Effects of silica dust

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An old acquaintance

Health effects of prolonged and excessive exposure at work to respirable dust of crystalline silica (i.e. mostly quartz and cristobalite) have long been recognized[1]. The risk of silicosis (i.e. a nodular fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica[2]) peaked with the industrial revolution. Fortunately, it has gradually declined with the implementation of appropriate control and preventive measures, and obviously also with the closing down of coal mines in Western Europe. The preventive measures included the introduction of occupational exposure limits and of safer working techniques (e.g. wet processes, automation and exhaust systems, personal protective equipment, etc.), as well as of medical surveillance.

According to national statistics[3,4], there is evidence that in industrialized countries these measures have resulted in a substantial reduction in the prevalence of silicosis during past years. However, as pointed out by ILO and WHO[5], new cases of silicosis are still declared each year, even where the dust suppression has been continuously practised for many years, as a result of the exposures from the past. While the long latency of the disease plays a role, the progress of the diagnosis does also influence the statistics. In addition, ILO and WHO noted that the situation remains particularly serious in developing countries, where millions of workers are at risk of developing silicosis. With the objective to significantly reduce the prevalence rate of silicosis by 2015 and to eliminate it world-wide as an occupational problem by 2030, an ILO/WHO International Programme for the Global Elimination of Silicosis has been developed.

A scientific controversy

Since the 1980s, a new health concern emerged with the suspicion that crystalline silica may exhibit carcinogenic properties[6]. In 1987, the International Agency for Research on Cancer (IARC)[7], on the basis of controversial results from experimental and epidemiological studies, concluded for sufficient evidence of the carcinogenicity of crystalline silica in animals, but limited evidence in humans (category 2A, probable human carcinogen).

Five years later, IARC updated its evaluation concluding that *crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1)*[8]. An unusual note qualified IARC's judgement. This would mean that at the workplace (not in the general environment), in certain (not all) industrial circumstances, exposure to respirable dust of quartz or cristobalite may lead to (lung) cancer in man.

Since the publication of the crystalline silica IARC Monograph in 1997, the scientific community has extensively debated the issue[9-21], but the scientific uncertainties are still not resolved. Some authoritative experts concluded that *data in humans demonstrate a lack of association between lung cancer and exposure to crystalline silica*[20]. Although supporting IARC's evaluation, a pooled exposure-response analysis of 10 silica-exposed cohorts indicated that should silica be a carcinogen it would be a significantly weaker carcinogen than other well known lung carcinogens (Figure 1)[21]. Together with the so-called variability of crystalline silica hazard, one of today's indisputable pieces of evidence is that silicotics are at a higher risk of developing lung cancer, although no causal role for crystalline silica has been proved.

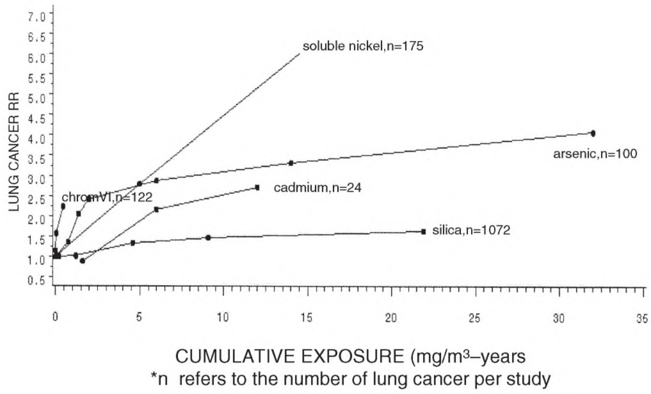

Figure 1. Cancer risk dose-response, K. Steenland *et al*.[21]

Evaluation and regulation in the EU Member States

Whatever the complexity of the scientific evidence, regulatory agencies have to assess the available data in order to decide whether regulatory measures at national level are needed[22]. By virtue of the subsidiarity principle, since the publication of the IARC Monograph, a limited number of European Member States have (re)-evaluated the crystalline silica dossier and came to sometimes conflicting conclusions[23-26].

