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HEALTH AND SAFETY COMMISSION

ADVISORY COMMITTEE ON TOXIC SUBSTANCES

Refractory Ceramic Fibres

Proposal for a MEL

Issue

1. A Maximum Exposure Limit (MEL) for Refractory Ceramic Fibres (RCFs).

Timing

2 Routine. At its November meeting, ACTS will be discussing the responses to the Discussion Document on the proposed new OEL framework. If a new OEL framework is approved it will be implemented in June 2004. Members should note that consultation on a MEL for RCFs will take place during the transition period between the old and new frameworks. This MEL is therefore likely to be implemented directly into the new framework along with other well-founded MELs. The process of transferring well-founded limits into the new framework is discussed in paper ACTS/43/2002.

Recommendation

3 That ACTS agrees to recommend consultation on a MEL of either 1f/ml or 0.5f/ml (airborne fibre concentration) (8-hour TWA). This will be separate and lower than the existing MEL for MMMFs which is currently set at 5 mg/m^3 and 2f/ml (8-hour TWA).

Background

4 This paper incorporates and updates the information provided to ACTS at its meeting in March 2002.

5 RCFs are alumino-silicate fibres which are used mainly in the ceramic, steel and metal treatment industries, as a lining for furnaces and kilns. In the UK they are currently grouped together for OEL purposes with mineral wools, special

purpose or superfine fibres and continuous filament fibres and are known generically as machine-made mineral fibres. They are also commonly known as man-made mineral fibres or MMMFs. MMMFs currently have a common MEL under the COSHH Regulations which is expressed in two ways; as a gravimetric limit of 5 mg/m^3 (total inhalable dust) and as an airborne fibre limit of 2f/ml, expressed as 8-hour time-weighted averages (TWA). The term RCF also includes non-oxide ceramic fibre such as boron and silicon carbides and nitrides.

6 When RCFs are removed from high-temperature kilns and furnaces, there is also the potential for their conversion to cristobalite, a crystalline form of silica. There is currently a MEL for all forms of crystalline silica of 0.3 mg/m^3 (8-hour TWA). ACTS current developments paper (Paper ACTS/49/2002) updates members on HSE's current action in respect of respirable crystalline silica.

Classification and labelling

7 In December 1997, the European Commission adopted Directive 97/69/EC which sets out the classifications of two types of randomly-oriented MMMF:

(a) mineral wools; and
(b) RCFs and special purpose fibres (SPFs).

The term "randomly-oriented" distinguishes these categories of MMMF from continuous filament fibres, which are generally thicker in diameter. Although RCFs and SPFs are covered by the same definition, this paper focuses solely on RCFs because SPFs are not widely used in Great Britain (see paragraph 17).

8 Under Directive 97/69/EC, mineral wools, RCFs and SPFs are classified both as skin irritants and carcinogens. Mineral wools are classified as Category 3 carcinogens and RCFs/SPFs as Category 2 carcinogens. There is a general exclusion for classification for carcinogenicity for fibres that have a length-weighted mean geometric diameter of more than 6 µm (such fibre products would be regarded as being too wide in diameter to be respirable, and would hence pose no carcinogenic risk from exposure by inhalation). Mineral wools can also be exempted from classification as carcinogenic if they can meet any of four specified conditions set out in the Directive. Directive 97/69/EC was implemented in Great Britain in 1999 by an amendment to the CHIP Regulations.

HSE review of exposure to RCFs

9 At the ACTS meeting in December 1998, HSE informed members that it had commissioned the Health and Safety Laboratory (HSL) to collate and review the airborne fibre concentrations generated by the manufacture, installation and removal of RCFs, and to produce a report (ACTS/45/98/INF). A copy of the report prepared by HSL was discussed by ACTS at is meeting in March 2000 (ACTS/05/2000) and the conclusions are summarised in paragraph 21 below.

10 In the same paper in March 2000, ACTS was asked to consider the feasibility of setting a separate lower MEL for RCFs because of their carcinogenic potential. ACTS agreed that HSE should progress this work by producing a Regulatory Impact Assessment (RIA) for a more stringent MEL for RCFs and report the outcome in due course. An RIA for RCF MEL proposals of 1f/ml and for 0.5 f/ml is attached at Annex 1.

11 A recommendation for a MEL was considered by ACTS at its meeting on 14 March 2002 (ACTS/04/2002), and this paper reproduces all of the information contained in that paper. At that meeting ACTS received a presentation from the European Ceramic Fibre Industry Association (ECFIA) who argued that there was no unequivocal link between exposure to RCFs and ill-health. They specifically made the following points:

(i) that there was data which had not been considered by WATCH and which showed that there were no adverse effects from exposure to RCFs. Pulmonary fibrosis, lung tumours and mesothelioma were the result of old age and were unrelated to RCF exposure;

(ii) large-scale manufacture of RCFs had been undertaken for the past 40 years, long enough to allow a meaningful assessment of the risk of carcinogenicity, and in the last 10 years epidemiological studies had not revealed any associated ill-health effects;

(iii) industry was already working towards much lower levels of exposure to RCFs through the CARE programme. 92% of samples showed exposure levels below 1 f/ml (8-hour TWA).

12 It was agreed that WATCH should consider the new evidence presented by ECFIA at its forthcoming meeting in May, and then advise ACTS accordingly. The May WATCH meeting also received a presentation from ECFIA representatives, and WATCH members were able to question them in depth about their findings. After further discussion, WATCH concluded that it was still appropriate for RCFs to carry the classification of Category 2 carcinogen. As a consequence, the logic which argued for a more stringent MEL for RCFs compared with other MMMFs remained unchanged.

Limits in other countries

13 Annex 1 attached to this paper includes occupational exposure limits for RCFs in some other EU countries (paragraph 5). In addition, the American Conference of Government Industrial Hygienists (ACGIH) has set a threshold limit value (TLV) at 0.5f/ml (8-hour TWA). In 2000 the meaning of this TLV was challenged by the Refractory Ceramic Fibers Coalition (RCFC). Legal action was dismissed, however, in July 2001, following the release of a statement by ACGIH

that TLVs are "developed as guidelines to assist in the control of health hazards. These recommendations or guidelines are intended for use in the practice of industrial hygiene, to be interpreted and applied only by the person trained in this discipline. They are not developed for use as legal standards, and ACGIH does not advocate their use as such".

Guidance

14 No CHAN has been prepared for RCFs, since the MEL for MMMF continues to apply to them. No draft EH64 entry has yet been prepared, because RCFs have not been subject to a full toxicological assessment by WATCH.

Argument

Limit proposal

15 On the basis of health considerations, practicalities and costs discussed below, and in the RIA at Annex 1, HSE recommends setting a separate airborne fibre limit for RCFs at either 1f/ml or 0.5 f/ml expressed as an 8-hour time-weighted average. No STEL is recommended. "Skin" and "Sen" notations are not considered appropriate.

16 HSE recommends the retention of the existing gravimetric limit of 5 mg/m^3 (total inhalable dust) 8-hour TWA. In terms of health effects, it is the concentration of respirable fibres (f/ml) that relates to effects in the deep lung (fibrosis and carcinogenicity). There is also a concern for the possibility of effects in the upper airways that are more likely to relate to the total inhalable dust concentrations than to the f/ml count. Hence, in occupational situations with the potential for generating high airborne dust levels (e.g. kiln wrecking), the gravimetric limit offers a useful risk management tool in addition to the f/ml limit. However, in all circumstances, it is control to the f/ml count that is the predominant requirement.

Special Purpose Fibres

17 The EU Directive referred to in paragraph 7 above also classifies Special Purpose Fibres (SPFs) as Category 2 carcinogens. Consequently, if ACTS agrees that a reduced MEL of 1 or 0.5 f/ml should be applied to RCFs, the reduced limit would also be applied to SPFs. The RIA does not include SPFs because very little use is made of them in the UK. Moreover HSE has evidence that the use of good occupational hygiene standards should result in personal exposures being below 1 f/ml, and, in most instances, reduced to 0.5 f/ml. It should be noted that the term "Special Purpose Fibres" is widely used in industry and that it may be applied to a wider range of fibres than the relatively small group of fibres covered by the same term in the Directive.

