HSC
Health & Safety
Commission

Control of Substances Hazardous to Health Regulations 2002 (as amended 2005)

Proposal for a Workplace Exposure Limit for Respirable Crystalline Silica

This consultative document is issued by the Health and Safety Commission in compliance with its duty to consult under section 16(2) of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

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to reach her no later than 13 March 2006

The Commission tries to make its consultation procedure as thorough and open as possible. Responses to this consultation document will be lodged in the Health and Safety Executive's Information Centres after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fees to cover costs.

Responses to this consultation document are invited on the basis that anyone submitting them agrees to their being dealt with in this way. Responses, or part of them, will be withheld from the Information Centres only at the express request of the person making them (Under Code of Practice on Access to Government Information; Environmental Information Regulations 1992 and the Data Protection Act 1998). In such cases a note will be put in the index to the responses identifying those who have commented as asked that their views, or part of them, be treated as confidential.

Many business e-mail systems now automatically append a paragraph stating the message is confidential. If you are responding to this CD by e-mail and you are content for your responses to be made publicly available, please make this clear in the body of your response that you do not wish any standard confidentiality statement to apply.

CONSULTATIVE
DOCUMENT

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Control of Substances Hazardous to Health Regulations 2002

Proposal for a Workplace Exposure Limit for Respirable Crystalline Silica

CONSULTATIVE DOCUMENT

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PREFACE

The Health and Safety Commission (HSC) would like your comments on a proposal for a new Workplace Exposure Limit (WEL) for respirable crystalline silica[1]. A form is included at the back of this booklet to help you do this. It repeats the questions set out in the main text below. Please feel free to copy this consultative document more widely. Further copies are available from the address on the back cover and on the Internet on the HSE home page at:

http://www.hse.gov.uk/consult/live.htm

Acknowlegements:

HSC wishes to thank all those who have assisted HSC and the Health and Safety Executive (HSE) with the development of these proposals.

Who should read this?

The proposals will be of particular interest to people who come into contact with respirable crystalline silica at work. Principally this includes those involved in the industries listed below:

Foundry industry
Ceramics industry
Brick manufacture and heavy clay
Quarry industry
Quarry industry – slate quarries
Underground mining of industrial minerals[2]
Industrial minerals – silica sand production
Industrial minerals - silica flour production
Industrial minerals - use of silica-containing industrial minerals
Construction industry
Stonemasonry industry

Why are we consulting you?

The Health and Safety Commission (HSC) seeks to inform its decision-making by consulting a wide range of interested bodies. HSC believes this will enable an open and transparent approach to decision-making, which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. HSC will decide on the best way forward based on consideration of the results of this consultation exercise.

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[1] For the purpose of this document, any reference to crystalline silica refers to all forms of crystalline silica, including quartz and cristobalite.
[2] Exposure limits for respirable quartz in coal mines are set out in the Coal Mines (Respirable Dust) Regulations 1975 and 1978. Proposals to revise these were subject to consultation in 2004.

What we would like you to do:

We would like you to comment on these proposals by 13/03/2006, please send your comments via one of the routes below:

(i) **Pauline Dillon, Health and Safety Executive, Room 101 Daniel House, Stanley Precinct, Bootle, Liverpool L20 3TW**
(ii) **Tel: 0151 951 3202**
(iii) **Fax: 0151 951 3418**
(iv) **email: silica.consultation@hse.gsi.gov.uk**

If you reply to this Consultative Document in a personal capacity, rather than as a postholder of an organisation, you should be aware that information you provide may constitute "personal data" in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the "data controller" and will process the data for health and safety and environmental purposes. HSE may disclose these data to any person or organisation for purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected. Please note all replies will be made public unless you specifically state you wish yours to be made confidential.

Responses in electronic form are welcome. Many business e-mail systems now automatically append a paragraph stating that the message is confidential. If you are sending your comments by e-mail please state clearly whether you are content for your response to be made public.

We have included a reply form summarising the areas where we would welcome your views; it would also help to analyse responses. It is not intended to restrict the scope of the comments: we would welcome any comments you wish to make on the proposal.

What happens next?

We will acknowledge all responses and give full consideration to the substance of arguments in the development of proposals; we may also contact you again if, for example, we have a query. When a decision has been made by HSC we will let you know how the work will proceed and how the decision reached reflects the results of the consultation.

At the time of publication of this consultative document it is intended to implement the new workplace exposure limit for respirable crystalline silica through an amendment to HSE's publication *EH40 - Workplace Exposure Limits*."

Making responses public:

To make our consultation process as thorough as possible we make the comments we receive available to the public at our information centre in Bootle. Copies will be made available at a small charge to cover costs from the following address:

Health and Safety Executive
Bootle Information Centre
Magdalen house
Stanley Precinct
Bootle
Merseyside L20 3QZ

Queries and complaints:

The Health and Safety Commission/Executive would also like to know what you think about this consultation, both the content and layout. Your views may help to improve further consultations. If you are not satisfied with the way in which this consultation exercise has been conducted you can complain by contacting:

Mr Mark Lawton
Health and Safety Executive
Room 108
Daniel House
Stanley Precinct
Liverpool
L20 3TW

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with the Director-General of HSE, Geoffrey Podger at the Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. You can also write to your MP to take up the case with us. Your MP may refer the matter to the Parliamentary Commissioner for Administration (the Ombudsman) who will investigate your complaint.

SUMMARY

1. The purpose of this Consultative Document is to seek views on a proposal for a new Workplace Exposure Limit (WEL) for respirable crystalline silica (RCS). In arriving at this proposal, HSE has taken into account the findings from a Regulatory Impact Assessment (RIA). A summary of the RIA is provided at the end of this Consultative Document (Annex 3). Copies of the full RIA are available free of charge from: **Peter Roberts, Health and Safety Executive, Room 103, Daniel House, Stanley Precinct, Liverpool L20 3TW.** The RIA is based on a recent survey of industry sectors in which workers are exposed to dust containing RCS. The primary purpose of the RIA was to provide information on the levels of exposure that are reasonably practicable to achieve in the workplace. If you have information on the levels of exposure that can be reasonably achieved, please do take a few minutes to fill in the response at the back of this document.

2. 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. HSE estimates that at least 100,000 workers are regularly exposed to dusts containing RCS in a variety of industry sectors. These include mines and quarries, iron and steel foundries, the heavy clay industry (including brick manufacture), potteries, construction, stonemasons and the industrial sand industry.

3. Particles of crystalline silica are harmful to the lungs, and can cause the lung disease silicosis which can cause breathing problems that range in severity from mild to severe; severe cases can be very disabling and lead to death. Exposure to RCS can also cause an increased risk of lung cancer.

4. Under the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended 2005), RCS is subject to a Workplace Exposure Limit (WEL) of 0.3 $mg.m^{-3}$ measured over an 8-hour time weighted average (8-hr TWA). However, current scientific evidence suggests that a more stringent limit is needed. The evidence suggests that long-term exposure to 0.3 $mg.m^{-3}$ would eventually result in up to a 20% risk of developing silicosis. With exposure of 0.1 $mg.m^{-3}$ the risks reduce to 2.5%. For exposure levels below 0.1 $mg.m^{-3}$ the risks continue to reduce, with 0.05 $mg.m^{-3}$ carrying a risk factor of less than 1%.

5. The RIA compares the costs to industry of controlling RCS to a range of possible WEL values against estimates of the associated health benefits. The findings indicated that with a WEL of 0.1 $mg.m^{-3}$ there would be increased compliance costs to industry. Estimates of compliance costs for control to levels below 0.1 $mg.m^{-3}$ were more substantial with the potential for plant closures in some industry sectors.

6. In relation to measuring airborne levels of RCS, analytical methods need to provide measures of exposure with sufficient precision to support enforcement activity, should this be deemed necessary. Ideally, analytical methods need to be able to cope with both 4-hour and 8-hour TWA periods, given that some workplace tasks may only be a few hours in duration. For RCS, if the WEL were set at 0.1 $mg.m^{-3}$, then the available analytical methods are perfectly adequate to support enforcement. However, if exposures to RCS were around 0.05 $mg.m^{-3}$ and a 4-hour sample was taken due to the intermittent nature of the exposure, then the amount of RCS collected

on the filter would be so low that it would not allow precise measurement. A table comparing the key issues for the two limits is on page 15 of this document.

7. It should be noted that with the legal requirements of WELs, the key emphasis is on the need to adhere to good occupational hygiene practice; if there was a clear breach of good practice, enforcement activity could go ahead irrespective of the airborne level of RCS.

8. WELs are set on the recommendations of the Health and Safety Commission's (HSC) Advisory Committee on Toxic Substances (ACTS). Taking into account the findings of the RIA, in particular the information on health risks, and issues relating to costs, compliance and measurement, ACTS advised that HSC should seek views on a proposal for a WEL of either 0.05 or 0.1 $mg.m^{-3}$ (8-hour TWA).

9. Weighing the views of ACTS alongside the current uncertainties over measurement and enforcement of the 0.05 mgm-3 limit, and its impact on industry, HSC's proposal in this CD is to:

- **Recommend the WEL is changed now from 0.3 mgm^{-3} to 0.1 mgm^{-3}**
- **Our intention is a WEL of 0.05 mgm^{-3} in the future, subject to resolution of the measurability difficulties and a regulatory impact assessment.**

We invite your views on these proposals.

10. The current intention is to bring the new WEL into force on the publication of the 2006 issue of HSE's booklet '*EH40 – Occupational Exposure Limits*" However, this is subject to the views received via this consultation process and the response of the Health and Safety Commission to them. Please send your views and comments on the proposal for a new WEL of 0.1 $mg.m^{-3}$ (8-hour TWA) for respirable crystalline silica to the Health and Safety Executive by 13/03/2006 by any of the methods outlined in the preface to this document.

BACKGROUND

What is Respirable Crystalline Silica (RCS)?

1. Crystalline silica is one of the most abundant minerals in the earth's crust. It consists of silicon and oxygen atoms (SiO_2) arranged in a regular crystalline structure. There are different crystalline forms of silica, with the most common one being that of quartz. In some circumstances, for example in the high temperatures of industrial furnaces and kilns, quartz may convert to another crystalline form of silica known as cristobalite. Quartz is found in varying amounts in almost all types of rock, sands, clays, shales and gravel. For example, sandstone is almost pure quartz, whereas granite might contain 15-30% quartz.

2. Crystalline silica is also a major constituent of construction materials such as bricks, tiles and concrete. Many common workplace activities such as cutting, drilling, grinding and polishing, produce fine dust containing respirable crystalline silica (RCS). The term 'respirable' means that the dust particles are small enough to enter the lungs when they are inhaled.