According to the Dutch experts' (DECOS) evaluation[23], quartz mediates its carcinogenicity by an indirect mechanism, which implies the existence of an exposure level of quartz below which the cancer risk can be considered nil, while the German MAK Committee concluded that quartz is a human carcinogen (category A1)[25]. The British Health and Safety Executive (HSE)[26] considered the variability of quartz hazard and deduced from this a *Potency Matrix* which could lead to a series of preventive measures.

Table I
Occupational Exposure Limit values in several EU countries

The following table shows the Occupational Exposure Limits (OEL) for quartz, cristobalite and tridymite in application in several EU countries. Please note that in the European Union, by virtue of the subsidiarity principle which prevails in health and safety matters, Member States may set up their own OEL values.

Country	OEL Type	Adopted by	Quartz	Cristobalite	Tridymite
Denmark	Threshold Limit Value	Direktoratet fot Arbeidstilsynet	0,1	0,05	0,05
France	Empoussiérage de référence	Ministère de l'Industrie (RGIE)	5 or 25k/Q		
	Valeur limite de Moyenne d'Exposition	Ministère du Travail	0,1	0,05	0,05
Germany	Maximalen ArbeitsplatzKoncentration	Grenzwerte in der Luft am Arbeitsplatz	0,15	0,15	0,15
Italy	Threshold Limit Value	Associazone Italiana Degli Igienisti Industriali	0,05	0,05	0,05
Netherlands	Maximaal Aanvarde Concentratie	Ministerie van Sociale Zaken en Werkgelegenheid	0,075	0,075	0,075
United Kingdom	Maximum Exposure Limit	Health & Safety Executive	0,3	0,3	0,3
	Occupational Exposure Standard				

Q : quartz percentage, Source : IMA-Europe
Remark: OEL's are applicable to 100% quartz, cristobalite or tridymite

None of these countries have notified their evaluation to the European Commission (EC). Some of them, currently the Netherlands[27] and Denmark[28], have listed crystalline silica (respirable) in their national transposition of the European Carcinogens Directive.

In Belgium, the IARC category 1 and 2 carcinogens are listed as carcinogens in the Belgian Decree on the protection of workers at work[29]. Nevertheless, whether a risk analysis demonstrates that it poses no carcinogenic risk for the workers, the substance would fall outside the obligations of the law. By virtue of the Belgian Decree, crystalline silica has been reported in a non-exhaustive list of IARC carcinogens requiring risk evaluation.

In addition, the Netherlands[30] and France[31] have decided for specific respirable crystalline limits, while, according to the Italian law, the new American Conference of Governmental Industrial Hygienists' (ACGIH) recommendation[32] for respirable quartz was implemented in Italy. Not surprisingly, these limits have different values (Table I). More worrying for the development of harmonised health policies, is that these limits are controlled according to various strategies, with dissimilar meanings.

The regulatory approach at EU level

Generally, harmonization is to be expected from the EU level. IARC having limited the crystalline silica hazard to the occupational sources, the classification of the substance would not provide a basis for regulatory action. The EU expert Working Group for the classification and labelling of dangerous substances (CMR Working Group of the European Chemicals Bureau—Joint Research Centre, ECB-JRC, Ispra, Italy) concluded in October 1998 that crystalline silica was not a priority substance for classification. This conclusion was repeated in September 2002, and it is therefore unlikely that EC classification of crystalline silica dust will be planned in the coming years.

Preventive measures could however derive. On a request from the Council of Social Affairs, the EC is considering to set up a crystalline silica exposure limit. Having reviewed the scientific evidence, the Scientific Committee on Occupational Exposure Limits (SCOEL) issued its draft opinion[33] in June '02 which was open to public comments until end of 2002. The main conclusion is that:

The main effect in humans of the inhalation of respirable silica dust is silicosis. There is sufficient information to conclude that the relative lung cancer risk is increased in persons with silicosis (and apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk. Since a clear threshold for silicosis development cannot be identified, any reduction of exposure will reduce the risk of silicosis. In addition, the experts indicated that: *An OEL should lie below 0.05 mg/m^3 of respirable crystalline silica dust.*

On the basis of the final opinion, the EC may possibly decide to propose an occupational exposure limit value which could be indicative (ILV) or binding (BLV) and could be established within the legal framework of the so-called Chemical Agents Directive (98/24/EC)[34] or Annex III of the Carcinogens Directive (90/394/EEC)[35]. In the case of BLV's, these are adopted through a long co-decision procedure involving the Council and the European Parliament, where socio-economic data submitted by industry would be considered to assess the impact of the proposed limit.