Other types of MMMF

18 For the remaining types of MMMF, i.e. mineral wools and continuous filament fibres (CFF), HSE proposes that they remain subject to the MEL of 2 f/ml and 5 mg/m^3 (both as 8-hour TWAs). Mineral wool manufacturers on the UK maintain that their products do not need to be classified as Category 3 carcinogens because they can meet one of the four specified conditions set out in the EU Directive, which can exempt them from the carcinogenic classification. However, HSE does not know whether any imported mineral wools can also escape the carcinogenic classification, nor whether the vast majority of mineral wool already installed as loft insulation, and as soundproofing in buildings, would be exempted from classification as a Category 3 carcinogen under existing EU criteria. In HSE's view, there are no grounds for proposing any changes to the current MEL position for mineral wools and continuous filament fibres.

Health effects

19 Lifetime inhalation studies in rats and hamsters were conducted with four different RCF products in the early 1990s, and the results showed that RCFs produced pulmonary fibrosis, lung cancer and mesothelioma. When the evidence from these studies was presented to WATCH in 1995, that Committee agreed that RCFs met the EU criteria for classification as a Category 2 carcinogen (R49). There are no epidemiology studies investigating the risk of lung cancer in RCF workers, although the large-scale industrial manufacture of RCFs has not been in place for long enough to allow a meaningful assessment of the risk of carcinogenicity in workers.

Compliance with the existing MEL for MMMF

20 As Category 2 carcinogens, RCFs justify more rigorous and stringent control than is the case for Category 3 carcinogen such as the mineral wools which currently share the same MEL. Although HSE has no epidemiological evidence to indicate the likely human health risks from exposure to RCFs at the current MEL, the review carried out by HSE (ACTS/05/2000) produced evidence to suggest that some employers are not only failing to reduce exposure to the current MEL, but are also failing in their duty to reduce exposure to as low as is reasonably practicable below the MEL. The new proposal would give HSE the opportunity of reminding employers in the various sectors of the RCF industry that they are handling a Category 2 carcinogen, and would signal the need for more effective and sustained control over exposure to RCFs.

Use and exposure

21 A detailed description of use and exposure is provided in the RIA. In the UK there are around 5000 employees exposed to RCFs. HSE's review of exposure to RCFs was discussed by ACTS in March 2000 (ACTS/05/2000).

Exposures considered in the review were for less than 8 hours, but data demonstrated the potential for high exposures to occur. The average fibre concentration from 1,117 samples was 1.03 f/ml. 12% of the values were above the current 8-hour MEL of 2 f/ml and 27% were above 1 f/ml. RCF removal showed consistently high exposures. Of the 92 samples taken, 29% were above the current 8-hour TWA MEL of 2 f/ml and 39% were above 1 f/ml. Hand-cutting/handling and band sawing also showed high exposures, each of these activities having more than 50% of the samples above 1 f/ml.

Costs and benefits

22 HSE sought information from industry (see paragraph 28 below) on the implications of a MEL set at 0.5 f/ml or 1 f/ml. Costs were considered on a business sector basis, although each sector will cover a range of tasks that involve RCF exposure, such as mixing and forming, finishing and assembly.

23 Estimates of the total compliance costs over 10 years associated with each proposed limit value are summarised in paragraphs 94-99 of the RIA in Annex 1. For a MEL set at 1 f/ml, total compliance costs over 10 years are about £2.7m - £2.8m in present terms. For a MEL set at 0.5 f/ml, total compliance costs are around £4.4m - £4.5m in present value terms.

24 The appendix to the RIA analyses additional information received from ECFIA following the March ACTS meeting. It compares the costs of compliance with a MEL of 0.5 f/ml as projected by the RIA, with evidence from two sites where controls have already been implemented to achieve maximum exposure of 0.5 f/ml. The new evidence suggests a compliance cost per site that is more than twice that estimated in the RIA. However, it is concluded that the new data, taken from only two firms, is not representative of the costs that all firms are likely to face, partly due to biases in ECFIA's measurement programme. Moreover, the two observed firms demonstrate that exposure reductions can be achieved, even if the cost is higher than anticipated.

25 As it is not usually possible to quantify projected benefits for a carcinogenic substance, it is instructive to consider the average projected cost per employee exposed to such substances. For RCFs, the cost per exposed employee over 10 years is estimated to be about £504 - £518 for a MEL set at 1 f/ml, and £825 - £846 for a MEL set at 0.5 f/ml. The RIA provides for comparison in Table 8 the estimated costs per employee for MELs adopted for other carcinogenic substances in recent years. It can be seen that the costs associated with MELs at 1 f/ml and 0.5 f/ml are comparable with other recent MELs. However, it should be noted that much of the data provided is based on large, well controlled operations and probably does not fully reflect difficulties that small firms could have in complying with a MEL at 0.5 f/ml (see RIA paragraphs 101-102, detailing the responses of some small businesses and 112-114 entitled

'Uncertainties', on the unpredictability of exposures in processes where it is difficult to apply engineering controls).

26 The EU classification, based on clear evidence for lung cancer and mesothelioma in animals, implies that occupational exposure to RCFs is associated with a risk of carcinogenicity, but from the data available it is not possible to quantify the risk reliably. However, it can be concluded that any reduction in exposure would be expected to reduce the risk.

Conclusion

27 Although extra costs will be incurred with a reduction in the RCF MEL, HSE believes that a reduction to 1 f/ml is practicable. Reduction to 0.5 f/ml is likely to have more far-reaching implications, in particular for small companies, some of which would find this limit extremely difficult to achieve

Consultation

28 In developing the RIA, HSE consulted the European Ceramic Fibre Industry Association (ECFIA), one RCF product manufacturer, one glass manufacturer and one pottery manufacturer.

Communication Plans

29 Subject to agreement by the Health and Safety Commission (HSC), the proposed MEL for RCFs would be published in a consultation document in the usual way for limits of this nature. HSE will report the results of this consultation exercise to the HSC.

30 If the new OEL framework does take effect, and the MEL is implemented directly into the new OEL framework, this will not result in changes to worker protection. Under the current system, employers are required to reduce exposure below the MEL so far as is reasonably practicable. Under the new framework, good practice guidance developed to help employers comply with the limit will relate directly to the hazard – the greater the hazard, the more stringent the good practice guidance will be. (Paper ACTS/43/2002 gives more information on the proposed OEL framework). Moreover, RCFs are classified as Category 2 carcinogens, and therefore employers will continue to have to reduce exposure as low as is reasonably practicable, in accordance with the Carcinogens Directive. HSE will ensure that this is explained to stakeholders in the CD.

Evaluation Plans

31 There are no current plans to evaluate the limit.

Relevant control systems

32 Efficient local exhaust ventilation (LEV) is vital to reduce exposures, particularly in finishing, where sanders, band-saws, die-cutters and routers are used. Although removal of RCF from kilns and furnaces has the potential for high exposures, RPE and disposable clothing are already routine controls, so there will be little additional cost. Because of the nature of this work, control by methods other than RPE is difficult.

Costs and Benefits

33 These are attached at Annex 1.

Environmental implications

34 None. Introduction of a more stringent limit for RCFs is not likely to result in a significant increase in RCFs to the environment.

European implications

35 MMMFs are on the programme of work of the EU's Scientific Committee on Occupational Exposure Limits (SCOEL). Although SCOEL is looking to recommend health-based limits for some specific fibre types (probably glass wools), these are quite separate to RCFs.

Other implications

36 None.

Action

37 ACTS is invited to:

(a) recommend that HSC consults on a separate and more stringent 8-hour TWA limit (either a MEL or new form of limit) for RCFs and special purpose fibres to be set at either 1 f/ml or 0.5 f/ml (airborne fibre limit); and

(b) agree to retain the existing gravimetric limit of 5 $mg.m^{-3}$ (total inhalable dust) for RCFs.