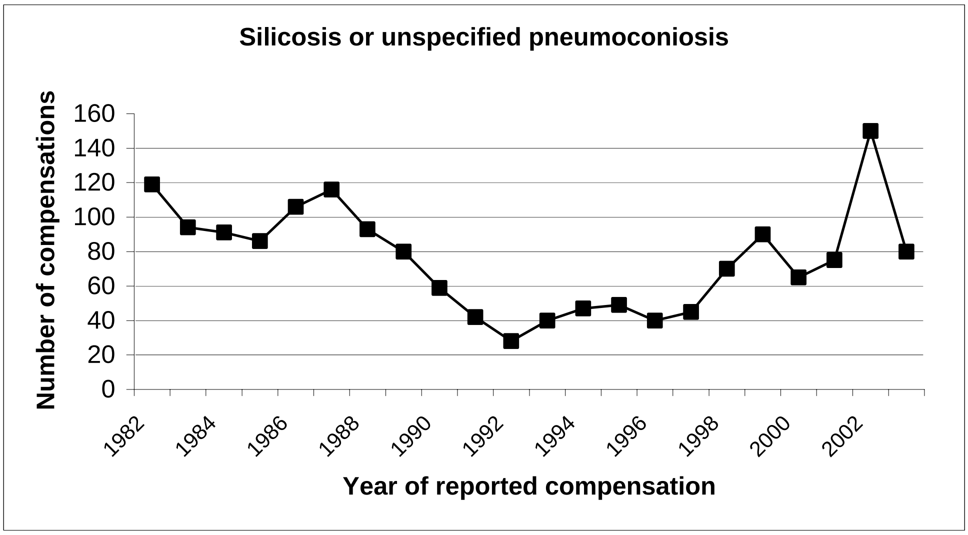
3. There is very widespread occupational exposure to RCS in a diverse range of industry sectors including mining and quarrying, construction, ceramics, heavy clay, foundries and stonemasonry. HSE estimates that at least 100,000 workers are regularly exposed, but many more workers may be exposed on a less regular basis.

What are the Health Effects?

4. RCS is harmful to the lungs, causing a lung disease known as **silicosis**. Silicosis is a slowly progressive, irreversible disease that usually takes some years to develop. It is characterised by the presence of rounded nodules of scar tissue in the lungs. The nodules are visible as white opacities on chest X-ray. Silicosis can cause breathing problems, the severity of which can range from mild through to severely disabling, depending on the amount of dust inhaled. In severe cases, silicosis leads to premature death. In people who have had exceptionally high exposures over just a few months or years, a rapidly progressive and often fatal condition known as "acute silicosis" can occur. Heavy and prolonged exposures to RCS under conditions that produce silicosis can also cause lung cancer.

5. In the early 20^{th} century, when modern ventilation and dust control methods were not widely available, workplace exposures to RCS caused a large amount of ill health. This was compounded by the fact that the lung damage caused by silicosis made people more susceptible to developing pulmonary tuberculosis. Improvements in workplace control standards mean that the scale of silicosis has been much reduced. There were 150 people that received compensation for silicosis through the Industrial Injuries Scheme in 2002. Most of these cases were in retired workers, and reflect exposure conditions that occurred many years ago. Nevertheless, 30% of cases were in people under the age of 65 years and statistics do not show any clear sign of a decline in the annual incidence of silicosis over the last 13 years (see Figure 1). Overall, it appears that the problem of silicosis is not completely eliminated.

Figure 1. Annual incidence of silicosis in Great Britain based on the number of compensations awarded by the Department of Work and Pensions Industrial Injuries Scheme.



What are Occupational Exposure Limits (OELs)?

6. Substances that may cause harm to health are subject to the Control of Substances Hazardous to Health Regulations 2002 (COSHH, as amended 2005). These Regulations require employers to prevent, or if that is not reasonably practicable, adequately control, employees' exposure to hazardous substances. The COSHH Regulations provide the legal basis for occupational exposure limits (OELs), which are tools to help protect workers against ill health. OELs refer to airborne concentrations of substances measured in the breathing zone of the workers, averaged over specified time periods. There are two specified time periods; an 8-hour time-weighted average (8-hr TWA), and a 15-minute reference period, referred to as short-term exposure limit (STEL).

7. When the COSHH Regulations were first implemented in 1989, there was provision for two types of OEL, Maximum Exposure Limits (MELs) and Occupational Exposure Standards (OESs). MELs were set for substances for which it was not possible to identify a level of exposure below which there would be no risk to health, or for which control to such a level was not reasonably practicable to achieve in the workplace. OESs were set at levels where there was no indication of adverse health effects, and that were reasonably practicable to achieve in the workplace.

Requirements of New OEL System

8. In April 2005, following a period of public consultation and endorsement by the Health and Safety Commission and its Advisory Committee on Toxic Substances (ACTS), a new OEL system was established in the UK. In this new system, there is a single type of OEL, known as a Workplace Exposure Limit (WEL). The new system

of WELs replaces the previous system of MELs and OESs. The requirements for compliance with WELs are set out in COSHH Regulation 7(7) as follows:

- *Reg. 7(7) Without prejudice to the generality of paragraph (1), where there is exposure to a substance hazardous to health, control of that exposure shall only be treated as being adequate if:*

  a) *The principles of good practice for the control of exposure to substances hazardous to health are applied; and*

  b) *Any Workplace Exposure Limit approved for that substance is not exceeded; and*

  c) *For a substance which carries the risk phrase R45, R46 or R49 or for a substance or process which is listed in Schedule 1, or a substance which carries the risk phrase R42 or R42/43, or is listed in the HSE publication "Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma", or any other substance which the risk assessment has shown to be a potential cause of occupational asthma, the level of exposure is reduced so far as is reasonably practicable.*

9. Requirements (a) and (b) emphasise the importance of following good practice to control exposure (see paragraphs 10 –12 for an explanation as to what this means). In addition, employers must not exceed a relevant WEL. The final requirement - (c) above - does not apply to RCS as it neither carries the relevant risk phrases (it is not within scope of the CHIP Regulations) nor is it listed as a carcinogen in Schedule 1 of COSHH.

<u>Requirement for Good Practice</u>

10. A key requirement of the new system of WELs, as stated in Regulation 7 (7) of COSHH, is the need to control exposure to substances hazardous to health according to the principles of good occupational hygiene practice. To help employers comply with this requirement, eight bullet points are listed in Schedule 2A of COSHH (as amended 2005) listing the general principles of good practice. The COSHH Approved Code of Practice (ACoP) provides additional guidance on the meaning and application of these principles.[3]

11. To further help employers comply with the duties of the WEL specifically for RCS, particularly those employers in small to medium sized enterprises where there may be a lack of in-house expertise in occupational hygiene, HSE is producing specific control guidance sheets under the direct advice route of its electronic COSHH Essentials package. This guidance covers approximately 50 tasks/processes in which exposure to RCS occurs. It comprises easy to understand, step-by-step control advice, which is consistent with the principles of good occupational hygiene practice. COSHH Essentials is freely available on HSE's website (http://www.coshh-essentials.org.uk/).

[3] Control of substances hazardous to health (Fifth edition), the Control of Substances Hazardous to Health Regulations 2002, Approved Code of Practice and Guidance, L5, HSE Books 200x, ISBN 0-7176-2369-6 *(insert number when known)*

Criteria for setting WELs

12. In the new OEL system, WELS are derived by the following criteria:

i) If possible, the WEL value will be set at a level at which no adverse effects on human health would be expected to occur based on the known and/or predicted effects of the substance. However, if such as level cannot be identified with reasonable confidence, or if this level is not reasonably achievable, then:

ii) The WEL value will be based at a level corresponding to what is considered to represent good control, taking into account the severity of the likely health hazards, and the costs and efficacy of control solutions. Wherever possible, the WEL will not be set at a level at which there is evidence of adverse effects on human health.

13. For RCS, criterion (i) is not satisfied by the available information in that it is not possible to identify reliably the level of occupational exposure at which there would be no risk of silicosis development. Hence, the new WEL for RCS needs to be set according to the second criterion. This requires agreement on the best level of control that can be achieved throughout all UK industries in which there is exposure to RCS, taking costs and health risks into account. These aspects are dealt with via Regulatory Impact Assessments as discussed in Annex 2 to this Consultative Document.

History of the OEL for Respirable Crystalline Silica

14. Before the introduction of the COSHH Regulations there was a "Recommended Limit" for RCS of 0.1 $mg.m^{-3}$ (8 hr TWA). When COSHH was first implemented in 1989, an OES of the same value was temporarily ascribed to RCS pending review by the HSC's Working Group on the Assessment of Toxic Chemicals (WATCH), and its Advisory Committee on Toxic Substances (ACTS). As a result of this review, a MEL for RCS of 0.4 $mg.m^{-3}$ (8-hr TWA) was introduced in 1992. In 1997, the value of the MEL was adjusted to 0.3 $mg.m^{-3}$ following adoption of the ISO/CEN sampling convention for respirable dusts[4]. This change reflected a modification in measurement methodology, not an increased stringency of control.

15. In making its original decision to change from the OES to a MEL, ACTS was influenced by representations from the quarrying industry that they could not reasonably comply with the OES of 0.1 $mg.m^{-3}$. However, in doing so, ACTS was concerned that there should be no relaxation in existing standards of control, particularly in those industry sectors that were already complying with the original OES of 0.1 $mg.m^{-3}$. Those industries that had already demonstrated their ability to control to 0.1 $mg.m^{-3}$ or below were expected to continue to do so. Accompanying the MEL was a package of industry-specific guidance. Also, HSE gave a commitment to emphasising the requirement to reduce exposure so far as is reasonably practicable below the MEL and to reviewing the position as new evidence became available. In 1998, as part of the on going review of the MEL, HSE published a document that compared exposures to RCS both before and after the setting of the

[4] European Committee for Standardization (CEN): EN 481 *Workplace atmospheres – Size fraction definitions for measurement of airborne particles*. Brussels 1993, Beuth Verlag, Berlin 1993

MEL.[5] The document also discussed control strategies for the different sectors affected.

16. The system of MELs and OESs has now been replaced by a new system with a single type of OEL known as a Workplace Exposure Limit (WEL). In this new OEL system, the MEL of 0.3 $mg.m^{-3}$ for RCS has been converted to a WEL of the same value. This is intended to be a temporary measure pending the development of a new WEL value according to the proposal outlined in this Consultative Document.