It must be noted that substances for which a limit value is allocated in Annex III of the Carcinogens Directive (at work) are not necessarily classified carcinogens within the meaning of the Dangerous Substances Directive (67/548/EEC)[36]. The Dangerous Substances Directive relates in general to classification, packaging and labelling of dangerous substances in order to protect users, consumers, and the environment. This is not the case of the Carcinogens Directive, the scope of which is limited to workers' health protection at the workplace. However, Member States' interpretations may diverge on this. Neglecting any risk consideration, some national agencies may be tempted to request the labelling of preparations containing a substance considered as a carcinogen at the workplace, its substitution, or its ban from public products.

In addition, very low limits (e.g. 0.05 mg/m^3 or below) are close to the detection limit and may cause serious feasibility problems of control.

These low limits would certainly be difficult to implement in most industrial circumstances, but particularly in SMEs, construction and building material enterprises, ceramics and foundry industries. Should such lowering be an effective solution to the elimination of silicosis, the necessary efforts should certainly be accorded. But, from the experience of labour inspectors, a strict compliance with existing limits should first be achieved, since in 30–50 per cent of the industries currently inspected in Europe and in the US, this is far from being achieved[37].

Should the regulatory decision favour a very low limit within the framework of the Carcinogens Directive, it would not necessarily lead to appropriate preventive measures. One may rather fear the development of a burden of overprotective constraints which could lead to the unnecessary phasing out of essential and beneficial materials.

The stakes of defining a limit which prevents silicosis

With silicosis being considered as a possible precursor of cancer, the estimate of silicosis is central to the setting up of a limit for the prevention of any adverse effects from respirable crystalline silica exposure. There certainly exist a body of evidence regarding silicosis dose-response. However, the literature provides several curves, showing quite different slopes (Figure 2). Therefore, the appraisal of the weight of evidence in the various existing dose-response curves is essential[38].

There could be several reasons for the observed discrepancies between various silicosis estimates. In most of the morbidity studies, the silicosis onset estimate is not accurate (using ILO 1/0 category as a silicosis indicator may lead to overestimate its incidence). Moreover, in some multi-exposure circumstances, the X-ray images from lung affections other than silicosis may confuse silicosis estimates, this could be the case in coal miners. In addition, there is generally no data providing information on the mineralogical nature of the dust to which workers are exposed. Still more dramatic, most of the exposure levels are qualitatively or semi-quantitatively assessed, making the dose-response uncertain. For instance, the risk estimates from a South African gold miners epi-study[39] are considered as 'relatively unreliable'[26], for the reason that conversion from particle counts to gravimetric units is a likely source of error, along with the assumption of a constant 30 per cent concentration of quartz in the dust. Moreover, the 1960s exposure values were used for the earlier period when exposures were likely to be 2–3 times higher[26].

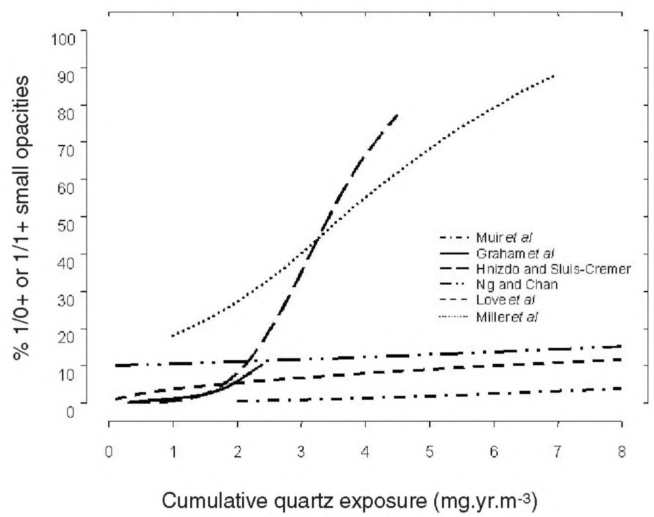

Figure 2. Estimates of silicosis risk are variable (Pilkington *et al.*, 1995[38])

A recent re-analysis[40] of the South African exposure original data confirmed that in the Hnizdo dose-response study[39], the actual dose had been under-estimated by a factor of about 2. As a consequence, estimated respirable quartz exposures, which were previously reported as varying from 0.03 to 0.14 mg/m^3, could well have been between 0.07 and 0.6 mg/m^3. The underestimate of the dose in Hnizdo's study may of course affect the conclusions drawn from the 10 studies pooled analysis[26]. Gibbs' new findings raise a general suspicion on the assessment of exposures from the past in mortality and morbidity studies, all the more when these have been based on particle count converted to mg/m^3.