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PROPOSED MAXIMUM EXPOSURE LIMIT FOR REFRACTORY CERAMIC FIBRES (RCFs)

REGULATORY IMPACT ASSESSMENT (PRE-CONSULTATION)

PURPOSE AND INTENDED EFFECT

Issues and objectives

1 Refractory ceramic fibres (RCFs) are alumino-silicate fibres which are used mainly in the ceramic, steel and metal treatment industries as a lining for furnaces and kilns. In the UK, they are grouped together with mineral wools, special purpose fibres and continuous filament fibres and known generically as machine-made mineral fibres (MMMF). As such, they have a common MEL under the COSHH Regulations which is expressed in two ways; as a gravimetric limit of 5 $mg.m^{-3}$ (total inhalable dust) and as an airborne fibre limit of 2 f/ml, expressed as 8-hour time weighted averages (TWA). This dual limit was intended to capture the mineral wools where the fibres tended to be heavier, and therefore exposure would approach the gravimetric limit before the airborne fibre limit. EH40 shows the gravimetric method limit with a footnote referring to the approved method for fibre counting.

2 In December 1997, the European Union adopted Directive 97/69/EC which sets out the classifications of two types of randomly-oriented MMMF. The two types, mineral wools, and the RCFs and special purpose fibres (SPFs), are distinguished on the basis of their chemical composition. The Directive's definition of RCFs (and special purpose fibres) is "Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkaline earth oxide content less than 18% by weight." The 1997 directive was implemented in the UK in 1999 by amending the CHIP Regulations.

3 In March 2000, ACTS noted the results of an HSE review of exposure to RCFs and agreed that HSE should take the work forward by producing an RIA for a more stringent MEL of 1 f/ml and report back the outcome to the Committee.

4 These proposals are the result, and the objective of these proposals is to reduce occupational exposure to RCFs by the setting of a Maximum Exposure Limit (MEL) as an 8-hour time weighted average (TWA). This document will inform ACTS as to the possible financial consequences of this procedure.

5 Current exposure limits for RCF in the EU (as at December 2001):

United Kingdom 2 f/ml (MEL)
France 0.6 f/ml (recommended)
Germany 0.5 f/ml (TRK)
Sweden 1.0 f/ml
Norway 1.0 f/ml
Finland 1.0 f/ml
Spain 0.5 f/ml (recommended)

Holland 0.5 f/ml
Denmark 1.0 f/ml

RISK ASSESSMENT

6 Mineral wools and RCFs are classified both as skin irritants and as carcinogens. RCFs are classified as Category 2 carcinogens on the basis of animal data. There is a general exclusion for carcinogenicity for fibres that have a length weighted mean geometric diameter of more than 6 µm.

7 The potential health hazards resulting from inhalation exposure to RCFs are the same as for asbestos; namely, pulmonary fibrosis, pleural plaques (calcification of the pleural membranes surrounding the lungs), lung cancer and mesothelioma (cancer of the pleural membranes). The only human data available derive from a limited number of studies in the RCF-manufacturing industry in the US and Europe. The US studies revealed an increased prevalence of pleural plaques in RCF-manufacturing workers; the prevalence was highest in workers with the longest durations of employment (Lemasters *et al.*, 1994; Lockey *et al.*, 1996). In the European studies there was only limited evidence for increases in pleural plaques with time since first exposure (Cowie *et al.*, 1994 and 2001; Rossiter *et al.*, 1994; Trethowan *et al.*, 1985 and 1994).

8 There are no mortality studies in RCF-workers investigating the carcinogenicity of RCFs, although the large-scale industrial manufacture of RCFs has not been in place for long enough to allow a meaningful assessment of the risk of carcinogenicity in workers. Walker *et al.*(2002) used quantitative risk models purporting to show that RCFs are not as potent carcinogens as amphibole asbestos, but concluded that the current epidemiological studies do not rule out a lower level of risk.

9 Lifetime inhalation studies in rats and hamsters have demonstrated the ability of RCFs to cause lung cancer and mesothelioma. The mechanism of RCF carcinogenicity has not been fully elucidated. Although the animal data are consistent with the possibility of a threshold mechanism, if a threshold does exist in humans, it is not possible to estimate what this threshold level of exposure might be from the available animal data.

10 The animal data are the basis of the classification of RCFs as category 2 carcinogens (‘May cause cancer by inhalation’). There is scope for derogation of this classification based on the fibre diameter characteristics, under Note R of the Dangerous Substances Directive. Additionally, all RCFs are classified as skin irritants.

11 Currently, the same MEL value applies to RCFs and mineral wools. There is less concern regarding the carcinogenicity of mineral wools (rock, slag and glass wools), and this is reflected in their classification as Category 3 carcinogens. The higher level of concern for RCFs justifies a more rigorous and stringent control for RCFs compared to mineral wools.

Exposure to hazard and methods of control

12 Total usage of RCFs in the UK is around 8000 tonnes per annum with 50% of the material being used for furnace/heater/kiln linings. Domestic appliances account for a further 20%, and metal processing, such as steel foundry and forging use, about 10%. Automotive use, fire protection and general industrial processes make up the remaining 20%.

13 In the UK, HSE believes that there are about 5000 employees exposed to RCFs. Many of these companies have a number of different functional job categories in the ECFIA classification. We have classified below the different functional job categories into eight groups.

Production

14 RCFs are manufactured at two sites within the UK from the raw materials (silica, alumina, zirconia). RCF is made by melt fiberisation processes, either where an airstream is blown onto molten material flowing from an orifice at the bottom of the melting furnace, or where molten material is directed onto a series of spinning wheels. The fibre can be further processed into a blanket to improve handling strength, or processed into boards, shapes, felts and papers. Blankets are produced by a needling machine and the formed blanket passes through an oven to burn off lubricant. Trimming is achieved by rotating knives or water jet. The main dust problem arises from manual handling and bagging of the trims. Bulk fibre is produced by a bulk press and bagging station.

Mixing/forming

15 This includes wet-end production of vacuum-formed shapes, board, felt and paper. Water and fibre are mixed in large tanks, the RCF being added from bags, and the mould is submerged and connected to an airline. Once the fibre has been formed to the required shape, the suction is removed and the fibre shape dried in a curing oven. When dry, these materials may be friable.

Modules

16 Modules are produced by lamination, either manual, or semi-automatic using a pre-cut blanket or pleated blanket. Manually, the blanket is cut using a hand knife and waste fibre bagged or boxed. The semi-automatic process is used for standard sized modules. Manual handling of blankets produces the highest exposures.

Finishing

17 In this category, we have included cutting or machining operations on RCF materials. Automated bandsaws and sanding procedures require efficient LEV to prevent high RCF exposure.

Assembly

18 Here RCF materials are inserted into, attached to or applied to other materials to form an intermediate product or a finished product. This includes factory assembly of industrial furnace components, when work is performed in an open area where engineering controls are practical.

Installation

19 This includes building or manufacturing large industrial equipment at end-user locations where the use of engineering controls is difficult. This category involves the installation of rooms or booths which are too large to be engineered in situ

Removal

20 This includes the removal of after-service RCF material from equipment that has completed its economic life, or its removal from furnaces during routine maintenance. This appears to be the major source of RCF exposure, as control is more difficult than in other areas. RPE usage is routine. Exposure is, however, usually sporadic.

Other

21 In this category, we have placed all the general jobs in the industry. This includes cleaning, supervisory and delivery work. This category also includes exposure in auxiliary industries, as defined by ECFIA, such as textiles and automotives.