HSE Review of Respirable Crystalline Silica

17. An increasing amount of new evidence on the health risks of RCS has become available in recent years. HSE published a review of the evidence in two phases; Phase 1 was published in 2002[6] and Phase 2 in 2003[7]. The HSC's scientific sub-committee WATCH endorsed the content of these HSE documents prior to their publication.

18. The aims of the Phase 1 review were to a) present the most accurate and up-to-date information available concerning the risks of developing silicosis; and b) to consider the evidence that for the same level of exposure, the risks of silicosis might vary according to factors such as the nature of the industrial process or the extent of contamination of the silica. The Phase 2 review dealt with the evidence on the ability of RCS to cause lung cancer. Details of the conclusions reached in the Phase 1 and Phase 2 reviews can be found in Annex 1 in this Consultative Document.

Risks of Silicosis

19. Table 1 below sets out the risks of developing silicosis based on the information presented in the HSE Phase 1 review. From all the information available, it is not possible to identify a threshold level of occupational exposure below which there would be no risk of developing silicosis. This is not to say that a practical threshold does not exist; all of us in the general population are exposed to low ambient levels of RCS, but cases of silicosis are only observed in workers, suggesting that a threshold must exist. However, perhaps due to the fact that there is so little documented information on the health consequences of low-level occupational exposure, a clear threshold cannot be discerned. Table 1 indicates that the risks of silicosis begin to increase steeply when average daily exposures to RCS exceed 0.1 $mg.m^{-3}$.

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[5] Respirable crystalline silica, Exposure assessment document, EH74/2, HSE Books 1998, ISBN 0-7176-1659-2

[6] Respirable Crystalline Silica - Phase 1. Variability in fibrogenic potency and exposure-response relationships for silicosis. Hazard Assessment Document. EH75/4. HSE Books 2002. ISBN 0-7176-2374-2

[7] Respirable Crystalline Silica - Phase 2. Carcinogenicity. Hazard Assessment Document. EH75/5. HSE Books 2003. ISBN 0-7176-2191-X

Table 1. Risks of developing silicosis presented in the HSE Phase 1 review

15 years exposure to respirable crystalline silica (8-hour TWA) mg.m^{-3}	**Predicted risks of developing silicosis* within 15 years following exposure**. (* *This refers to a category of silicosis normally associated with some breathing impairment*)
0.02	0.25%
0.04	0.5%
0.1	2.5%
0.3	20%

20. These risk estimates are based on findings in workers who breathed in dust containing RCS that was produced by mechanically cutting into sandstone. Sandstone is almost pure quartz. The surfaces of the RCS particles to which the workers were exposed had been freshly cut (fractured) and were relatively uncontaminated by other minerals.

Variability in Silicosis Risks

21. The HSE Phase 1 review concluded that for any particular level of exposure, there is likely to be some variability in the risks of silicosis according to the circumstances of the exposure conditions. The highest risks are predicted to result from exposures to very fine particles, and to dry freshly fractured particles of RCS. Somewhat lower risks are predicted from exposure to "aged" particles that have not been freshly fractured, and where the particle surfaces are closely contaminated with aluminium-containing minerals. The quantitative risk estimates presented in Table 1 above refer to exposures to freshly fractured particles of RCS and thus represent risks at the upper end of the spectrum of toxicity. Exposure to freshly fractured particles of RCS occurs as a result of many common workplace tasks such as drilling, cutting, grinding, crushing, fettling, blasting and milling. Hence, the risk estimates are believed to have widespread applicability. It is possible that lower risks might pertain where there are exposures to RCS that has not been freshly fractured and where the particle surfaces may be closely contaminated with adsorbed minerals. However, there are no suitable data with which to quantify any potential reductions in risk that might exist.

Lung Cancer

22. The HSE Phase 2 review identified a number of studies that investigated lung cancer in workers exposed to RCS. The findings showed considerable variability; some studies suggested no increased risk of lung cancer due to RCS, but others showed an excess of lung cancer deaths that could only be explained by exposure to RCS. Alternative explanations such as cigarette smoking, asbestos, or socio-economic status could not adequately explain the lung cancer findings.

23. The observed excess risks of lung cancer were all seen in workers who commenced employment (usually in the granite and other stone industries) in the

1930s and 1940s, times when modern dust control systems would not have been in place, and when workplace dust exposures were likely to have been considerably higher than current levels. These workers generally stayed in these industries for all of their working lives. It is difficult to judge retrospectively what the historical levels of exposure would have been in these industries. However, the pattern of evidence suggests that an increased risk of lung cancer would only be apparent with very heavy and prolonged occupational exposures.

24. The pattern of evidence was also strongly suggestive, but not entirely definitive, that an increased risk of lung cancer will only occur in workers with silicosis.

Recommendation from the European Commission

25. The European Commission's Directorate General for Employment (DG Emp) obtains advice on Occupational Exposure Limits from a committee of independent scientific experts drawn from the various member states. This committee is the Scientific Committee on Occupational Exposure Limits (SCOEL). In June 2002, DG Emp published a recommendation from SCOEL concluding that to protect against silicosis, exposure to RCS should be maintained below 0.05 $mg.m^{-3}$ (8-hr TWA). This recommendation was however based solely on health considerations and other issues such as the measurement issue and reasonable practicability were not taken into account.

26. It is possible that this SCOEL assessment will form the basis for future negotiations in Europe on a Binding Occupational Exposure Limit for RCS, although any limit set by Europe would take other issues such as technical feasibilty into account. If a Binding Occupational Exposure Limit is set in Europe, then this will need to be implemented in all Member State countries including Great Britain. The negotiations on the value for a Binding Occupational Exposure Limit will take into account the technical feasibility of control as well as the sensitivity and reliability of analytical techniques to measure exposures. There is no information on the likely timescale for such negotiations.

REGULATORY IMPACT ASSESSMENT

27. Before any new piece of legislation can be introduced the Health and Safety Commission is obliged to carry out an assessment of the costs it would impose on industry and the benefits it is expected to bring. Since October 1998, this assessment has been included in Regulatory Impact Assessments (RIAs). Annex 2 of this document gives a description of the methodology behind the formulation of cost benefit assessments for RIAs and a general statement on their application.

28. A copy of the detailed RIA is available free of charge from **Peter Roberts, Health and Safety Executive, Room 103, Daniel House, Stanley Precinct, Liverpool, L20 3TW** (email: peter.roberts@hse.gsi.gov.uk). If you have any comments on the RIA we would welcome these also.

29. Annex 3 of this consultative document presents a summary of the RIA. The RIA sets out the costs to industry of complying with WEL values of 0.3, 0.1, 0.05 and 0.01 $mg.m^{-3}$ (8-hour TWA). It also presents estimates of the benefits that would be derived in terms of the monetary costs saved (e.g medical costs and productivity losses) from preventing cases of ill health. An option to retain the current WEL (0.3 $mg.m^{-3}$ as an 8-hour TWA) was not supported in view of the health risks associated with this level of exposure. The setting of a lower WEL will impose a series of extra costs on UK industry. 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 RCS levels are not currently discernible from background concentrations. If the WEL were set at a very low level (at 0.05 $mg.m^{-3}$ or below) there is the potential for the closure of parts of some industry sectors. The quarrying industry, for example, is based in predominantly rural sites where alternative employment may be difficult to find. Some brick manufacturing sites, especially those employing Hoffman kilns or having large areas of old plant, may well follow suit. This level would also create special difficulties for many small businesses that use silica sand and flour for a wide range of products.

30. A WEL set at 0.05 $mg.m^{-3}$ (8-hr TWA) would also lead to difficulties in relation to measurement and enforcement. Analytical methods for the measurement of airborne RCS need to provide measures of exposure with sufficient precision to support enforcement activity, should this be deemed necessary. Ideally, analytical methods need to be able to cope with both 4-hour and 8-hour TWA periods, given that some workplace tasks may only be a few hours in duration. For RCS, if the WEL were set at 0.1 $mg.m^{-3}$, then the available analytical methods are perfectly adequate to support enforcement. If the WEL were set at 0.05 $mg.m^{-3}$, there would be no enforcement problems if workplace exposures were markedly in excess of the WEL (>0.1 $mg.m^{-3}$). In such circumstances there would be no difficulty in showing an exceedence of the WEL. However, if exposures to RCS were hovering around 0.05 $mg.m^{-3}$ and only a 4-hour sample was taken, then the amount of RCS collected on the filter would be so low that it would not allow precise measurement. Hence, there might be a difficulty in respect of enforcement in this particular circumstance.

31. A WEL of 0.1 $mg.m^{-3}$ (8-hour TWA) for RCS should impose extra costs 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. Overall, a WEL set at 0.1 $mg.m^{-3}$ (8-hour TWA) is a level at which HSE believes UK industry could comply (with costs) and where compliance could bring a significant health benefit. Furthermore, a WEL set at 0.1 $mg.m^{-3}$ (8-hr TWA) would be augmented by advice on good practice. This would be freely available in the form of “Silica Essentials”, a series of COSHH Essentials-style control advice sheets covering a wide range of tasks and processes in which RCS dust is produced. For a WEL set below 0.1 $mg.m^{-3}$ (8-hr TWA), for some industries there could be additional technical challenges such that the specific control advice in Silica Essentials may not be sufficient.

PROPOSALS FOR THE DEVELOPMENT OF A NEW WEL FOR RCS

32. In view of the information presented in the HSE Phase 1 review describing the risks of silicosis, and the SCOEL assessment published by the European Commission, HSE considers that the current WEL of 0.3 $mg.m^{-3}$ (8-hour TWA) for RCS is not sustainable, and that a lower limit commensurate with a lower risk to health needs to be developed. In order to alert stakeholders to this intention, HSE issued Chemical Hazard Alert Notice (CHAN) No 35[8] in May 2003. The CHAN provided interim control advice, and explained HSE's plan to consult on a more stringent limit for RCS just as soon as the new OEL system came into force.

