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ADVISORY COMMITTEE ON TOXIC SUBSTANCES**Proposals to introduce a new WEL for Silica****A Paper by Pauline Nash****Cleared by Steve Coldrick on 19th October 2004****Issue**

1. Proposal for a new workplace exposure limit (WEL) for respirable crystalline silica (RCS).

Timing

2. Routine

Recommendation

3. That ACTS agrees to recommend consultation on a new WEL of 0.1 mg.m⁻³ as an 8-hour TWA for RCS (draft consultation document attached at Annex 1).

Background*Health risks*

4. Crystalline silica is found in almost all types of rock, sands, clays, gravels and shales. It also occurs in building materials such as bricks, tiles and concrete products. HSE estimates that at least 100,000 workers are regularly exposed to dusts containing RCS in a diverse range of industries. These include mines and quarries, iron and steel foundries, the heavy clay industry (including brick manufacture) potteries and the industrial sand industry.

5. Exposure to RCS can cause the development of silicosis, an irreversible fibrotic lung disease that usually takes many years to develop. The effects of silicosis range from mild to severe depending on the extent of exposure. Severe cases are disabling and can lead to premature death. Historically, occupational exposure to RCS caused a huge burden of disease but with improvements in standards of control the current incidence of silicosis is now much reduced. However, there has been no evident sign of a downward trend in annual incidence in recent years, and in 2002 there were 150 cases of silicosis that received compensation under the Industrial Injuries Scheme.

6. In 1997, the International Agency for Research on Cancer (IARC) concluded that RCS was a cause of lung cancer in humans. An HSE review

published in 2002 and endorsed by WATCH also confirmed that there is sufficient evidence to indicate that RCS can cause lung cancer in humans. The HSE review also noted that the evidence for lung cancer is strongly suggestive, although not definitive, that there is an increased risk of lung cancer only in those with silicosis.

7. Lung cancer due to RCS has been a prescribed industrial disease in Great Britain since 1993 and is subject to compensation through the Industrial Injuries Scheme. Statistics show that only a handful of cases receive compensation each year, with the highest number in 1999 when 7 men were diagnosed with lung cancer due to RCS. It is possible that the statistics underestimate the true number of lung cancer cases due to crystalline silica. This is because many workers or ex-workers with lung cancer might fail to suspect that past occupational exposures to RCS were the cause, and they would therefore be unlikely to come forward for compensation. Concerns about lung cancer emphasise the importance of reducing the risks of silicosis.

Current Control Levels

8. Under the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended), RCS is currently subject to a Maximum Exposure Limit (MEL) of 0.3 mg.m^{-3} as an 8-hour TWA. However, when the COSHH Regulations were first implemented in 1989 there was an Occupational Exposure Standard (OES) for RCS of 0.1 mg.m^{-3} and when the MEL was first introduced those industries that had been able to comply with the original OES were still expected to do so (see pg 6 of the draft CD for the history of the OEL – Annex 1).

9. The current control limits in many other countries are below the current GB MEL of 0.3 mg.m^{-3} as shown on page 7, table A in the RIA (Annex 2).

The New OEL Framework

10. At its meeting on 8th July 2004 ACTS approved a new Occupational Exposure Limit (OEL) framework in which the current system of OESs and MELs will be replaced by a single type of limit known as a Workplace Exposure Limit (WEL). This paper is consulting on a new WEL for RCS in advance of the implementation of the new OEL framework.

11. Subject to approval by the Health and Safety Commission (HSC) and Ministers, the new OEL framework is expected to come into force at the beginning of April 2005. It is the intention of HSE to consult on a new WEL for RCS immediately following the introduction of the new OEL framework in April 2005. An earlier date for consultation was decided against in order to avoid confusion among stakeholders while the current OEL system is still in force. This timing will enable the new WEL on RCS to be implemented through the publication of the 2006 edition of HSE's booklet EH40 – "Workplace Exposure Limits".

Argument

12. A number of industries will be affected by HSE's proposal to set a WEL for RCS of 0.1 mg.m^{-3} as an 8-hour TWA. The main sectors have been arranged into the ones most clearly understood by UK industry and are listed below:

- Foundry Industry
- Ceramics Industry
- Brick manufacture and Heavy Clay
- Quarry industry
- Stonemasonry industry
- Industrial minerals and the production and use of Silica sand and flour
- Construction industry

Coalmines are excluded because they are subject to different regulations.