Current levels of risk

22 HSE examined exposure data from the monitoring of airborne fibre release during the manufacture and use of RCFs and RCF products. The data sources comprised:

(a) HSE's National Exposure Database (NEDB), which holds details of both airborne fibre count and gravimetric measurements;
(b) data generated by HSL (airborne fibre and gravimetric measurements);
(c) data from the European Ceramic Fibre Industry Association's (ECFIA) Control and Reduced Exposure (CARE) programme, which only comprises airborne fibre concentrations.

23 The HSE NEDB data and the HSL data were predominantly in the form of task-based exposures and it was often not possible to confidently convert to 8-hour TWAs. The ECFIA data was in the form of 8-hour TWAs for RCF production, and in the form of task-based exposure for secondary manufacture and use of RCF products. This newer data could be converted to 8-hour TWAs.

24 The ECFIA sampling programme consists of a certain number of annual planned visits plus a variable number of reactive visits to sites which request sampling. It is likely that these sites contain a greater number of problem areas than would be expected from random visits. All uses of RCFs are included in this sampling, but little data was

available from removal activities because of the short notice available for much of this work.

25 The data from all three sources provide a good spread of work activities. The only major activity which is under-represented in the newer data is the removal of RCF from kilns and furnaces.

26 In addition, visits were made to a small number of sites to assess particular conditions. Removal activities were targeted as these were of most interest.

27 Before using the ECFIA data, HSL and ECFIA carried out an inter-laboratory validation exercise to check that there were no major discrepancies between sampling and counting techniques. In hygiene terms, there were no significant differences between them. A similar exercise has been carried out between ECFIA and the Caisse Régionale d'Assurance Maladie (CRAM).

28 Because the ECFIA data is more recent and is available as 8 hour TWAs, we have used this data for costing the increased controls required by a more stringent MEL.

29 Table 1 summarises the ECFIA exposure data in the period 1996-2000

<u>Table 1. Summary of ECFIA data on RCF exposure (1996-2000). All data has been converted to 8-hour TWAs</u>

Functional job category	Number of samples	Range f/ml	% above 2 f/ml	% above 1 f/ml	% abo 0.5 f/m
Production*	304	-	1	5	10
Mixing/forming	25	0.05 - 1.44	0	12	20
Modules	6	0.09 - 0.38	0	0	0
Finishing	45	0.04 - 5.61	20	49	76
Assembly	67	0.02 - 5.28	3	7	13
Installation	26	0.01 - 0.90	0	0	12
Removal	24	0.06 - 11.56	17	33	38
Other	91	0.01 - 1.01	0	1	8
All	**588**	**0.01 - 11.56**	**5**	**14**	**24**

*Production data is restricted to the period 1996-1998

30 To bolster and update the exposure data from the RCF removal category, we visited two sites while removal activities were taking place. RCF sampling and video-visualisation exercise were carried out at both sites and the results are summarised in Table 2 below.

Table 2 Removal activities - RCF exposure data from two sites (task-based data)

Site	Number of personal samples	Range f/ml	% of samples above 2 f/ml	% of samples above 1 f/ml	% of samples above 0.5 f/ml
Site one	14	<0.01 - 3.83	7	29	50
Site two	1		100		

31 Site one was a well-controlled RCF removal operation from a furnace with efficient extraction and with all operators wore powered respirators. The furnace was cold but no wetting operations took place. Site two was a well-controlled stripping operation from a kiln and all operators wore powered respirators. Again the kiln was cold but no wetting operations took place. The personal sample showed a value of 4.3 f/ml during a period of 26 minutes of active stripping. Two static samplers outside the enclosure showed values of 0.07 and 0.12 f/ml.

Options considered

32 At its meeting in March 2000, ACTS asked HSE to build a case for a single MEL for RCF and special purpose fibres alone at a level of I fibre per ml (airborne). According to HSE research in the late nineteen eighties (Phillips, 1990), compliance to a limit of 5 mg/m3 usually ensures compliance to an airborne limit of 1 f/ml. However, few gravimetric measurements are now undertaken and it is proposed to leave this limit at 5 mg/m3.

33 As part of this case for a single MEL, HSE has undertaken a Regulatory Impact Assessment for a MEL at the following two airborne levels.

- (i) A level of 1 f/ml as suggested by ACTS
- (ii) A level of 0.5 f/ml which is current in some other European countries.

Information sources

34 The following information sources were consulted in this document.

- (i) European Ceramic Fibre Industry Association.
- (ii) One RCF product manufacturer.
- (iii) One glass manufacturer.
- (iv) One pottery manufacturer.

Technical assumptions

35 Costs and benefits of this regulation are calculated over the appraisal period 2002 - 2012 and are expressed in net present terms. In arriving at ten-year cost figures,

two assumptions are made. Firstly earnings are assumed to increase by 1.8% per year in real terms which is the observed increase for the whole economy over the past twenty-five years or so. Secondly, costs are discounted to present value using the Treasury recommended 6% discount rate.

HEALTH AND SAFETY BENEFITS

36 In total, it is assumed that in the UK, 5,000 people may be exposed to RCFs. However, there is insufficient data to determine cases affected and workdays lost due to illness caused by RCF exposure, but a reduction in exposure is assumed to reduce the risk of any carcinogenic effects**.**

COSTS

Business sectors affected

37 The costs were considered on a business sector basis despite most of the exposure data being categorised as an 8-hour TWA from individual tasks. Within a business sector, there will be a range of different tasks, but we have grouped them together for convenience.

Primary Production

38 RCFs are manufactured at two sites in the UK with a total of about 350 exposed employees. Operators typically rotate through several jobs within a shift. Overall dust concentrations are low and the main exposures result from manual handling of fibre, especially following a line blockage. We have data supplied by ECFIA which details costs of controls and the reduction in RCF exposures achieved as a consequence.

Mixing-forming

39 We have assumed about 275 employees are exposed at 120 sites. Generally, exposures are not high. At the mixing stage, the operator fills the mix tank with water, weighs out and introduces fibre to the tank. The forming stage is where the operator submerges a mould and the fibre is sucked into the required shape. The shape is removed and dried in a curing oven. Finally dry shapes are removed and packed into boxes, and handling the sometimes friable nature of the shape may be responsible for the relatively higher RCF exposures.

Modules

40 Around 165 employees at 80 sites are involved in the production of modules. This category includes compressing veneers, slabs and modules. Modules are laminated blocks of blanket produced by lamination using manual, semi-automatic with pre-cut blanket, or semi-automatic with pleated blanket methods. In manual methodology, the blanket is cut into sections using a template and a knife. The use of LEV reduces exposure considerably. If modules are trimmed using band saws or circular saws, there is potential for higher exposures.

Finishing

41 1250 employees are employed at about 500 sites. In finishing, the RCF is subjected to concentrated mechanical energy from powered equipment or machinery such as sanders, saws, die-cutters routers and others. Efficient local exhaust ventilation is vital to reduce RCF exposures, particularly at band-saws. The siting, working and efficiency of LEV and other containment measures are investigated as part of the ECFIA CARE inspection programme.

Assembly

42 There are about 1600 employees at 300 sites involved in assembly. The work is often on a production line with a variety of packing and assembling tasks, which may involve some minor cutting and trimming. Control is usually by down draught benches or, in the larger units, by flexible trunking.

Installation

43 Around 600 employees at 100 sites are involved in installation of RCFs. As RCFs are commonly used as high-temperature lining in a variety of furnaces, Installation is a dust-generating task but controls are usually portable.

Removal

44 Around 700 employees are employed in removing RCF material from kilns and furnaces in a variety of industries. After-use RCF is more friable than new, and because large quantities of material may be removed from a confined space, furnace dismantling has the potential for the very highest exposures. Disposable clothing and RPE are routine controls, with powered respirators the commonest form. Although surface wetting is used in some cases, dry removal of RCF still occurs even when the material has cooled. It is difficult to thoroughly wet RCF and the dust suppression is limited to the initial stages. The number of sites where removal occurs annually is very variable but for the purposes of the RIA, we have assumed 100. By its nature, removal of RCF from furnaces and kilns is difficult to control by methods other than RPE

Other

45 This category includes jobs in which employees are passively exposed to RCF or where RCF may be handled, albeit with only a small probability of significant exposure. Examples include warehouse workers, forklift truck drivers, maintenance workers and QC Inspectors. Although about 400 employees are included in this classification, exposure to RCF tends to be sporadic and low.

