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Book Reviews

Respirable Crystalline Silica—Phase 1: Variability in fibrogenic potency and exposure–response relationships for silicosis. Hazard assessment document. EH75/4 Health & Safety Executive 2002. ISBN 0 7176 2374 2. 80 pp.

Respirable Crystalline Silica—Phase 2: Carcinogenicity. Hazard assessment document. EH75/5 Health & Safety Executive 2003. ISBN 0 7176 2191 X. 91 pp.

The Health & Safety Executive (HSE) has carried out a detailed review on crystalline silica and published it as two documents in their Hazard Assessment Document series; both documents are reviewed here. Hazard Assessment Documents are produced to facilitate the development of a regulatory position on a specific health-related issue. Phase 1 of this HSE project addresses the issues of variability of fibrogenicity and quality of silicosis exposure–response data, while Phase 2 reviews the evidence with regard to carcinogenicity of respirable crystalline silica (RCS).

The first document deals with the basic yet complex question of whether all RCS exposures are equally fibrogenic, regardless of form or other characteristics. A familiar topic of debate in the silica policy arena is whether a particular crystalline silica-containing dust, e.g. dust generated by industry 'X' is 'safer' because it possesses characteristic 'Z'. 'Z' could be related to particle size, number and surface area, presence of other minerals, 'age', industrial process or polymorphic form. The HSE document reviewed six 'potency factors' with regard to their ability to cause silicosis and summarized them in the 'RCS Potency Matrix'. The HSE concluded that extremely small particle size enhances the potency, while three factors (wetting, ageing and aluminium-containing clay coatings) reduce the potency. One potency factor was mentioned as a 'reference point' of comparison for the other factors (i.e. production of dry, freshly cut surfaces), and on the last factor (polymorphic form) cristobalite is considered to have the same potency as quartz. However, HSE emphasized that the Potency Matrix 'should not be used as a basis for suggesting relaxation in control standards in any industry or process involving exposures to crystalline silica'—an important caveat that deserved more emphasis, at least visually, in the document.

The Phase 1 document is divided into three sections: (1) *in vitro* studies of crystalline silica's cytotoxicity; (2) *in vivo* studies of cytotoxic and fibrogenic effects in experimental animals; and (3) epidemiological studies of silicosis in workers, with particular attention to gaining a 'coherent perspective' of the variety of different reported risk estimates. The Appendix includes a brief and helpful description of the International Labour Organization's (ILO) 1980 classification system for pneumoconiosis radiographs.

Observant readers will notice that the document presents predicted risks for development of silicosis with an ILO score of 2/1+—a more severe endpoint definition than that used in most epidemiological studies. HSE considered category 2/1+ to be 'the most reliable basis for identifying true cases of silicosis in large-scale occupational studies'. Those risks are presented in a tabular format, while the corresponding (and higher) risk estimates for ILO category 1/0+ are presented nearby in the text, which lends some balance to the discussion. For example, based on the study of Scottish coal-miners (which the Phase 1 report considers to be the most reliable), the predicted risk from 15 yr exposure to 0.1 mg/m^3 8 h time-weighted average (TWA) is 2.5% for category 2/1+ and 25% for 1/0+, 15 yr post-exposure.

The Phase 2 document addresses similar key questions, except that in this document the outcome of interest is lung cancer, rather than silicosis. The HSE (http://www.hse.gov.uk/flist/june.htm) described this May 2003 document as a report of 'scientific information that underpins the assessment of a specific substance'. However, the document lacks a visual linchpin that brings the information (i.e. 'weight of evidence') together for the reader. Phase 1 had the 'Potency Matrix'—a simple table in the 'front summary' that summarized the findings of the epidemiological and experimental studies. This table organized the forthcoming issues before the reader reached the study descriptions; the Phase 2 document does not have a similar table, or any tables at all, in fact. The entire document, about 90 pages, is mainly single-spaced narrative filled with details of each study. The reader may find the lengthy descriptions useful, in that she/he will rarely need to look up further details in the original papers. (For example, in

the section describing studies of gold-miners, each description averages about ten paragraphs in length.)

The document begins with a summary that is not repeated at the end of the document; actually the document ends rather abruptly with a section about a 'widely accepted' mechanism of lung cancer induction. The summary and Section 1 give the HSE's conclusions about three key RCS issues:

1. The weight of toxicological and occupational epidemiological evidence supports the view that RCS has the potential to cause lung cancer in humans.
2. Evidence for a relationship between lung cancer and silicosis tended to show that excess lung cancer mortality in RCS-exposed workers was restricted to those workers with silicosis and risk increased with severity of silicosis. However, there was no definitive evidence to conclude that occupational exposures to RCS insufficient to cause silicosis would not lead to an increased risk of lung cancer.
3. Evidence for variability in the carcinogenic potency of RCS was less clear than for fibrogenic potency (Phase 1 document).

The heart of the Phase 2 document is Section 2: 'Individual appraisal of key epidemiological studies' of stone workers, diatomaceous earth workers, industrial sand workers, metal ore miners, and pottery and refractory brick workers. The determination of 'key' studies was apparently derived from published reviews by other organizations and authors, with the HSE conducting its own review of those studies and later ones. Each study description begins with a brief bold-print summary and concludes with a summary of the strengths and weaknesses of the study. The critiques reflect a good knowledge of occupational epidemiological methods as well as 'dust' issues. Particular attention was paid to the assessment of confounding exposures to other lung carcinogens, such as cigarette smoke. However, the reader is cautioned to check any measurement units that seem unusual; a few times 'mg' appeared in the original papers as 'μg'. The final section summarizes the published 'experimental and animal data' and the current body of knowledge pertaining to mechanisms of carcinogenicity.

Both reports are highly technical research documents and readers should be prepared to allocate a substantial period of time to grasp adequately the content of these documents. Although clearly written, tables are few and the experimental and epidemiological studies are carefully described in a detailed, narrative style. Those readers with basic questions, such as 'What is crystalline silica?' and 'Where is it found?' are strongly advised to seek out HSE pamphlets (e.g. online leaflets 'CHAN35—Respirable Crystalline Silica' and CIS36 'Silica') and other brief silica publications. However, for those scientists and others who have long grappled with questions about variability of crystalline silica, the Phase 1 document will be a welcome addition to their literature collection. For scientists and others interested in reading an evaluation of the epidemiological and experimental evidence of RCS carcinogenicity, but lacking previous experience with the subject, I suggest starting with International Agency for Research on Cancer (IARC) monograph Volume 68 in order to become familiar with the studies. Readers looking for history, research needs or more details of experimental studies may find useful information in the reviews by the World Health Organization (WHO) and the National Institute for Occupational Safety and Health (NIOSH). [The IARC (1997), WHO (2000), and NIOSH (2002) reviews are cited and referenced in the Phase 2 document; the WHO document is referenced as 'Concise International Chemical Assessment Document'.] Once a level of familiarity with the body of past research is achieved, the HSE Phase 2 review may be easier to digest. It is a good-quality, in-depth review that also critiques the most recently published studies, an advantage for those readers trying to stay current with the published RCS lung cancer literature.

Although the authors' names do not appear to be included in the document, they are to be commended for their substantial effort and production of these useful reviews.

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