13. It should be noted that there is considerable overlap with these industries; many brick manufacturers have a quarry nearby to supply the raw material; stonemasons work in the construction industry as well as in isolated workshops. Slate production is associated with quarrying. The production and use of silica flour emphasises this difficulty as this material is produced and used for a multitude of purposes in several different sectors.

Risk Estimates

14. The draft consultative document provides an overview of the health risks from exposure to RCS (pages 7-9 and Annex 1 refers). Table 1 below presents the risk estimates for the risk of developing silicosis. It can be seen from this table that when exposures rise above an average of 0.1 mg.m^{-3} as an (8-hour TWA), then the risks of developing silicosis rise very steeply.

Table 1 - Estimated quantitative risks of developing silicosis

15 years daily exposure to respirable crystalline silica dust at average airborne concentrations (for an 8-hour shift) of: (mg.m^{-3})	Risk of developing silicosis within 15 years following cessation of exposure
0.02	0.25%
0.04	0.5%
0.1	2.5%
0.3	20%

Why HSE proposes to consult on 0.1 mg.m^{-3}

15. HSE has undertaken a Regulatory Impact Assessment (RIA) on RCS (Annex 2) and has taken the findings into account in reaching its proposal to lower the current MEL. The objective of the RIA was to estimate the costs

and benefits of a new Workplace Exposure Limit (WEL) for RCS and to provide information on the levels of exposure that are reasonably practicable to achieve in the workplace. Four WEL values of 0.3, 0.1, 0.05, and 0.01 mg.m⁻³ (8-hr TWA) were investigated.

16. The RIA also includes an assessment of the health benefits that would arise from the setting of a new WEL. The health benefits can be expressed in monetary values based on the medical costs and productivity losses avoided by the prevention of cases of silicosis and deaths from silicosis and lung cancer. Monetary values are also assigned to take account of pain and suffering. There are always uncertainties surrounding such estimates, including uncertainties pertaining to the numbers of workers exposed, their exposure conditions, exposure-response relation, staff turnover etc. However, the most realistic estimates that could be derived by HSE suggest that over a sixty-year period the following number of RCS lung cancer fatalities, silicosis fatalities and non-fatal silicosis cases will be prevented at the various proposed limits (Table 2).

Table 2 – RCS fatal and non-fatal prevented over 60 years

Exposure	Lung cancer fatalities	Silicosis fatalities	Total fatalities	Non-fatal silicosis cases
0.3mg/m ³	36	36	72	110
0.1mg/m ³	185	185	370	547
0.05mg/m ³	300	300	600	883
0.01mg/m ³	455	455	910	1326

17. The RIA is based on a recent survey of industry sectors in which workers were exposed to dust containing RCS. It compares the costs to industry of controlling to four potential WEL values against estimates of the associated health benefits. The result of the RIA can be seen in Table 3 below.

Table 3 - Total estimated industry compliance costs and benefits (both discounted at present value)

Proposed WEL for RCS	60 year total costs to industry (£ million)	60 year total prevented costs arising from the health benefits (£million)
0.3 mg.m ⁻³	5.1 to 5.3	39.4 to 78.8
0.1 mg.m ⁻³	638 to 650	209 to 414
0.05 mg.m ⁻³	3453 to 3603	340 to 671
0.01 mg.m ⁻³	12024 to 14663	515 to 1015

18. In addition to the RIA, HSE also took into account the ability of sampling and analysis methods to reliably measure RCS at various exposure concentrations. It was found that the available methods lack sufficient precision to be able to determine compliance with a limit set at 0.05 mg.m⁻³ or

below. The distribution of results from measurements on an amount of dust collected on a filter from a concentration in air of RCS in the region of 0.05 mg.m^{-3} is close to the limit of detection for a sample of 4-hours duration, and would not allow an accurate interpretation of a measurement to be made. HSE feels this is an important consideration when deciding on a suitable WEL for RCS. A limit set at 0.05 mg.m^{-3} or below might severely compromise HSE's ability to take enforcement action.

19. Exposures in some industry sectors are often related to job specific tasks that may last for relatively short periods of time and the periods of sampling are related to the period of the task e.g. 30 minutes or 2 hours. If the sampling period is for the full working day and the sample is relatively free from interferences, then 0.05 mg.m^{-3} is practical. However, the duration of the sampling period is a compromise between cost and practicality and a sampling period of 4 hours is taken as an average sampling time. If HSE were to insist on a minimum sampling duration this may involve extra sampling and would be an added cost to industry.