<u>Nature of compliance costs to business, charities and voluntary organisations</u>

Compliance costs to each sector of business

46 For each business sector, the extra control costs will be calculated for each potential MEL value. However, some costs are common to all potential MELs and the basis of these costs is given below.

Monitoring

47 Monitoring of RCFs would be required at sites where the risk assessment suggests that there may be a problem. The risk assessment would be based on previous monitoring results if available, or results from similar sites. Once a MEL is set, it is possible that sites would require an initial survey. This survey and the rest of the risk assessment will indicate what sort of further actions are needed. In many cases, depending on the level of the MEL set, no further action may be needed unless conditions change significantly.

48 For RCF monitoring, we can calculate some typical costs. A day's time for a consultant is estimated to cost between £500 and £600. A day's time for a technician is estimated to cost between £200 and £300 and the cost of RCF analysis (fibre counting) is estimated at £40 per sample.

Engineering controls

49 For work with fibre where cutting or machining takes place, the use of efficient LEV is vital. We assume a unit cost of £5,000 for each unit with recurring annual examination and maintenance costs of 10% (£500).

Respiratory protective equipment

50 The cost of an RPE programme has been calculated by HSE in a document published in 1996 (McAlinden JJ, Costing a Respiratory Protective Equipment (RPE) Programme, Specialist Inspector Report Number 50), based on 1994 prices. It gives the total cost of using and maintaining various sorts of RPE. These figures are used to estimate the RPE control costs. For a single-use disposable filtering face piece respirator, assuming only one face piece is used per shift, the annual cost of replacement would be between £288 and £840. The training is assumed to take two hours annually and brings the total costs to between £310 and £880 per person annually, in 2001 prices.

51 RPE is used for a variety of work activities which involve the handling of RCF. Data from the ECFIA CARE programme show that the observed RPE usage between 1996 and 1998 varied with the task being performed. The percentage of operatives who wore RPE during certain activities was as follows:

- 29% in fibre production.
- 50% in finishing
- 53% in installation
- 80% in removal work

52 These figures include associated operatives working in the area. The RPE varied from a half mask respirator with a medium efficiency particle filter (P2) up to airline breathing apparatus. We will use these values to calculate how many more operatives will need to use RPE when we calculate the costs.

(a) Production

Monitoring

53 There will be no extra monitoring costs for the two RCF production sites as they are both currently monitored on a regular basis.

Engineering controls

54 We have assumed that no new engineering controls will be needed for a MEL set at 1 f/ml. For a MEL set at 0.5 f/ml, we have assumed that two new engineering units will be needed at each site, a total capital cost of **£20k** and **£2k** maintenance costs per year over ten years.

RPE

55 The current RPE usage in production is 29%, and we assume that no increase in this rate is likely with the setting of a MEL at 1 f/ml or 0.5 f/ml.

Total Production

56 Thus, the total increased costs in production for a MEL set at 1 f/ml is **zero**, and for a MEL set at 0.5 f/ml, it will be £20K initial costs and £14k maintenance costs. That is, a total of around **£34k** over ten years in net present value terms.

(b) Mixing-forming

Monitoring

57 Following the setting of a new MEL, there will be a need for an initial survey at any site where mixing-forming activities take place and the risk assessment suggests that there may be a problem. This initial cost is calculated as one consultant for a day plus 4 samples per site, a total of £500 plus £160 per site (£660). We have assumed that for a MEL set at 1 f/ml, 12% of sites will need extra monitoring and, for a MEL set at 0.5 f/ml, 20% of sites will need extra monitoring. Of these sites we anticipate there will be a recurring cost every five years for one technician/day and 4 samples to be analysed (£200 plus £160 equals £360).

58 Thus, for a MEL set at 1 f/ml, initial costs will be 660 x 12% x 120 = £9.5k, and total recurring costs will be between £12k and £15k. For a MEL set at 0.5 f/ml, initial costs will be 660 x 20% x 120 = £15.8k and total recurring costs will be between £19k and £25.

Engineering controls

59 For a MEL set at 1 f/ml, we have assumed that 12% of sites will require an extra unit of engineering control and the costs will be 12% x 120 x £5k = £72k with maintenance costs of 12% x 120 x £0.5k = £7.2k per year over ten years.

60 For a MEL set at 0.5 f/ml, we have assumed that 20% of sites will require an extra unit of engineering control and the costs will be 20% x 120 x £5k = £120k with maintenance costs of 20% x 120 x £0.5k = £12k per year over ten years.

RPE

61 We have assumed that current RPE usage is 30% (similar to that for production), as the RPE usage is related to the RCF exposure. We have further assumed that, as this is above the percentage of sites showing exposures above the MEL, there will be no increased costs for RPE.

Total Mixing-Forming

62 Thus, the total increased costs in mixing-forming for a MEL set at 1 f/ml will be between **£138k to £142k** over ten years in net present value terms (Initial costs will be approximately £82k to £83k, recurring costs will be approximately £57k to £59k).

63 For a MEL set at 0.5 f/ml, it will between **£231k and £237k** in net present value terms (Initial costs will be approximately £136k to £138k, recurring costs will be approximately £95k to £98k).

(c) **Modules**

Monitoring

64 Following the setting of a new MEL, there will be a need for an initial survey at any sites where monitoring activities take place and the risk assessment suggests that there may be a problem. On the basis of the figures we have (no exposures above 1 f/ml), we believe there will no costs for any extra monitoring.

Engineering controls

65 Currently no sites producing modules show exposures above 0.5 f/ml. We therefore assume there will be no extra costs for engineering controls for either MEL.

RPE

66 We have assumed that current RPE usage is 30% (similar to that for production), as the RPE usage is related to the RCF exposure. We have further assumed that there will be no increased costs for RPE.

Total Modules

67 Thus, the total increased costs in module production for a MEL set at 1 f/ml or 0.5 f/ml is **zero.**

(d) Finishing

Monitoring

68 Following the setting of a new MEL, there will be a need for an initial survey at all sites where finishing activities take place and the risk assessment suggests that there may be a problem. This initial cost is calculated as one consultant for a day plus 4 samples per site, a total of £500 plus £160 per site. We have assumed that for a MEL set at 1 f/ml, 49% of sites will need to monitor and, for a MEL set at 0.5 f/ml, 76% of sites will need to monitor. Of these sites we anticipate there will be a recurring cost every five years for one technician/day and 4 samples to be analysed (£200 plus £160).

69 Thus, for a MEL set at 1 f/ml, initial costs will be between 660 x 49% x 500 = £162k and £186k. Total recurring costs will be between £195k and £249k. For a MEL set at 0.5 f/ml, initial costs will be between £251k and £289k. Total recurring costs will be between £302k and £386k.

Engineering controls

70 To reduce RCF exposure to below 1 f/ml using engineering controls, we have assumed that one unit of LEV will need to be installed at some sites at a cost of £5000 per item, plus annual costs of £500. For a MEL set at 1 f/ml, we have assumed that 49% of 500 sites (245 sites) will install these controls at a cost of 245 x £5k = £1225k with ten yearly annual costs of 245 x £0.5k = £122.5k. For a MEL set at 0.5 f/ml, we have assumed that 76% of 500 sites (380 sites) will install this equipment at a cost of 380 x £5k = £1900k and annual costs of 380 x £0.5k = £190k.

RPE

71 Current RPE usage is 50% (ECFIA data). We anticipate that this will not change as a consequence of the change in the MEL

Total Finishing

72 Thus, the total increased costs in finishing for a MEL set at 1 f/ml will be approximately **£2.4m.** (Initial costs will be approximately £1,387k to £1,411k, recurring costs will be approximately £967k to £1,004k).