33. Taking into account the findings of the RIA, the information on the health risks from RCS, as well as issues relating to airborne measurement and compliance, the Health and Safety Commission has decided that HSE should consult on a proposal for a new WEL of 0.1 $mg.m^{-3}$ (8-hour TWA). To assist decision-making, Table 2 below summarises the arguments surrounding this proposed value and a theoretical value of 0.05 $mg.m^{-3}$ (8-hour TWA):

Table 2. Comparison of arguments for and against 0.05 or 0.1 $mg.m^{-3}$ (8-hour TWA)

	0.05 $mg.m^{-3}$ (8-hour TWA)	**0.1 $mg.m^{-3}$ (8-hour TWA)**
Health risks	Exposures at this level would reduce the health risks to less than a 1% risk of silicosis.	Exposures at this level would greatly reduce health risks (up to 2.5%) compared to the current WEL of 0.3 $mg.m^{-3}$ (up to a 20% risk of silicosis).
Practicability	Control to 0.05 $mg.m^{-3}$ (8-hour TWA) may not be reasonably practicable in some industry sectors. The costs of control to 0.05 $mg.m^{-3}$ are likely to lead to closure of some parts of industry and job losses.	Control to 0.1 $mg.m^{-3}$ (8-hour TWA) is believed to be reasonably practicable across all industry sectors although additional costs would be incurred in some sectors particularly the quarries.
Enforcement	Due to the limitations of current methods for airborne measurement, it may be difficult for HSE to enforce a WEL of 0.05 $mg.m^{-3}$.	Current measurement methods are adequate to support enforcement with a WEL of 0.1 $mg.m^{-3}$
Good practice	The challenges of control to 0.05 $mg.m^{-3}$ (8-hour TWA) may mean that the specific good practice advice in Silica Essentials may not be sufficient and other sources of control advice may also need to be pursued.	The key legal requirement of the new WEL system is that control practices must be consistent with good occupational hygiene practice. Good practice advice will be available to support a WEL of 0.1 $mg.m^{-3}$ in the form of Silica Essentials.

[8] http://www.hse.gov.uk/pubns/chan35.htm.

Question 1: **Do you agree with the proposal for a WEL for respirable crystalline silica of 0.1 $mg.m^{-3}$ (8-hour TWA)?**

If you disagree, please explain why.

Question 2: **In your workplace (please describe), do you consider it would be reasonably practicable to comply with a WEL of 0.1 $mg.m^{-3}$ (8-hour TWA)?**

Question 3: **Which version of the RIA have you read – the summary (in Annex 3 of this Consultative Document), or the full RIA (see paragraph 28 above for details of how to obtain the full RIA)?**

Question 4: **Do you agree with the exposure information presented in the RIA?**

If you disagree, or can provide further information concerning the levels of exposure that can be reasonably achieved in your industry sector, then please provide the relevant evidence.

INVITATION TO COMMENT

34. The Health and Safety Commission would welcome comments on proposals set out in this Consultative Document. For convenience, all the questions are repeated in a form (Annex 5) set out at the back of this document that you may find helpful to use for your reply. We will acknowledge receipt of all comments sent to us and will give careful consideration to all comments received in developing our proposal. We may contact you, for example, if we have a query.

35. If you reply to this Consultative Document in a personal capacity, rather than as a postholder of an organisation, you should be aware that information you provide may constitute "personal data" in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the "data controller" and will process the data for health and safety and environmental purposes. HSE may disclose these data to any person or organisation for purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected. Please note all replies will be made public unless you specifically state you wish yours to be made confidential.

ANNEX 1 Summary Criteria for a Workplace Exposure Limit (EH64)

RESPIRABLE CRYSTALLINE SILICA

Workplace exposure limit
8-hour TWA: (TO BE AGREED)

IDENTITY AND PROPERTIES

CAS No: 14808-60-7 quartz

14464-46-1 cristobalite
15468-32-3 cristobalite
1317-95-9 tripoli

Empirical formula: SiO_2

Synonyms: alpha-quartz, agate, chert, flint, crystalline silica, millstone, sandstone, silica flour

Melting point: 1610^0C (quartz)

Crystalline silica is a solid substance which exists in several forms. It is transparent and colourless when pure, and insoluble in solvents and water. It is not included in the Approved Supply List.

OCCURRENCE AND USE

Crystalline silica (silicon dioxide, SiO_2) is common in minerals, clay, sand and aggregates. The most common forms of silica found in industry are α-quartz and cristobalite. Respirable dust, containing respirable crystalline silica (RCS) is often emitted through work with minerals and synthetic products such as concrete.

Workers are exposed to RCS in a broad range of industries including quarries, mines, foundries, in construction, ceramic manufacture, the heavy clay industry and brick making and stonemasonry.

Workers can also be exposed in the manufacture and use of silica flour, used as filler in products such as surface coatings, grouts, plastics, abrasives, and soil improvers.

EXPOSURE AND CONTROL

HSE estimates that at least 100,000 workers are exposed to RCS on a daily basis and that many more can be exposed on an intermittent basis. Factors affecting overall exposure include the silica content of the material and weather conditions, but the use of high-speed cutting tools without water suppression is likely to produce high RCS exposure. Chasing out mortar prior to repointing can produce short-term exposures above 6 $mg.m^{-3}$ and as exposure at just 2 $mg.m^{-3}$ for 25 minutes will produce an 8-hour TWA above 0.3 $mg.m^{-3}$, short-term sporadic tasks carry a risk of high exposure to RCS. Suitable controls are essential to control RCS exposure, and the potential effectiveness of these controls is high.

Suitable types of control include:

- General ventilation and cleanliness (eg ceramic casting)
- Ventilated refuge (eg mineral crushing)
- Water suppression (eg stone sawing)
- Dust extraction (eg brick facing)
- Extracted booth (eg glaze and colour spraying)

- Downdraught booth or local air displacement (e.g. slate splitting)
- Respiratory protective equipment and booth (e.g. arc-air gouging).

'COSHH essentials' will give good practice advice on the mechanical, administrative and behavioural measures required to control exposure to RCS. This is anticipated for publication in late 2004.

MEASUREMENT

Air monitoring

Monitoring is by sampling the workplace air at a specified flow rate with a pump through a cyclone[1] onto a suitable filter, followed by analysis with x-ray diffraction or infrared spectrometry. Analytical methods for the most common polymorphs of crystalline silica are described in HSE methods for the determination of hazardous substances[2,3,4]. These methods have satisfactory precision for the measurement of silica in air concentrations above 0.05 mg/m^3. With the instruments currently available, the relative precision of analysis for air concentrations of 0.05 mg/m^3 is not adequate to satisfy the European performance criteria[5] for occupational hygiene measurements, unless a full 8-hour work period is sampled. Measurements at 0.02 mg.m^{-3} are just practicable for the quartz polymorph of silica in ideal conditions on laboratory test filters.

Biological monitoring

There are no published methods for the biological monitoring of exposure to respirable crystalline silica. RCS does not meet the criteria for biological monitoring as skin absorption is not relevant, and there is no marker of exposure upon which a biological monitoring method could be based.

TOXICOKINETICS

Deposition and clearance

RCS particles (less than 10 µm aerodynamic diameter) deposit in the lungs following inhalation exposure. Due to the insoluble nature of crystalline silica, no significant absorption from the lungs into the bloodstream is anticipated. Retention in the lungs is likely to be prolonged, particularly as crystalline silica is toxic to alveolar macrophages resulting in impairment of hence normal macrophage-mediated clearance mechanisms. Following deposition of crystalline silica particles in the lungs, some particles translocate to the pulmonary interstitium, and there is some clearance to the lung-associated lymph nodes.

Health Effects

Experimental studies

There is a large database of experimental studies on crystalline silica[6]. Species differences in the pulmonary effects of crystalline silica mean that quantitative exposure-response relationships observed in experimental animals are of uncertain relevance to human risk assessment. Therefore, this section provides only a very brief qualitative overview of the pattern of evidence from animal studies.

Single and short-term exposure studies in laboratory animals show that crystalline silica particles are cytotoxic in the lungs, causing influxes of neutrophils and raised levels of protein, cytokines and enzymes in the fluid obtained from broncho-alveolar lavage. Pathological and biochemical changes tend to persist for some time post-exposure. Long-term repeated inhalation exposure to respirable crystalline silica dust produces chronic inflammation, nodular fibrosis (silicosis) and malignant tumours in the lungs of rats. In contrast, the lungs of hamsters and mice show milder signs of chronic inflammation and fibrosis, and these species do not develop tumours following long-term repeated exposures to crystalline silica[7].

The potential mutagenicity of crystalline silica has been examined in a large number of standard *in vitro* assays but the solid nature of the silica particles means that it is difficult to test. In most standard tests the results are negative. Recent research in rats indicates that chronic lung inflammation caused by crystalline silica causes genotoxic changes in lung epithelial cells, apparently as a result of oxidative DNA damage. The pattern of findings suggests that this damage is mediated as a result of a response to silica by inflammatory cells (neutrophils) rather than by the silica particles directly. It is possible, but not certain, that this indirect genotoxicity may contribute to the mechanism of silica-induced lung cancer, at least in the rat.

Observations in humans

Silicosis

Long term repeated inhalation exposure to crystalline silica causes chronic lung inflammation and silicosis[8]. Silicosis is a progressive and irreversible condition in which fibrous nodules develop throughout the lungs. The nodules can be detected as opacities on chest X-ray. With time, the nodules can enlarge and adjacent nodules can merge eventually leading to progressive massive fibrosis. Silicosis leads to an increased risk of developing tuberculosis. Normally, silicosis can take some years to develop, and in some cases may not manifest until some time after a worker has ceased employment.

Workers who are repeatedly exposed to very high levels of crystalline silica over a period of just a few years are at risk of developing a condition known as “acute silicosis” which is usually rapidly fatal. The pathological features of acute silicosis involve severe inflammation in the lungs (alveolar proteinosis) and are very different to conventional silicosis. Quantitative information on the exposure conditions leading to “acute silicosis” is not available.

HSE identified twelve epidemiological studies that provide quantitative information on the risks of conventional silicosis[3]. The studies have been carried out on miners (coal, hard rock, gold and tin), granite workers, diatomaceous earth workers, iron foundry workers, and workers from the UK heavy clay industry and pottery industry. The design of the studies is variable; some are longitudinal cohort studies and some are cross-sectional surveys. Some studies involved long-term follow up to allow the detection of silicosis in leavers and retired workers, some examined silicosis only in current workers. The latter type of study is likely to underestimate risk given the long latency for the development of silicosis. Most studies identified silicosis on the basis of chest X-rays, but in one study reliance was placed on the diagnosis of silicosis from death certificates. The quality of the exposure estimates from the studies is usually extremely limited. Historically dust levels were measured in terms of particle counts whereas current methods are based on gravimetric sampling for respirable dust. Conversion of old particle count data to gravimetric measures is likely to have introduced error, as well as uncertainties in the interpretation of static (area) sampling in terms of personal exposures. Analysis of respirable dust to determine the crystalline silica content was not carried out in all studies and assumptions were made about the % silica content.

