica Task Force and calls on the Commission to consult widely before considering any targeted action on respirable crystalline silica and to avoid any actions that would cause undue public fear and damage to EU industry. For example, it would serve no purpose to make a general classification or universal exposure limits for silica when it is clear that the hazards are specific and varied.

References

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