73 For a MEL set at 0.5 f/ml, it will be approximately **£3.7m.** (Initial costs will be approximately £2,151k to £2,188k, recurring costs will be approximately £1,500k to £1,558k).

(e) Assembly

Monitoring

74 Following the setting of a new MEL, there will be a need for an initial survey at all sites where assembly activities take place and the risk assessment suggests that there may be a problem. This initial cost is calculated as one consultant for a day plus 4 samples per site, a total of £500 plus £160 per site. We have assumed that for a MEL set at 1 f/ml, 7% of 300 sites (21 sites) will need to monitor and, for a MEL set at 0.5 f/ml, 13% of sites (39 sites) will need to monitor. Of these sites we anticipate there will be a recurring cost every five years for one technician/day and 4 samples to be analysed (£200 plus £160).

75 Thus, for a MEL set at 1 f/ml, initial costs will be 660 x 7% x 300 (sites) = £14k. Total recurring costs will be between £18k and £20k. For a MEL set at 0.5 f/ml, initial costs will be 660 x 13% x 300 (sites) = £26k. Total recurring costs will be between £31k and £40k.

Engineering controls

76 To reduce RCF exposure to below 1 f/ml using engineering controls, we have assumed that one unit of LEV will need to be installed at some sites at a cost of £5000 per item, plus annual costs of £500. For a MEL set at 1 f/ml, 21 sites (7% of 300) will install this equipment at initial and ten year annual costs of 21 x £5k = £105k and 21 x £0.5k = £10.5k respectively. For a MEL set at 0.5 f/ml, 39 sites (13% of 300) will install this equipment at initial and ten yearly annual costs of 39 x £5k = £195k and 39 x £0.5k = £19.5k respectively.

RPE

77 Current RPE usage in assembly is assumed to be around 50% (similar to production and installation) and therefore we do not anticipate any increased RPE usage because of the MEL change.

Total Assembly

78 Thus, the total increased costs in assembly for a MEL set at 1 f/ml will be between **£202k and £207k** over ten years in net present value terms. (Initial costs will be approximately £119k to £121k, recurring costs will be approximately £83k to £86k).

79 For a MEL set at 0.5 f/ml, it will be between **£375k and £385k** over ten years in net present value (Initial costs will be approximately £221k to £225k, recurring costs will be approximately £154k to £160k).

(f) Installation

Monitoring

80 Following the setting of a new MEL, there will be a need for an initial survey at all sites where installation activities take place and the risk assessment suggests that there may be a problem. This initial cost is calculated as one consultant for a day plus 4 samples per site, a total of £500 plus £160 per site. We have assumed that for a MEL set at 1 f/ml, no sites will need extra monitoring and, for a MEL set at 0.5 f/ml, 12% of sites will need extra monitoring. Of these sites we anticipate there will be a recurring cost every five years for one technician/day and 4 samples to be analysed (£200 plus £160).

81 Thus, for a MEL set at 1 f/ml, there will be no extra costs and for a MEL set at 0.5 f/ml, initial and ten yearly costs will be 660 x 12% x 100 = £7.9k and total recurring costs will be between £5k and £6k.

Engineering controls

82 To reduce RCF exposure to below the new MEL using engineering controls, we have assumed that one unit of LEV will need to be installed in some sites at a cost of £5000 per item, plus annual costs of £500. For a MEL set at 1 f/ml, no sites will need extra engineering controls. For a MEL set at 0.5 f/ml, there will be 12 sites (12% of 100) that will install these controls at an initial and ten yearly annual cost of 12 x £5k = £60k and 12 x £0.5k = £6k respectively.

RPE

83 Current RPE usage in installation is 53% and we assume this will not increase with a change in MEL.

Total Installation

84 Thus, the total increased costs in installation for a MEL set at 1 f/ml is **zero**, and for a MEL set at 0.5 f/ml, it will be between **£115k and £118k** over ten years in net present value terms. (Initial costs will be approximately £68k to £69k, recurring costs will be approximately £47k to £49k).

(g) Removal

Monitoring

85 For removal activities, we have assumed that no extra monitoring will be required. There is a reasonable assumption that in many cases, RCF exposures will be above any new MEL. We have calculated no extra costs for either a MEL set at 1 f/ml or one set at 0.5 f/ml.

Engineering control

86 In the case of RCF removal, engineering controls are more restricted. Enclosures with extraction are already routine, but static LEV is not usually considered.

RPE

87 Currently 80% of employees in removal activities use RPE of various forms. With the current MEL set at 2 f/ml, and the nature of RCF removal, this figure should be 100%. A powered respirator should be suitable for a MEL of 1 f/ml or of 0.5 f/ml, as long as the face fit is appropriate and training and supervision during use is adequate. This will apply to any of the MELs suggested, therefore there will be no extra costs associated with RPE usage.

88 It is difficult to quantify extra costs for wetting of all fibres where possible, but this measure is an extra one to be considered for both MELs.

89 Thus, there are no calculated increased costs for removal activities for a MEL set at either 1 f/ml or 0.5 f/ml.

(h) Other

Monitoring

90 Following the setting of a new MEL, we believe the monitoring stimulus will be based on other activities and there will be no need for any extra costs.

Engineering controls and RPE

91 Currently, only 8% of RCF exposures in this category are above 0.5 f/ml, and only 1% are above 1 f/ml. We believe that alterations to controls in the other six categories will result in reduced RCF exposure as a consequence. Therefore no extra costs are envisaged for this sector.

92 Table 5 summarises the capital and ten year running costs for the two potential MELs as calculated in the previous sections.

Table 5. Total costs in all sectors for a MEL reduced to either 1 f/ml or 0.5 f/ml.

Industry sector	MEL option f/ml	Monitoring costs £k	Engineering costs £k	RPE costs £k	Total costs £k (NPV)
production	1	0	0	0	0
	0.5	0	34	0	34
Mixing-forming	1	17 - 21	121	0	138 - 142
	0.5	19 - 35	202	0	221 - 237
Modules	1	0	0	0	0
	0.5	0	0	0	0
Finishing	1	296 - 318	2,058	0	2,354 -

					2,376
	0.5	495 - 554	3,192	0	3,651 - 3,747
Assembly	1	25 - 31	176	0	202 - 207
	0.5	47 - 57	328	0	375 - 385
Installation	1	0	0	0	0
	0.5	14 - 18	101	0	115 - 118
Removal	1	0	0	0	0
	0.5	0	0	0	0
All sectors	1	338 - 370	2,355	0	2,694 - 2,725
	0.5	575 - 664	3,823	0	4,396 - 4,521

Compliance costs to charities and voluntary organisations

93 There will be no compliance costs to charities or to voluntary organisations.

TOTAL COMPLIANCE COSTS

MEL set at 1 f/ml

94 Total compliance costs over ten years are equivalent to between approximately £2,700k and £2,800k in net present value terms.

95 Table 6 below shows the undiscounted annual costs over ten years for a MEL of 1 f/ml. All of these costs are policy costs. There are no implementation costs.

Table 6. Annual undiscounted costs for a MEL of 1 f/ml.

	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Yr10
Cost (£k) min	1,587	140	140	140	247	140	140	140	140	257
max	1,615	140	140	140	276	140	140	140	140	289

MEL set at 0.5 f/ml

96 Total compliance costs over ten years are equivalent to between approximately £4,400k and £4,500k in net present value terms.

97 Table 7 below shows the undiscounted annual costs over ten years for a MEL of 0.5 f/ml.

Table 7 Annual undiscounted costs for a MEL of 0.5 f/ml.

	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Yr10
Cost (£k) min	2,595	230	230	230	402	230	230	230	230	418
max	2,641	230	230	230	450	230	230	230	230	471

Costs to HSE

98 Because of the proposed change to a MEL, there will be an increased emphasis on RCF exposure at all premises during inspection visits. However any increased workload for inspectors, in HSE or the local authority enforced areas, is likely to be minimal. Hence it is estimated that additional enforcement costs should also be low.