One study was identified that provided robust estimates of the risks of silicosis[9]. This was a study in a particular Scottish coalmine that had taken part in the British Pneumoconiosis Field Research Programme. It should be noted that the conditions in this mine were unusual and not representative of typical coalmining situations. Typically, respirable coalmine dust contains less than 10% quartz, which usually derives from dirt bands in the coal strata. In one part of this mine, major seams of sandstone (almost pure quartz) were encountered in the 1970s. For a period of about 10 years the miners had to cut through the sandstone to get at the coal. At times, the airborne respirable dust in this part of the mine contained up to 60% quartz. This study provided more detailed and reliable exposure data compared to any other cohort study on silica. In this study, quarterly investigations of exposure to respirable dust, with compositional analysis to determine the content of crystalline silica, had been undertaken from the mid-1950s until the mine closed in 1981. Chest X-rays were carried out every five years during this time. The final round of chest X-rays before the mine closed showed an unusually rapid progression of radiographic changes, which were thought to be more suggestive of silicosis rather than coalworker's pneumoconiosis. Therefore, in 1900-91, 547 of the 1032 men thought to be still alive were traced and agreed to further chest X-rays.

Records showed that at one seam in the mine, mechanical cutting into the sandstone strata led to high levels of respirable quartz (>10% of exposures exceeded 1 $mg.m^{-3}$ 8-hr TWA). In contrast, at the other seam, <10% of exposures exceeded 0.3 $mg.m^{-3}$ (8-hr TWA).

Silicosis was identified epidemiologically in this study on the basis on radiographic scores of 2/1 + using the International Labour Organisation (ILO) scoring system. There were 47 men with a score of at least 2/1. Analyses of exposure-response relationships showed that most of the risk of silicosis was accounted for by the period of time in the 1970s when the sandstone seams were encountered; previous dust exposures contributed very little. The lowest level of exposure to respirable crystalline silica associated with an observed risk of silicosis was for a worker exposed for about 12 years to an average of 0.1 $mg.m^{-3}$. No cases of silicosis were observed with cumulative exposures below this level, although as few workers were exposed to low levels it was difficult for the study to reliably measure low level risk. In order not to extrapolate significantly outside the range of observed data, the risk estimates derived from statistical modelling reflect a 15-year period of exposure, and were not extrapolated to the standard 40-year working lifetime exposure in view of the uncertainties that would involve.

The risks of developing silicosis for exposures to 0.02, 0.04, 0.1 and 0.3 $mg.m^{-3}$ (8-hr TWA) were estimated to be 0.25%, 0.5%, 2.5% and 20% respectively. These risk estimates indicate a steeply increasing risk once average levels of respirable crystalline silica reach 0.1 $mg.m^{-3}$. It should be noted that the silicosis findings from this study were based on chest X-rays taken in 1990/91, ten years after the coalmine had closed down. Therefore, the risk estimates for silicosis given above refer to the longterm development of silicosis up to 15 years following the cessation of exposure.

In view of the very detailed exposure information, and the long-term chest X-ray follow-up, this study is considered to provide more reliable estimates of risk than any study. A well-reported study in Vermont granite workers was not able to inform on the quantitative exposure-response relationship for silicosis, but is useful in being able to describe the consequences of long-term exposure to low levels of respirable crystalline silica[10]. Historically, there had been an epidemic of silicosis and tuberculosis among the workers in this industry, and as a result, the US government instigated a programme of improvements in dust control that began in 1938-40. Within about 15 years, levels of respirable quartz were controlled to an average of 0.06 $mg.m^{-3}$ (8-hr TWA). In 1996, chest X-rays were examined in 600 retired workers from this industry. The results showed that in the 350 retirees hired after 1940, there was an increasing decline in the prevalence of silicosis. In the 28 men hired 1940-44 there were 5 (17.9%) with chest X-ray abnormalities; in 106 men hired 1945-49 there were 8 (7.5%) abnormalities; in 52 men hired 1955-59 there were 2 (3.8%) abnormalities; in 68 men hired >1959 there was 1 (1.5%) abnormality. The mean years worked across these groups declined steadily from 37.6 – 20.5 years. The severity of chest X-ray abnormalities found in these retirees was very minor (mainly 0/1 or 1/0 on the ILO scale). The authors concluded that after 1955, respirable quartz levels in this industry stabilized to 0.05 – 0.06 $mg.m^{-3}$. Overall, the findings from this well-reported study are consistent with the risk estimates for low levels of exposure to respirable quartz obtained in the study in Scottish coalminers.

Of the remaining studies that reported quantitative risk estimates for silicosis, four studies suggested higher levels of risk than indicated by the Scottish coalminers' study (Colarado hard rock miners, South African gold miners, US goldminers, and Chinese tin miners). However, HSE has identified significant problems with either the exposure assessments and/or the silicosis assessments in these studies such that the risk estimates are considered to be of uncertain reliability. Six studies reported lower risks than the Scottish coalminer's study but but four of these were based on chest X-rays only in current workers with no follow-up to monitor the progression of silicosis. Hence, it is possible that these studies yielded an underestimate of the true risk.

Overall, the risk estimates from the study in Scottish coalminers seem realistic and plausible when set against the pattern of results from other studies. However, it is important to recognise that the exposures in the study of Scottish coalminers were to freshly fractured quartz particles relatively uncontaminated by other minerals. The HSE review of silicosis[7] concluded that the toxic potency of RCS is likely to vary according to whether or not the particle are freshly fractured or "aged", and according to surface adsorption of aluminium-containing minerals. Therefore, it is possible that the risk of developing silicosis in exposure situations where the RCS is not freshly fractured and is contaminated with aluminates may differ from the risk values presented above. However, the magnitude of such differences is impossible to assess from the data currently available.

Lung Cancer

There are a large number of cohort studies in which the potential for crystalline silica to cause lung cancer has been investigated[7]. There is a mixed pattern of results from these studies, but there are a number of studies, in particular in granite[11], stone[12] and industrial sand workers[13], that provide reasonably convincing evidence for an increased risk of lung cancer compared to external population groups. The studies in granite and stone workers included internal stratified analyses that reveal exposure-response trends for an increased risk of lung cancer with increasing cumulative exposure and/or duration of exposure. The relative risks for those in the highest exposure categories tend to be of the order of 2-fold compared to the lowest exposure categories. The fact that the increased risks are apparent in internal cohort analyses means that differences in socio-economic status, cigarette smoking or other potential sources of confounding are unlikely to be able to account for the findings. These studies also show that the excess lung cancers are restricted to the workers from the highest exposure categories. The groups with the highest exposure tend to be the early hire workers who commenced employment before the introduction of effective dust controls. Exposures were probably far in excess of current permitted workplace levels but there is a lack of reliable measured exposure data from these times (1930s-1940s). The balance of evidence suggests that heavy and prolonged exposures to respirable crystalline silica has caused an increased risk of lung cancer in working populations.

Where evidence is available concerning the relationship between lung cancer and silicosis, it tends to show that excess lung cancer mortality is restricted to those with silicosis, and the more severe the category of silicosis, the higher the risk of lung cancer. However, given that definitive evidence can only be derived from autopsy examinations, and even then there can be difficulties, an absolutely firm conclusion on the relationship between silicosis and lung cancer cannot be reached.

Other chronic health conditions

There is evidence, particularly from coal and goldmining populations, for an increased risk of pulmonary emphysema associated with exposure to respirable crystalline silica[6]. In addition, there are reports associating crystalline silica with systemic sclerosis and increased rates of kidney disease[6]. However, the latter two health effects have not been systematically studied in silica-exposed cohorts hence at this time it is not possible to reliably establish the situation for these claimed relationships.

Basis for the limit *(TO BE COMPLETED POST-CONSULTATION)*

The lead health effect from occupational exposure to respirable crystalline silica is silicosis. Lung cancer is now also a recognised health hazard for respirable crystalline silica. The pattern of evidence suggests that control measures driven by concerns about silicosis can be expected to produce associated gains in the reduction of the risk of lung cancer.

The most reliable evidence available suggests that the eventual risks of developing silicosis would be 0.25%, 0.5%, 2.5% and 20% following 15 years exposure to 0.02, 0.04, 0.1 and 0.3 $mg.m^{-3}$ (8-hr TWA) respectively. A threshold below which there would be no risk of developing silicosis cannot be clearly identified. The criteria for setting a Workplace Exposure Limit (WEL) for such a situation require that the WEL be set at the lowest level of exposure that is reasonably practicable for industry to achieve, taking into account the cost and effectiveness of control solutions.

As there is no evidence that exposure to respirable crystalline silica could cause asthma, a Sen notation is not appropriate. The insoluble nature of respirable crystalline silica means that dermal absorption would not occur, therefore a Sk notation is not appropriate. There is currently no biological monitoring method for respirable crystalline silica and hence there is no basis for development of a Biological Monitoring Guidance Value.

ANNEX 1 Summary Criteria for a Workplace Exposure Limit (EH64)

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ANNEX 2
EXPLANATORY NOTE- COST BENEFIT ASSESMENT METHODOLOGY FOR THE REGULATORY IMPACT ASSESSMENT AND APLLICATION TO OCCUPATIONAL EXPOSURE LIMITS: AN OVERVIEW

It is government policy that the costs of all new or revised regulations must be assessed. Since 1982 the Health and Safety Commission (HSC) has required cost benefit assessments (CBAs) to be undertaken for all major proposals for health and safety regulations unless the costs resulting from their introduction are negligible. This approach has also been extended to the consultation period for Occupational Exposure limits (OELs). Since October 1998, costs and benefits are discussed in the regulatory impact assessment (RIA) framework.

The complexities of applying CBA/RIA methodology to occupational ill-health issues as opposed to accident prevention mean that the results need to be considered with particular caution. The uncertainties resulting from imperfect information on the costs of controls, and validation of exposure compliance data can be more pronounced in relation to health issues, so that estimates of the costs often need to be viewed as rough estimates. The extent of uncertainty will vary according to each substance and the availability of accurate information.

On the other side of the scale, quantifying the benefits of an OEL also poses some particular problems. Quantification is normally based upon how far the OEL reduces the risk to employees exposed using dose-effect information. However, for substances such as carcinogens the dose-effect information is commonly not established, and alternative ways of deriving a monetary value to represent the benefits of setting OELs have been developed.

In addition, there are a number of underlying benefits that can accrue from the introduction of an OEL and lead to more general improvements in worker protection but cannot easily be quantified. Such benefits are often less tangible, longer term, or relate to the general principles of introducing an OEL rather than to its specific level. They may also lead to consequential improvements in productivity, reduction in product loss and improvements in employee recruitment and retention, some of which are difficult to quantify. These potential benefits include factors such as:

- Defining a level playing field for all users.
- Defining adequate control.
- Providing clearer guidance on the level considered reasonably practicable.
- Reducing/limiting scope of ‘discretion’ by enforcing authority.
- Providing consistency with international developments.
- Reinforcing/improving good practice.
- Encouraging/stimulating proper reporting of ill-health.
- Promoting more effective health surveillance.
- Reducing ambient air contamination generally.