Because the silicosis onset estimate was not accurate and exposure estimates in the available studies tended to be qualitative or only semi-quantitative in nature, the existing dose-response curves and silicosis risk estimates appear uncertain and unreliable for the purpose of defining an OEL. It is essential that the gaps, the uncertainties and the (poor) quality of the studies, which are decisive in fixing an occupational standard, are carefully taken into account before recommending to keep a limit below the level of detection of any available analysis method (no international or European standard method being anyway available to detect crystalline silica in workplace airborne dust).

The European industry initiatives

The European producers of industrial silica products recommend the strict observation of current national OELs and to minimize (using the best available techniques) exposure to respirable crystalline silica dust in industrial processes. This applies not only to the mineral processing industry itself but also to silica consuming industries, including the construction and building materials industry.

EUROSIL Members are committed to contribute to the development and implementation of actual preventive measures to reduce exposure to respirable crystalline silica dust at work and to a better scientific knowledge of the health effects on man of exposure to crystalline silica.

To this end, pursuing a policy initiated since its foundation in the 1990s, EUROSIL has been commissioning a series of scientific projects, including mortality studies[41] and *in vitro—in vivo* research[42-45], which will be published soon. The silica industry closely follows up these research projects and formulates proposals for new scientific work based on epidemiological and toxicological expert advice. Moreover, EUROSIL, a member of the European Industrial Minerals Association, IMA-Europe, has joined IMA's industrial hygiene project on the implementation of a standard dust monitoring protocol in the industrial minerals industry.

A step further, the industrial silica products industry is looking for developing a 'Good practices document on dust prevention—Respirable crystalline silica' which would describe in a series of fact sheets how to safely use, handle and transport silica based products reducing respirable crystalline silica exposure to a level at which the risk of silicosis would be minimal.

Towards an harmonized dust control strategy

In the second half of the 1990s, aiming to contribute to the current regulatory debate on quartz dust (and in general on dust), IMA's Members were willing to document workers exposures in the mineral industry. Therefore they started to look for existing dust exposure monitoring data in their sectors. Willing to assemble the European quartz exposure data collected over time, the industrial silica producers realized that only a few relevant data[46] had been collected. All member companies strictly complied with their national obligations and a lot of measurements had been made in this aim, but it was not sufficient.

Several issues were at the origin of this poor result: traceability and quality of the data recording, differences in monitoring strategy, sampling, analysis and reporting practices. In addition, most of the data collected came from monitoring exercises undertaken for compliance reasons and for this reason these were not necessarily representative of long-term occupational exposure. It appeared indeed that in most cases, the workplace was not randomly monitored, so most of the monitoring strategies favoured sampling of 'worse case scenario' situations or 'clean' ones. Furthermore, such 'compliance monitoring' generally provided only little information on the activities being carried out during sampling, and practically no information on the external factors possibly influencing it.

Should the aim be to collect representative and comparable dust exposure data, this preliminary overview made clear that there was a vital need to look for a harmonized policy. Such a harmonized policy should have different features, far beyond simple compliance. It should address workers' health protection and the implementation of planned exposure prevention. This was all the more true since the long-term aim of such an exercise would be to collect data which could be integrated into epidemiological surveys. With the automation of processes leading to a drastic reduction of the numbers employed in the sector, it is indeed critical, in order to study significant workers' cohorts, to assemble data collected for similar exposures in several companies, even though they may be located in various countries.