Total costs to society

99 The majority of the societal cost is borne by industry. This is detailed above.

IMPACT ON SMALL AND MEDIUM SIZED BUSINESSES, "LITMUS TEST"

100 Five SMEs were contacted and the proposed change in the MEL for RCF briefly explained. All were aware that a change was imminent and all were very concerned about the financial implications, particularly with a MEL set at 0.5 f/ml. One company, involved in making RCF products for twenty years, said that "Compliance with a MEL below 1 f/ml will be almost impossible to achieve." They were concerned that the work would have to go overseas..."where standards are lower."

101 Another company suggested that because of their relatively cramped premises, a MEL set below 1 f/ml would mean they would have to relocate to allow for the increased space for extraction. This, they thought, could be terminal for the company. Another small company, having recently spent large sums of money on control, would need even larger sums for a MEL set at 0.5 f/ml.

102 One company believes that a MEL set below 1 f/ml will reduce RCF usage and increase the less thermally-efficient firebrick usage with much increased energy costs.

103 A company involved in finishing operations emphasised the problem of reducing exposure below 0.5 f/ml even with efficient extraction. The lighter fibres are more difficult to capture and excursions above 0.5 almost inevitable.

104 Overall, they believed that a MEL set at 0.5 f/ml would have far reaching implications and would be extremely difficult to achieve.

ENVIRONMENTAL IMPACTS

105 There are no environmental impacts other than the health effects already discussed.

COMPETITION ASSESSMENT

106 A very large number of firms are engaged in the activities identified, and will therefore be affected by the proposed MEL. These firms represent various industries, such as domestic appliance manufacturing, metal processing, kiln lining manufacture and use and fire protection. Given the large number of companies involved (other than

the two firms only engaged in production), and the fragmented market structure, the proposals would have no marked effect on competition in any market concerned with RCFs. There is no provision for differential treatment of firms, new or existing, in implementing the proposed MEL, so new entrants to any market will not face cost barriers. Finally, costs imposed are not very high, and should not have an adverse impact on technology and choice in the affected industries.

BALANCE OF COSTS AND BENEFITS

107 There will be a cost to industry associated with compliance to a lower MEL for RCF set at either 1 f/ml or 0.5 f/ml. The total cost of a MEL set at 1 f/ml is expected to be in the range of £2,700k and £2,800k in present values over a ten year appraisal period. The total cost of a MEL set at 0.5 f/ml is expected to be between approximately £4,400k and £4,500k over the same appraisal period. However, the RIA has to group companies together and multiply up the "average" costs of the groups. In some cases, this means small companies may have disproportionately large costs per worker.

108 The benefits are subject to substantial uncertainties. It has not been possible to quantify benefits as there is no conclusive evidence regarding dose and effects.

109 However, it is useful to consider what the costs per worker exposed are from setting this MEL, and how these costs compare with past MELs. The table below shows the cost to employers per worker exposed (rounded figures) of approved MELs for substances that were labelled with the risk phrase R45 'may cause cancer'.

Table 8: Cost of exposure per worker in several recent MELs

Substance	**Cost per worker exposed (£, 1999/2000 prices)**
Dimethyl sulphate and diethyl sulphate	410-550
Hydrazine	390-1,330
Vanadium pentoxide	
MEL 0.5 mg.m^{-3} Engineering control strategy	390-1,480
RPE control strategy	440-1,390
MEL 0.1 mg.m^{-3} Engineering control strategy	430-1,590
RPE control strategy	680-1,800
MEL 0.05 mg.m^{-3} Engineering control strategy	550-1,830

RPE control strategy	1130-2,670
Phenol	
MEL (2 ppm)	13.54 - 15.47
MEL (3 ppm)	2.48- 2.84
RCF	
MEL (1 f/ml)	**504-518**
MEL (0.5 f/ml)	**825-846**

110 Table 8 shows that if employers follow the suggested MELs for RCF, the cost per employee exposed is likely to be around the same as the costs per employee exposed when a MEL was set for other carcinogenic substances. In other words the cost per exposed worker for either of the MELs considered for RCF is lower than that which was thought acceptable for past MELs which were approved.

111 On the basis of the above figures it is not possible to compare benefits to costs. However, the cost per worker exposed can be used as an indicator of likely benefits. In the absence of data on predicted cases that will be prevented, the cost per worker exposed figures provide justification for approving this MEL, particularly considering the relatively small cost levied on industry.

Uncertainties

112 There are many uncertainties in any estimate of compliance costs for a MEL These uncertainties are increased where an industry involves a variety of tasks within one site and a preponderance of smaller companies.

113 The costs to some sectors of industry, particularly small businesses, of meeting a fibre limit at 0.5 fibres/ml are likely to be far higher than the modest costs associated with the 1 fibre/ml level. This is largely due to the ease with which fibre levels between 0.3 - 0.8 fibres/ml can be generated through light handling of some RCF products. Whereas it is very unlikely 1 fibre/ml (8-hour TWA) will be exceeded through this type of activity, exposures above 0.5 fibres/ml are often unpredictably produced at processes where it is difficult to apply engineering controls. HSE surveys in the late 1980's/early 1990's support this conclusion (Phillips, 1990).

114 Because of these uncertainties, which could significantly increase the costs of compliance with a MEL set at the lower level, the bottom line figures need to be understood in this context.

Arrangements for monitoring and evaluation

115 The proposed MEL will be enforced by HSE at the premises where they are the enforcing agency and by the Local Authority at premises where they are the enforcing authority. The change in the MEL is likely to lead to an increased emphasis on RCF exposure at all these premises. This may result in an increased workload for all

Inspectors with the potential for an increase in prosecutions for Health and Safety offences for the sectors concerned.

SUMMARY AND RECOMMENDATIONS

116 Although extra costs will be incurred with a reduction in the RCF MEL, we believe that a reduction to 1 f/ml is practicable. Reduction to 0.5 f/ml is likely to have far reaching implications, in particular for small companies which would find this extremely difficult to achieve.

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APPENDIX – ADDITIONAL INFORMATION RECEIVED FROM ECFIA FOLLOWING THE MARCH ACTS MEETING

1 At the ACTS meeting in March 2002, concern was expressed because assumptions in the RCF RIA were based on relatively little data. In particular, the mixing / forming section conclusions were based on only 25 samples, representing fewer than six companies.

2 In response, HSE agreed to re-evaluate the data and, by studying selected examples, see if the conclusions were an accurate reflection of reality. ECFIA offered to supply detailed exposure results and costing to allow HSE to undertake this exercise.

3 Table 1 below shows data from the RCF RIA presented to the March 2002 meeting of ACTS.

Table 1: RCF RIA data. Mixing/forming – RCF exposures (8-hour TWAs) between 1996 and 2000

Group	Number of samples	% above 2 f/ml	% above 1 f/ml	% above 0.5 f/ml
Customers	**25**	**0**	**12**	**20**

4 Table 2 below shows the latest RCF exposure data from ECFIA. Covering the period 2001 to 2002.

Table 2: RCF exposure data (8-hour TWAs) from ECFIA sampling undertaken between 1996 and 2001

Group	Number of samples	% above 2 f/ml	% above 1 f/ml	% above 0.5 f/ml
Manufacturers	181	3	10	27
Customers	**34**	**0**	**13**	**31**
All groups	215	2	10	28

The enlarged data set shows similar results.

5 To examine the accuracy of the costing, two sites were available at which initial sampling had shown elevated RCF exposures that required action. These companies were included in the original results presented to ACTS (Table 1). These two companies then installed improved control measures. Re-sampling of RCF exposure by ECFIA allows the effects to be evaluated.

6 *Site 1*

This company manufactures backboards and shaped logs/coals for gas fires and this process involves mixing/forming, finishing and spraying. It employs 39 workers in these tasks.

7 Table 3 below shows the RCF 8-hour TWA results (f/ml) from three separate sampling periods for mixing/forming operations between 1998 and 2002.