The Health and Safety Commission’s Advisory Committee on Toxic Substances (ACTS) takes such uncertainties and potential benefits into consideration when discussing and agreeing proposals for OELs. It fully recognises that CBA is an aid to decision-making. During the process for deciding on the proposal for an OEL, ACTS will consider the CBA/RIA and the existence of the potential benefits, and will make a recommendation in the context of its responsibilities for employee health protection, and the provision of help to industry in risk management. The CBA/RIA provides a tool, which enables the HSC to make decisions based on a knowledge of available factors including the socio-economic impact of the proposed OEL. It is not, however, the over-riding determining factor.

ANNEX 3
Summary of the Regulatory Impact Assessment (RIA) for Respirable Crystalline Silica (RCS)

1. Purpose and intended measure of effect

The objective of the RIA was to estimate the costs and benefits of a new Workplace Exposure Limit (WEL) for RCS. The findings were provided to the Health and Safety Commission (HSC) and HSC's Advisory Committee on Toxic Substances' (ACTS) to help inform their deliberations. The RIA was also intended to be available as an information source during future discussions in Europe on a possible Binding Limit.

2. Risk assessment

Summary of Occupational Exposure

Workers are exposed to RCS in a diverse range of industries as summarised below. Although there is exposure to RCS in underground coalmines, dust exposures in this industry are subject to separate legislation outwith the COSHH Regulations (2002 as amended 2005), therefore coalmining is not included in the RIA. It should be noted that there are limitations in the amount of quantitative exposure data available for many of the industry sectors in which exposure to RCS occurs.

(i) Foundries

HSE estimates that there are about 500 foundry sites that use sand and that there are about 25,000 employees in the foundry industry. Limited data from the foundries indicates that some exposures exceed 0.3 $mg.m^{-3}$ but these are task-based exposure measurements, not time-weighted.

(ii) Ceramics industry

HSE estimates that there are about 70 pottery companies in the UK with about 25,000 employees. There will also be a number of small "craft" potteries around the country where RCS exposure is sporadic. Data for the larger potteries indicates that exposures are generally below 0.1 $mg.m^{-3}$ (8-hr TWA).

(iii) Brick-making

HSE estimates that there are about 70 brick-making sites in the UK with about 6000 employees. Clay tile manufacture is similar to brick manufacture. The total workforce in tile making is around 1000 spread over about 15 sites. Exposure data available to HSE suggests that only a small percentage of exposures exceed 0.3 $mg.m^{-3}$ (8-hr TWA), but this is based on data from only 3 work sites.

(iv) Quarry Industry

There are some uncertainties in the precise number of quarry sites in the UK but the estimate used by HSE is for 2000 sites with around 35,000 employees. Exposures in the quarrying sector show a wide variation and depend on the rock type. From the data available, there is a low to moderate percentage of personal exposures that exceed 0.1 mg.m^{-3} (8-hr TWA).

(v) Industrial minerals and the production and use of silica sand and flour

There are 25 silica sand sites in Great Britain. There are also about 20 working mines in which industrial minerals (such as potash, gypsum, limestone) are extracted, but with one exception the silica content is low. Recent data indicates that for certain tasks exposures can exceed 0.3 mg.m^{-3} (8-hr TWA) but in these circumstances respiratory protective equipment is used.

(vi) Construction Industry

HSE estimates that several hundred thousand workers in the construction industry could be exposed to RCS on an occasional basis, and about 140,000 workers exposed on a more regular basis. There is very little information on quantitative exposures to RCS in construction although some tasks can generate high airborne concentrations.

(vii) Stonemasonry

HSE estimates that 2,000 stonemasons are exposed to RCS. Exposures vary according to the type of stone used but this industry sector has potential for exposures in excess of 0.3 mg.m^{-3} (task-based).

3. Options

The RIA presented a consideration of the following options:

Option 1: Do nothing. This would mean leaving in place the current WEL of 0.3 mg.m^{-3}. This option was not supported particularly in view of the health risks predicted to arise at this exposure level.

Option 2: Get industry to impose a voluntary code (self-regulation) or produce joint HSE/industry guidance. This option was not supported for a number of reasons one being the possibility that a future European directive might well supersede the option of a voluntary code.

Option 3: Introduce a revised Workplace Exposure Limit (WEL). This is the preferred option. The current WEL of 0.3 mg.m^{-3} is a direct replacement for the previous Maximum Exposure Limit (MEL) of the same value. The legal duty associated with MELs was to reduce exposure so far as reasonably practicable, whereas the requirement with WELs is simply not to exceed the WEL. This was part of the reasoning in support of Option 3.

4. Benefits

Health benefits

This section examines the benefits from reducing three types of ill health outcomes associated with exposure to RCS. These are lung cancer, fatal silicosis, and silicosis. The WELs considered in this exercise are those listed below:

1. 0.3 $mg.m^{-3}$ *Although this is the current limit, HSE believes that there are workers who are currently exposed above this limit.*
2. 0.1 $mg.m^{-3}$
3. 0.05 $mg.m^{-3}$
4. 0.01 $mg.m^{-3}$

In general, three major types of health benefits can be expressed in monetary values and attached to a prevented case of ill health. These are associated with avoided costs of:

- Pain, grief and suffering (human costs)
- Medical treatment
- Lost output and consumption

Other minor benefits, mostly associated with administration, are also relevant. However these are small and are not usually included in RIAs. To this extent, the benefits estimated below are understated.

Lung cancer

HSE predicts that over a sixty-year period the following number of RCS lung cancer fatalities will be prevented at the various proposed limits:

- 0.3 $mg.m^{-3}$: 36 fatalities
- 0.1 $mg.m^{-3}$: 185 fatalities
- 0.05 $mg.m^{-3}$: 300 fatalities
- 0.01 $mg.m^{-3}$: 455 fatalities

Cancer is usually assumed to instil particular dread among people. Although the form of this dread is not specified, fear of acute suffering, extremely unpleasant treatment and the low survival rate for some cancers are thought to play a part. To try to account for these fears, HSE has doubled the DfT roads VPF[9].

The medical cost of treating cancer is highly variable depending on the form of chemotherapy chosen by the specialist and the number of hospital visits. HSE has assumed that the average cost of treatment lies between £5,000 and £10,000[10].

[9] This approach is mentioned in the Treasury's Green Book.
[10] This is loosely based on 5 to 10 hospital admissions for chemotherapy and appropriate palliative care. A rough cost per admission plus treatment was derived from DoH reference costs for 2002/03.

Because lung cancer is highly virulent, treatment is assumed to occur in the year of death.

HSE has no information either on the average age at diagnosis of RCS related lung cancer or the distribution of ages. Given this uncertainty and the possibility that most people are diagnosed beyond the age of retirement, HSE has not estimated lost output for cases of RCS related lung cancer.

Combining all the assumptions and evidence presented above leads to the following estimated sixty-year benefits from preventing cases of lung cancer for the four limits (Table 1).

Table 1. Benefits Over Sixty Years from Preventing Cases of Lung Cancer at Different Limit Values

	$0.3mg.m^{-3}$			$0.1mg.m^{-3}$			$0.05mg.m^{-3}$			$0.01mg.m^{-3}$		
	£million			£million			£million			£million		
Prevented human costs	21.73	to	36.21	115.6	to	192.6	187.9	to	313.2	284.8	to	474.6
Prevented medical costs	0.08	to	0.16	0.4	to	0.9	0.7	to	1.4	1.1	to	2.1
Prevented lost output	0.00			0.00			0.00			0.00		
Total prevented costs	21.81	to	36.37	116.0	to	193.5	188.6	to	314.6	285.8	to	476.8

Silicosis (or silicosis that does not lead to premature death)

HSE estimates that over a sixty-year period the following number of silicosis cases will be prevented at the various proposed exposure limit values.

- $0.3mg.m^{-3}$: 110 cases
- $0.1mg.m^{-3}$: 547 cases
- $0.05mg.m^{-3}$: 883 cases
- $0.01mg.m^{-3}$: 1326 cases

HSE has no specific value that it can place on the human costs endured by victims of severe non-fatal silicosis. In such cases in the past, HSE has sometimes resorted to a three-step process: Firstly the Department for Transport value of preventing a fatal road accident (Roads VPF[11]) is converted into the value of a life year (VOLY)[12]. Secondly, an assumption is made about how badly a disease affects the quality of a person's life. This is usually expressed in percentage terms, with 0% representing

[11] The Roads VPF is taken by HSE as a reasonable estimate of the value of preventing the majority of deaths in the occupational health and safety context. This follows recommendations produced by Beattie et al, HSE research report 273.
[12] On average a victim of a road accident has 39 remaining years of life. The VPF is assumed to represent a present value, in which discounting of 1.5% is implicit.

unaffected health and 100% representing death[13]. Finally the first two elements are multiplied together to give a monetised human cost per year, which is then applied to each year of suffering. Although this hybrid approach is not supported by theory, it nevertheless yields values in circumstances where no direct evidence is available.

In the case of silicosis, HSE took the human costs element of the Roads VPF (£819,000 in 2002 values), converted it into a figure representing the human cost per life year (£27,500 in 2002 values). For an estimate of the degree to which silicosis affects quality of life, HSE referred to DWP's Industrial Injuries Scheme. The diagnosis of "silicosis" takes into account the size and profusion of abnormalities detected on chest x-rays[14]. These abnormalities in themselves are not accurate predictors of the degree of disability. Indeed some patients with substantial chest X-ray abnormalities may only be marginally affected by the condition. Consequently, a broad disability band of 1% to 60% was chosen to capture the true level of disability suffered by silicosis patients[15]. Combining the cost per year and quality of life elements gave an estimated range of £300 to £16,500 for each year of suffering. The average age at which silicosis is diagnosed is 67. ONS reports that in 2002 the expected age at death of people who reach 65 was 81. On this basis, HSE assumed that on average people suffer silicosis for 14 years.

The prevented costs of medical treatment are difficult to estimate. The Department of Health publishes reference costs for medical treatment. The 2002/3 cost of hospital outpatient treatment for a sufferer of pneumoconiosis/fibrosis was £338. HSE has assumed that the average non-fatal silicosis sufferer requires outpatient treatment once every five to ten years, but visits his GP two to four times a year. HSE has previously estimated from Department of Health data that the cost of a GP consultation and subsequent prescription is £34 (in 2002 prices).