20. The current limit of 0.03 mg.m^{-3} was not supported by the RIA due to the significant health risks associated with this exposure limit. As indicated in the RIA, a WEL set at 0.01 mg.m^{-3} is of theoretical interest only because it would dramatically affect many well known and established industry sectors and could well impinge on several more sectors where silica is not currently discernible from background concentrations.

21. A WEL set at 0.05 mg.m^{-3} or below would lead to the potential for closure of parts of some industry sectors. Also, as noted in paragraph 18, WELs of 0.05 or 0.01 mg.m^{-3} would not be enforceable in all instances given the limitations of present sampling and analytical methods.

22. A limit of 0.1 mg.m^{-3} (8-hour TWA) for RCS, set as a WEL, would impose extra compliance costs on industry but without causing major redundancies. The largest costs could well occur in the quarry industry – a consequence of the processes, the large number of sites and the large capital costs that would be required to make significant reductions in RCS exposure. This therefore is the level at which HSE believes UK industry could comply (with costs) and where compliance could bring a significant health benefit.

Link to HSC Strategy

23. The proposals are in keeping with HSC's strategy 2010 and beyond for workplace health and safety in GB. They will have a positive influence on the intervention strategy which will help to achieve a reduction in occupational exposure and will therefore lead to an improvement in occupational health. They also link to the Chemicals sub programme on respiratory disease, which includes silicosis.

Communication Plan

24. Subject to agreement by HSC, the proposed WEL for RCS will be published in a consultation document (see Annex 1) in the usual way for

proposed occupational exposure limits. HSE will report the results of this consultation exercise to ACTS and to HSC.

Evaluation Plan

25. Compliance with the new WEL for RCS, including the requirement to adopt good occupational hygiene practice will be evaluated as part of the Silica Action Plan – one of the main strands of the Occupational Respiratory Disease sub-programme within HSE's chemical programme.

Relevant Control Systems

26. After elimination and substitution of the hazardous material, which is only occasionally possible, engineering solutions are considered and costed first.

27. Enclosure may be practicable in some sectors; in any case, segregation of dusty processes is important. Although local exhaust ventilation (LEV) reduces potential exposure, and dust suppression and good housekeeping reduces airborne RCS, personal protective equipment (PPE) may still be needed for some tasks.

Consultation

28. A significant amount of informal consultation has taken place with industry. Relevant trade associations and over twenty UK companies were visited and consulted about the RIA and a range of HSE publications and publications from peer-reviewed literature were consulted for relevant information.

29. A range of small businesses were contacted by telephone or by e-mail and in the region of fifteen sites were visited where fewer than 50 workers were employed.

30. Consultation is currently taking place with the Cabinet Office, Department of Trade and Industry, Department of Health, Department for the Environment, Food and Rural Affairs and Department for Work and Pensions. The RIA is likely to be considered by the Prime Minister's Panel for Regulatory Accountability early in 2005. The CD will not be published until this consultation has finished.

Costs and Benefits

31. The costs and benefits are detailed in the RIA (Annex 2).

Financial/Resource Implications for HSE

32. Although the costs of enforcing the limits, particularly the lower ones, are expected to be significant, HSE anticipates that enforcement costs would be absorbed within existing budgets. Although this would almost mean a re-allocation of resources, the subsequent opportunity costs are not readily quantifiable. HSE is also planning a survey of targeted industry sectors to monitor the impact of the new limit.

Environmental implications

33. None.

European Implications

34. In Europe the Scientific Committee on Occupational Exposure Limits (SCOEL), which comprises experts in occupational health drawn from all Member States, issued a recommendation to the European Commission in 2002 stating that to control against silicosis, any Occupational Exposure Limit (OEL) would need to be below 0.05 mg.m^{-3} (8-hr TWA).

35. This does not constitute a formal proposal for a limit. However, it is possible that at some point in the future the European Commission could request information from Member States and social partners on a proposed limit for RCS, and given the SCOEL conclusion, we anticipate that discussions on a proposed binding limit value are likely to centre on 0.05 mg.m^{-3} . There is no information on the likely timescale for this to happen, and given the lack of activity in Europe on the development of Binding Limits it could be many years before any progress is made towards the development of a Binding Limit for RCS.

36. The SCOEL recommendation strongly undermines the current MEL (0.3 mg.m^{-3}) and supports HSE's proposal to develop a more stringent regulatory position on RCS.

Other implications

37. None

Action

38. ACTS is invited to agree that HSC be asked to consult on the establishment of a WEL for RCS set at 0.1 mg.m^{-3} as an 8-hour TWA.

Contact ACTS Secretariat

Tel: 0207 717 6196

Fax: 0207 717 6190