Table 3: RCF exposure (f/ml) during mixing/forming operations at site 1.

Unit	1998	2001	2002
1	1.1	0.57	-
1	1.4	0.52	0.49
1	1.2	0.96	-
2	-	0.61	-
3	-	1.53	0.47

The fibre is added to a tank of water and mixed well. Between 1998 and 2001, the mixing tanks were lidded. Since 2002, a new dust collection system has been added.

8 Table 4 below shows the RCF 8-hour TWA results (f/ml) from three separate sampling periods for hand/machine finishing between 1998 and 2002.

Table 4: RCF exposure (f/ml) during finishing operations at Site 1.

Unit	1998	2001	2002
3	-	2.18	-
4	4.40	1.18	0.30
4	-	2.41	0.44
4	1.50	0.91	-
2	-	0.97	-
2	-	-	2.28

Between 1998 and 2001, a new extraction bench was installed and between 2001 and 2002, the extraction was improved and finishing was segregated from the forming/mixing operations.

9 Table 5 below shows the RCF 8-hour TWA results (f/ml) from three separate sampling periods for packing. The shapes are coated before packing and any dust measured is from loose fibres from the drying trays.

Table 5: RCF exposure (f/ml) during packing operations at site 1

Unit	1998	2001	2002
4	0.60	0.54	-
4	0.60	0.34	-

10 The total costs for materials (extraction equipment, vacuum cleaners, lids, ducting), at site 1 during the first year were £22,450 and total time costs were £7,450. Currently, because RCF exposure is above 2 f/ml at one or two finishing tasks, PPE is used to ameliorate the exposures. A new extraction system is being commissioned and a full time hygienist has been employed on site.

11 The extra costs of the PPE for is currently broken down as follows:

Overalls £850 month, masks £250 month and gloves £300 month -making a total cost of £1400 monthly.

12 *Site 2*

This company manufactures shapes for gas fires and employs 11 workers in these processes of mixing/forming, finishing, and packing.

13 Table 6 below shows the RCF 8-hour TWA results from three separate sampling periods for mixing/forming operations. These values were included in the information submitted to ACTS previously (Table 1).

Table 6: RCF exposure (f/ml) during mixing forming operations at Site 2.

Sample number \ Date	1997	1999	2002
1	-	0.21	0.08
2	0.2	0.2	0.09

14 Table 7 below shows the RCF 8-hour TWA results (f/ml) from three separate sampling periods for routing and finishing procedures.

Table 7: RCF exposure (f/ml) during finishing operations at Site 2.

Sample number \ Date	1997	1999	2002
1	-	3.05	2.1
2	2.2	1.62	-
3	-	1.58	-
4	1.9	-	0.76

Between 1997 and 1999, the company separated each procedure into small cubicles and introduced improved extraction. Between 1999 and 2002, the company employed ventilation engineers to optimise their extraction. Since 2002, the company use PPE at the machine finishing.

15 Table 8 below shows the RCF 8-hour TWA results (f/ml) from three separate sampling periods for dipping/spraying operations.

Table 8: RCF exposure (f/ml) during dipping/spraying operations at Site 2

Sample number \ Date	1997	1999	2002
1	-	0.18	0.07
2	-	0.19	0.11

Comparison of observed and estimated costs:

Estimated costs in the RIA

16 *Mixing/forming*: The RIA on RCFs, presented to ACTS in March 2002, suggested that of the 25 8-hour TWA samples, 3 (12%) were above 1 f/ml and 5 (20%) were above 0.5 f/ml. On this basis, we calculated additional costs would be needed if a lower MEL for RCF (0.5 f/ml or 1 f/ml) were set.

17 Extra monitoring was calculated at £17K - £21K in ten-year present value terms for a MEL of 1f/ml, and £19K - £35K for a MEL of 0.5f/ml. However, in the two observed cases the extra monitoring costs were borne by ECFIA, and cannot be compared to the RIA estimate.

18 Extra engineering control costs were calculated at either £121k (for a MEL set at 1.0 f/ml) or £202k (for a MEL set at 0.5 f/ml). This represents an initial cost of £5k for each affected site and annual running costs of £0.5k.

19 We assumed no extra costs for PPE.

20 *Finishing*: The RIA of RCFs, presented to ACTS in March 2002, suggested that of the 45 samples, 9 (20%) were above 2 f/ml, 22 (49%) were above 1 f/ml and 34 (76%) were above 0.5 f/ml. And on this basis, we calculated additional costs would be needed if a lower MEL for RCF were to be set.

21 Extra monitoring was costed for some companies in the RIA, amounting to a ten-year net present value of £296K - £318K for a MEL of 1f/ml, and £495K - £554K for a MEL of 0.5 f/ml. However, in the two observed cases the extra costs were borne by ECFIA again, and cannot be compared to the RIA estimate.

22 Extra engineering control costs were calculated at either £2,058 (for a MEL set at 1.0 f/ml) or £3,192k (for a MEL set at 0.5 f/ml). This represents an initial cost of £5k for each affected site and annual running costs of £0.5k.

23 We assumed no extra costs for PPE.

24 At both observed sites, mixing/forming and finishing take place, and it is difficult to separate the costs. Based on the calculations presented to ACTS in March 2002, the combined costs would be an initial cost of £10k and running costs of £1k annually per

site for these two processes, making a ten yearly cost of **£16,802** per site in present value terms. These are the costs of engineering controls only. Monitoring costs have not been included, as they cannot be compared with the observed costs. However, if monitoring were included, the total costs per site would not rise significantly: only to about £17,248 in ten-year present value terms.

<u>Observed costs</u>

25 To reduce RCF exposures below 0.5 f/ml, the company at Site 1 produced estimated total costs of £30,000 (£22.5k for materials and £7.5k for labour). The material costs included vacuum cleaners, a new extractor bench, new extraction for shapes and for the fettling area, and a new fan for the spray booth. Running costs were not stated, but assuming 10%, this represents about £2,250 annually. Consumable costs were stated to be £1,400 per month (£16.8k annually) but these included gloves and disposable overalls, much of which would be needed for the current MEL and we have not used this data. So the overall costs were £30,000 with recurring annual costs of £2,250, around £45,300 in present value terms.

26 At Site 2, approximately £32,000 has already been spent and this does not include the costs of training and installation of the equipment. To reduce the RCF exposures below 0.5 f/ml, the company estimates that there will be an extra capital investment of £20,000 to £25,000 with additional PPE costing £6,000 annually. Extra running costs would therefore be £2,000 – £2,500 annually, around £37,800 in present value terms.

27 The ECFIA data implies that, at a MEL of 0.5f/ml, the average cost per site is around **£41,500** in present value terms.

<u>Conclusion</u>

28 The ECFIA data should not be seen as more or less accurate than the RIA estimates, and therefore has not been added to or averaged with that earlier data. The RIA estimates were ex ante projections of probable costs to all the firms affected. This ECFIA data presents ex post values for two affected firms, and may not be representative of the costs to other firms. However, ECFIA's occupational hygienists did observe these figures as fairly accurate for the two sites concerned, so it merits comparison with the RIA.

29 The extra data suggests that our original values were accurate. However, as well as pre-programmed sampling, ECFIA includes requests in their measurement programme. These may result from HSE inspectorial activity or other perceived problems and will be biased towards the sites with higher exposures in a similar manner to HSE measurements.

30 Hence, the fact that we have underestimated costs by a factor of more than 2 should not be cause for alarm. Average costs per site should be significantly lower than those implied by the ECFIA data in practice. Still, these companies demonstrate that

the exposure reductions can be achieved even if the cost may be higher than we anticipated.

Comparison of average cost per site, RIA and ECFIA estimates.

ESTIMATE	Initial cost	Recurring costs	10-year NPV
RIA	10,000	1,000	**16,802**
ECFIA	26,250	2,250	**41,554**

(MEL 0.5f/ml, £)