Although the average age at diagnosis of silicosis is beyond the normal age of retirement, there will nevertheless be some sufferers who will be diagnosed while they are still working. IIS figures (published on the HSE website) suggest that one third of non-coaldust and non-asbestos related pneumoconiosis cases are diagnosed in the 45 to 64 age group. Assuming that the average age at diagnosis within this sub-group is 60[16], HSE further assumes that the average loss of output per worker lies between two and five years[17]. The loss of one year of output is valued at £27,000[18].

[13] This is the approach followed in determining QALYs – Quality adjusted life years.
[14] The medical definition is 2/1 and above.
[15] The assumption is made that the degree of disability and loss of quality of life are synonomous.
[16] This is justified on the basis that the distribution within the age category is likely to be skewed towards the upper limit.
[17] Workers in the relevant industries may on average retire at a lower age than 65. Furthermore, workers at risk from silicosis may operate in workplace that is generally more risky than average and consequently the chances of reaching retirement age without suffering some other form of injury or illness are lower than average.
[18] Data from the 2002 New Earnings survey: SOC 89 "Plant and machine operatives", multiplied by 1.3 to account for non-wage labour costs.

Combining all the assumptions and evidence presented above leads to the following estimated sixty-year benefits from preventing cases of non-fatal silicosis for the four limits (Table 2).

Table 2. Benefits Over Sixty Years from Preventing Cases of Non-Fatal Silicosis at Different Limit Values

	0.3mg.m^{-3}			0.1mg.m^{-3}			0.05mg.m^{-3}			0.01mg.m^{-3}		
	£million			£million			£million			£million		
Prevented human costs	0.30	to	17.92	1.5	to	90.3	2.4	to	145.7	3.6	to	218.7
Prevented medical costs	0.10	to	0.20	0.5	to	1.0	0.8	to	1.7	1.2	to	2.5
Prevented lost output	0.90	to	2.21	4.5	to	11.1	7.3	to	17.9	11.0	to	26.9
Total prevented costs	1.30	to	20.33	6.5	to	102.4	10.6	to	165.3	15.9	to	248.0

Fatal silicosis (silicosis that leads to premature death)

Over a sixty-year period, HSE predicts that the following number of silicosis fatalities will be prevented at the various proposed limits:

- 0.3mg.m^{-3}: 36 fatalities
- 0.1mg.m^{-3}: 185 fatalities
- 0.05mg.m^{-3}: 300 fatalities
- 0.01mg.m^{-3}: 455 fatalities

HSE has applied the human costs element of the DfT Roads VPF to each silicosis fatality[19]. Human costs of a fatal road accident are usually associated with nearly instantaneous death. However, silicosis fatalities are likely to involve a prolonged period of suffering before death. To account for this, HSE has adopted the methodology that it applied to non-fatal silicosis deaths but has used a different set of assumptions. After consulting a DWP Industrial Injuries Scheme expert, HSE has adopted a range of 50% to 100% disability to represent the loss of quality of life before death. Combining the VOLY (human costs) and quality of life elements gives an estimated range of £13,700 to £27,500 for each year of suffering. HSE has assumed that the average length of suffering prior to death ranges between 5 and 10 years.

Due to their acuteness, fatal cases of silicosis are likely to be more expensive to treat medically per year than the cost of treating non-fatal cases. The DoH 2002/03 reference costs for treating an inpatient with pneumoconiosis/fibrosis was £1521. HSE has assumed that such treatment is required between one and two times in the five year period of suffering, while outpatient treatment is given once every year or two years (at a cost of £338 per “finished consultant exercise”) , and GP consultations are required four to eight times a year (at a cost of £34 per visit, including prescription costs).

[19] Although most silicosis deaths affect people who are significantly older than the typical road traffic accident victim, HSE has not use age-adjusted human costs. This approach is likely to be endorsed by forthcoming Treasury guidance on valuing risks.

ANNEX 3
Summary of the Regulatory Impact Assessment (RIA) for Respirable Crystalline Silica (RCS)

HSE has assumed that a case of fatal silicosis generates the same amount of lost output as for other silicosis cases (see the assumptions above).

Combining all the assumptions and evidence presented above leads to the following estimated sixty-year benefits from preventing cases of fatal silicosis for the four limits (Table 3).

Table 3. Benefits Over Sixty Years from Preventing Cases of Fatal Silicosis at Different Limit Values

	$0.3mg.m^{-3}$	$0.1mg.m^{-3}$	$0.05mg.m^{-3}$	$0.01mg.m^{-3}$
	£million	£million	£million	£million
Prevented human costs	15.85 to 20.76	84.4 to 110.6	137.1 to 179.3	207.8 to 271.9
Prevented medical costs	0.06 to 0.25	0.3 to 1.4	0.5 to 2.2	0.7 to 3.3
Prevented lost output	0.36 to 1.12	1.9 to 6.0	3.1 to 9.7	4.7 to 14.7
Total prevented costs	16.27 to 22.13	86.6 to 118.0	140.7 to 191.2	213.2 to 290.0

Summary table:

Table 4. Benefits Over Sixty Years from Preventing All Diseases at Different Limit Values

	$0.3\ mg.m^{-3}$	$0.1\ mg.m^{-3}$	$0.05\ mg.m^{-3}$	$0.01\ mg.m^{-3}$
	£million	£million	£million	£million
Total prevented costs	39.38 to 78.83	209.2 to 413.9	339.9 to 671.1	514.9 to 1014.8

5. COSTS

The RIA acknowledges that there are considerable uncertainties in the estimation of the compliance costs that would arise with a new WEL for RCS, for example the costs would be influenced by future changes in the pattern of employment and changes in technology. The RIA indicates that compliance costs will differ from one industry sector to another, but are likely to be largest in the quarries sector, partly as a consequence of the large number of sites. Table 5 below summarises the potential compliance costs and benefits that would arise across all industry sectors with a WEL for RCS set at 0.3, 0.1, 0.05 and 0.01 $mg.m^{-3}$.

Table 5: Costs and benefits to society over sixty years (in present values).

Table 5: Costs and Benefits to Society Over Sixty Years (in present values)

	0.3mg/m3			0.1mg/m3			0.05mg/m3			0.01mg/m3		
	£million			£million			£million			£million		
Total Costs	5.1	to	5.3	638	to	650	3453	to	3603	12024	to	14663
Total Benefits	39.4	to	78.8	209.	to	414	340	to	671	515	to	1015

6. Consultation with small businesses: The small firm's impact test

A range of small businesses were contacted by phone or by e-mail and more than fifteen sites were visited where fewer than 50 workers are employed. The view most often expressed was that a new WEL for RCS set at 0.1 $mg.m^{-3}$ would be achievable but that a limit set at 0.05 $mg.m^{-3}$ or below would cause severe financial difficulties.

7. Competition assessment

Brick manufacture, the heavy clay industry and the quarrying of silica sand and flour were identified as likely sectors to suffer most from adverse competition effects if a WEL for RCS limit was set below 0.1 $mg.m^{-3}$.

8. Enforcement and sanctions

The extra costs to HSE as a result of a change in the RCS limit are difficult to quantify but it is assumed that a WEL set at 0.3 $mg.m^{-3}$ would impose few extra costs. A new RCS exposure limit set at 0.1 $mg.m^{-3}$ would involve an increased inspection activity in a wide variety of sectors. Were the new WEL to be set at 0.05 $mg.m^{-3}$, it is likely that the increased inspection activity would be supplemented by more sampling visits and an increased number of enforcement notices being served. There would also be a need to develop and validate improvements on the present methods of sampling and analysis. HSE costs involved in a new WEL set at 0.01 $mg.m^{-3}$ would be difficult to assess because of the wide range of activities affected. The large extra costs to HSE for inspection could be offset slightly by the reduced industrial activity likely to occur.

9. Monitoring and review

Compliance with the requirements of the new WEL will be evaluated through a research project, which has been commissioned to gather data on exposures and controls in selected industry sectors.

10. Consultation

a) Within Government

Prior to publication of this consultative document HSE consulted the Cabinet Office, Department of Trade and Industry and Department of Health. The consultative document is itself being circulated more extensively around Government.

b) Public consultation

A questionnaire was circulated to all relevant industry sectors in June 2003. The responses are summarised in the full RIA and drawn upon in the calculations of costs.

Trade associations were approached directly for their views, and in addition, over 20 UK companies were visited and consulted about this RIA.

11. Summary and recommendations

An option to retain the current WEL (0.3 $mg.m^{-3}$ as an 8-hour TWA) was not supported in view of the health risks associated with this level of exposure. The setting of a lower limit for RCS will impose a series of extra costs on UK industry. 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 RCS levels are not currently discernible from background concentrations. If the WEL were set at a very low level (at 0.05 $mg.m^{-3}$ or below) there is the potential for the closure of parts of some industry sectors. The quarrying industry, for example, is based in predominantly rural sites where alternative employment may be difficult to find. Some brick manufacturing sites, especially those employing Hoffman kilns or having large areas of old plant, may well follow suit. This level would also create special difficulties for many small businesses that use silica sand and flour for a wide range of products.

A WEL of 0.1 $mg.m^{-3}$ (8-hour TWA) for RCS should impose extra costs without causing major redundancies. The WEL will be linked to good practice to augment the numerical limit. 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. Overall, a WEL set at 0.1 $mg.m^{-3}$ (8-hour TWA) is a level at which HSE believes UK industry could comply (with costs) and where compliance could bring a significant health benefit.

ANNEX 4 List of Consultees

List of organisations and individuals to whom this document has been sent for consultation.