IMA's standardized dust monitoring protocol

In response to these conclusions, the IMA-Europe members decided to launch an industrial hygiene 3-phase project aimed at developing and implementing a common monitoring strategy in the minerals industry. The objective was to generate a standard dust monitoring protocol integrating common practices and obligations in such a way that it would facilitate greater acceptance of its requirements by the IMA members who would have to commit to the programme. The project was commissioned to the 'Institut d'Hygiène Industrielle et de l'Environnement de l'Ouest' (Cnam-IHIE Ouest, Angers, France), which designed a three-phase 'training-action' programme starting in 1999 and ending in 2003.

Run in 99–00, Phase I aimed at defining common ground between existing monitoring strategies in a selection of member companies representing different minerals (5 amongst 7), Member States (9 amongst 13) and company sizes. To this end, this preparatory phase scrutinized industries dust monitoring practices and national regulatory obligations relating to dust exposure assessment, through a series of company visits and the filling in of a questionnaire. It helped to define the recommendations and criteria for defining a common monitoring strategy taking as much as possible account of the existing practices and regulatory constraints.

As a result, Phase II of the project got under way. This consisted in the preparation of a standardized dust monitoring protocol intended to be implemented by IMA companies after proper training.

An IMA Hygiene Task Force was intensively involved in IHIE's work. At this stage of the project, it was agreed that, to collect at the end comparable and representative exposure data, it would be essential to impose through the protocol a monitoring strategy as harmonized as possible, with strict minimal criteria to be followed. These criteria were defined for measurement conditions (personal measurements, respirable fraction), sampling equipment (in conformity with EN 481[47]), analytical techniques (standard X-ray diffraction or Fourier transform infrared spectroscopy), procedures and data handling. Minimal requirements have also been defined for the selection of external laboratories performing sampling and/or sample analysis when these are sub-contracted.

Other important criteria of the methodology include the definition of exposure groups and of sampling locations corresponding to common job functions. Eight principal job functions (with some possible sub-categories) have been identified as present in most sites of the mineral industry. In addition to sampling and campaign characteristics (duration time, number of samples, periodicity, etc.) and metrology aspects, the protocol details data management and provides a quality control manual.

In the format of a handbook, the protocol was given to all IMA-Europe's member companies, and a 2-day training, including workshops, was organized. About 40 trainees (H&S and quality control managers, medical physicians, engineers, laboratory assistants in charge of dust control) who had to implement the protocol in their companies participated in the workshop. The handbook was made available in five EU languages (Dutch, English, French, German, and Spanish) and, at the initiative of member companies, further training courses were organized in different countries.

Phase III of the project, i.e. the implementation phase, started immediately after the training. In 2002, a summer dust monitoring survey was planned, followed by a winter survey. The data are collected by the IMA Secretariat thus guaranteeing confidentiality, whilst the statistical handling of the data and the compilation of the dust exposure database is managed by the IHIE. IMA-Europe's member companies are progressively joining the project at their own speed. Their participation is sealed by a commitment letter signed by the company CEO. This obviously depends on a high level company decision and proper investment in equipment and human resources.

Currently, more than 20 companies joined the exercise, which means that IMA-Europe's monitoring covers around 5000 employees, potentially exposed to the dust of six different minerals, in some 70 sites located in 9 Member States plus Norway. As the exercise may be joined at any time, the number of participants is continuously growing.

As a result of this initiative, a first job-exposure matrix of the industrial minerals industry will become available by mid-2003.

The way forward

The IMA industrial hygiene project is without doubt one of the first voluntary initiatives of this type in the industrial minerals sector. With its harmonization objectives and the extent of commitment this requires from industry, it is an ambitious project. Ultimately, industry would seek validation of the standardized protocol by the national institutes, laboratories and experts who are involved in dust exposure control in Europe. To this end, the protocol has been submitted for consideration to around ten institutes from different countries, and further standardization steps could be considered within the European Committee for Standardization (CEN).

It must also be emphasised that IMA's industrial hygiene programme objectives are going far beyond this 3-phase project. One of the main objectives of the programme is to induce a sustainable health policy culture in the industry. It is indeed the intention to continuously compile dust monitoring data collected according to the standardized protocol from an increasing number of companies.

Furthermore, it could lead, considering the success of this first initiative, to a second project aimed at defining a standard medical surveillance strategy in the IM industry. Together with the development of a Good Practices Document promoted by the industrial silica products sector, this would certainly promote the development of a real dust exposure prevention policy within the sector and the continuous improvement of working conditions.

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