Government Departments

Cabinet Office – European Secretariat
Cabinet Office – Office of Public Service
Cabinet Office – Regulatory Impact Unit
Central Office of Information
Crown Estate Commissioners
Department for Education and Skills
Department for Environment, Food and Rural Affairs
- Agricultural Resources Policy Division
- Central Directorate on Environmental Protection
- Chemicals and Biotechnology Division
- Global Atmosphere Division
- Waste Policy Division

Department of Agriculture and Rural Development – Northern Ireland
Department of Health
Department of Trade and Industry
Department of Trade and Industry – Small Firms Policy Branch
Department of Transport
Department of Work and Pensions – HSSD
Foreign and Commonwealth Office
Health and Safety Agency for Northern Ireland
HM Customs and Excise
HM Prison Service
HM Treasury
Home Office
Law Officer's Department
Lord Chancellor's Department
Ministry of Defence
National Assembly for Wales
Northern Ireland Department of Economic Development
Northern Ireland Office
Office of the Deputy Prime Minister
Property Advisers to the Civil Estate
Scottish Executive

European Union, Crown Dependencies and Overseas Territories

Government of Gibraltar
Health and Safety Authority – Republic of Ireland
Health and Safety Inspectorate, Guernsey
Isle of Man Local Government Board
Social Security Department. Jersey
UK Permanent Representation to the European Union

ANNEX 4 List of Consultees

Local Government Organisations

Association of Local Authorities of Northern Ireland
Association of London Authorities
Convention of Scottish Local Authorities
Local Government Association
London Boroughs Association
National Association of Local Councils

Employers' Organisations and Small Firms' Representatives

Alliance of Independent Retailers
Association of British Chambers of Commerce
British Pottery Managers Association
Building Employers Federation
Confederation of British Industry
CBI – Smaller Firms Council
Engineering Employers' Federation
Federation of Small Businesses
Institute of Directors
National Federation of Self Employed and Small Businesses
Union of Independent Companies
Universities and Colleges Employers' Federation

Trade Unions and Employee Organisations

Amicus
Association of Teachers and Lecturers
Bakers Food and Allied Workers Union
BECTU
BIFU
British Medical Association
Ceramic and Allied Trades Union
Communications Workers Union
Confederation of Shipbuilding and Engineering Unions
Fire Brigades Union
General Federation of Trade Unions
GMB
Graphical Paper and Media Union
National Association of Colliery Overmen, Deputies and Shotfirers
National Association of Fire Officers
NUMAST
Police Federation of England and Wales
Prospect
Royal College of Nursing
Scottish Police Federation
Scottish Trades Union Congress
Society of Radiographers
Trades Union Congress

ANNEX 4 List of Consultees

Transport and General Workers Union
UCATT
UNISON
USDAW

Trade Associations and Learned Bodies

Adhesive Tape Manufacturers Association
Agricultural Engineers Association
Association of Bakery Ingredient Manufacturers
Association of British Launderers and Cleaners
Association of British Mining Equipment
Association of British Pharmaceutical Industry
Association of Ceramic Training
Association of Concrete Industrial Flooring Contractors
Association of Light Metal Founders
Bakery Allied Traders Association
BCL Leather Technology Centre
Brick Development Association
British Adhesive and Sealants Association
British Aerosol Manufacturers Association
British Aggregate Construction Materials Industries
British Aggregates Association
British Agricultural and Garden Machinery Association
British Agrochemicals Association
British Apparel and Textile Confederation
British Association of Chemical Specialities
British Association of Feed Supplement Manufacturers
British Battery Manufacturers Association
British Cable Makers Confederation
British Cast Iron Research Association
British Ceramic Confederation
British Chemical Distributors and Traders Association
British Chrome and Chemicals
British Coatings Federation
British Colour Makers Association
British Concrete Association
British Drilling Association
British Floor Covering Manufacturers Association
British Foundry Association
British Glass
British Lubricants Association
British Metal Castings Council
British Metal Finishing Suppliers Association
British Metallurgical Plant Constructors
British Non-Ferrous Metals Federation
British Pest Control Association
British Polymer Training Association
British Precast Concrete Federation
British Rigid Urethane Foam Manufacturers

ANNEX 4 List of Consultees

British Rubber Manufacturers Association
British Secondary Metals Association
British Textile Technology Group
British Veterinary Association
British Wood Preservation and Damp Proofing Association
Castings Development Centre
Castings Technology International
Cast Metals Confederation
Chemical Industries Association
Company Chemists Association
Concrete Flooring Association
Confederation of British Wool Textiles
Confederation of UK Coal Producers (CoalPro)
Construction Confederation
Cosmetics, Toiletries and Perfumeries Association
Craft Potters Association of Great Britain
Dairy Industry Federation Ltd
Drilling and Sawing Association
European Association of Industrial Silica Producers
European Ceramic Fibres Industry Association
Farmers Union of Wales
Federation of Building Specialist Contractors
Federation of Civil Engineering Contractors
Federarion of Plastering and Drywall Contractors
Fertiliser Manufacturers Association
Food and Drink Federation
Foundry Trade Equipment and Supplies Association
Freight Transport Association
Grain and Feed Trade Association
Kaolin and Ball Clay Association
Law Society of England and Wales
Law Society of Scotland
Mining Association of the UK (MUAK)
National Association of Memorial Masons
National Farmers Union of Scotland
National Federation of Demolition Contractors
National Firplace Association
National Specialist Contractors' Council
Natural Slate Quarries association
Offshore Contractors Association
Paint Research Association
Quarry Products Association
Retail Motor Industry Federation
Road Haulage Association
Royal Agricultural Society of England
Royal Highland and Agricultural Society of Scotland
Royal Pharmaceutical Society of Great Britain
The Royal Society
Royal Society of Chemistry
Scotch Whisky Association

ANNEX 4 List of Consultees

Scottish Pharmaceutical Federation
Scottish Seed and Nursery Trade Association
Seed Crushers and Oil Processors Association
Shoe and Allied Trades Research Association
Silica and Moulding Sands Association
Soap and Detergent Industry Association
Society of British Aerospace Companies
Society of British Gas Industries
Society of Chemical Industry
Society of Dyers and Colourists
Solvents Industry Association
Steel Castings Research and Trade Association
Stone Federation of Great Britain
Surface Engineering Association
Tank Storage Association
Textile Services Association
Tile Association
Timber Trade Federation
Timber Packaging and Pallet Confederation
UK Cast Stone Association
UK Cleaning Products Industry Association
United Kingdom Agricultural Supply Trade Association
Water Companies Association
Water Services Association of England and Wales
Welding Manufacturers Association

Police and Emergency Services Bodies

Association of Chief Police Officers of England, Wales and Northern Ireland
Association of Chief Police Officers of Scotland
Association of Scottish Police Superintendents
Chief and Assistant Chief Fire Officer' Association

Health and Safety Specialists

Association of Port Health Authorities
Biotechnology and Biological Sciences Research Council
British Industrial Biology Research Association
British Institute of Occupational Hygiene
British Occupational Hygiene Society
British Safety Council
Chartered Institute of Environmental Health Officers
Institute of Occupational Hygienists
Institute of Occupational Medicine
Institution of Occupational Safety and Health
Natural Environment Research Council
Newcastle Occupational Health
Royal Environmental Health Institute of Scotland
Royal Society for the Prevention of Accidents
Society/Faculty of Occupational Medicine

ANNEX 4 List of Consultees

Individual Companies

Acorus Therapeutics Ltd
Albright and Wilson
Aon Ltd
Aplin and Barrett Ltd
Arkady Craigmillar Ltd
Baggeridge Bricks
British Bakels Ltd
Broadland Foods Ltd
Burlington Slate Ltd
Carbolite
Cereform Ltd
City Technology Ltd
Eternit Building Materials
Finnfeeds International Ltd
Fisons plc
Freshfield Lane Brickworks
Gardner Baker Ltd
Genencar International
Genesis Environmental Ltd
Hanson Aggregates
Hoben International Ltd
Homecare Technology Ltd
Huntsman Surface Sciences
Ibstock Brick Ltd
ICI Chemicals and Polymers
Josiah Wedgwood Ltd
Lever Brothers Ltd
Liquid Plastics Ltd
Lloyds (Animal) Feeds Ltd
London Underground
Lucite International UK Ltd
Morgan Advanced Ceramics
Novo Nordisk Bioindustries UK Ltd
Pilkington plc
Portmeirion Potteries Ltd
Premier Poultry Ltd
Prismo Product Services
Procter and Gamble Ltd
R.S. Clare & Co Ltd
Robert McBride Ltd
Royal Doulton (UK) Ltd
RMC Roadstone Ltd
RMC Group Services
Staffordshire Stone
Stanford Industrial Concrete Fooring
St Gobain Industrial Ceramics
Tarmac Concrete Products

ANNEX 4 List of Consultees

Thermal Ceramics
Unilever
Unilever Research
Washington Mills Ltd
WBB Minerals
Weston Beamor Ltd

Academic Institutions

Ceram Research
Imperial Cancer Research Fund
Institute of Cancer Research
Refractories and Building Products Training Council
Stoke on Trent College
University of Birmingham – Institute of Occupational Health
University of Dundee – Wolfson Institute of Occupational Health
University of Manchester – Department of Occupational Health
University of Newcastle-upon-Tyne – Department of Occupational Health

Other Organisations

The Consumers Association

ANNEX 5

Response Form

Control of Substances Hazardous to Health Regulations 2002 (as amended 2005)
Proposal for a Workplace Exposure Limit for
Respirable Crystalline Silica

We would like you to tell us what you think about the proposals set out in this consultative document. The proposals are summarised below in this reply form that you may wish to copy or tear out and use. Please add extra sheets if you wish.

Name of company or organisation	
Name of individual	
Address:	……………………………………………… …...………………………………………… ……………………………………………… ……………………………………………… ……………………………………………… ………………………………………………
Telephone number:	

Question	Comment
1. Do you agree with the proposal for a WEL for respirable crystalline silica of 0.1 $mg.m^{-3}$ (8-hour TWA)? **If you disagree, please explain why.**	
2. In your workplace (please describe), do you consider it would be reasonably practicable to comply with a WEL of 0.1 $mg.m^{-3}$ (8-hour TWA)?	
3. Which version of the RIA have you read – the summary (in Annex 3 of this Consultative Document), or the full RIA (see paragraph 28 above for details of how to obtain the full RIA)?	
4. Do you agree with the exposure information presented in the RIA?	

ANNEX 5

If you disagree, or can provide further information concerning the levels of exposure that can be reasonably achieved in your industry sector, then please provide the relevant evidence.	
5. In your view how well does this consultation document represent the different policy issues involved in this matter? Tick one box.	❑ **Very well** ❑ **Well** ❑ **Not well** ❑ **Poorly**
6. Is there anything you particularly liked or disliked about this consultation? **(please add extra sheets if you wish)**	

Please return this response form to:

Pauline Dillon
Health and Safety Executive
Room 101, Daniel House
Stanley Precinct, Bootle,
Liverpool L20 3TW

Fax: 0151 951 3418
e.mail: silica.consultation@hse.gsi.gov.uk

The Health and Safety Commission would welcome comments on proposals set out in this Consultative Document. We will acknowledge receipt of all comments sent to us and will give careful consideration to all comments received in developing our proposal. We may contact you, for example, if we have a query.

If you reply to this Consultative Document in a personal capacity, rather than as a postholder of an organisation, you should be aware that information you provide may constitute “personal data” in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the “data controller” and will process the data for health and safety and environmental purposes. HSE may disclose these data to any person or organisation for purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected.

Please note: all replies will be made public unless you specifically state you wish yours to be made confidential.

CONSULTATIVE DOCUMENT

The full text of this and other Consultative Documents can be viewed and downloaded from the Health and Safety Executive web site on the internet:

www.hse.gov.uk/consult/

Consultative Documents are available from:
HSE Books, PO Box 1999
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