Workplace Exposure Standard (WES) review

SYNTHETIC VITREOUS FIBRES (SVF)

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New Zealand Government

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1.0
Introduction

This WorkSafe New Zealand (WorkSafe) review considers whether the **WES** for synthetic vitreous fibres (**SVF**) should be changed.

It considers, among other things, the potential for exposures to SVF in New Zealand, the health effects and risks, exposure standards in other jurisdictions around the world, and the practicability of measuring exposure to SVF.

The review includes a recommendation to change the WorkSafe WES, which is currently set at a **WES-TWA** of 1 respirable fibre per millilitre of air and 5 **mg/m³** inhalable dust, as published in the Special Guide *Workplace Exposure Standards and Biological Exposure Indices*, 9th Edition, (WorkSafe New Zealand, 2017).

Terms that are **bold** (first occurrence only) are further defined in the Glossary. Also note:

- 1 **ml** = 1 **cm³** = 1 cc.
- Synonyms of synthetic vitreous fibres (SVF): synthetic mineral fibres (**SMF**); man-made mineral fibres (**MMMF**); mineral wool fibres; man-made vitreous fibres (**MMVF**).
- Subgroups of SVF: continuous glass filament; glass wool; rock (stone) wool; slag wool; fibrous glass dust; glass, fibrous or dust; refractory ceramic fibres (*also* aluminosilicate wool, ASW).

2.0 Physical and chemical properties

Synthetic vitreous fibres are a heterogeneous group of fibrous inorganic materials formed from molten rock, slag, clay, glass or synthetic ceramic mixes which are spun, blown or drawn into amorphous fibrous forms.

Synthetic vitreous fibres (SVFs) are non-crystalline (glassy, vitreous or amorphous). They are manufactured by a variety of processes based on the attenuation of a thin stream of molten inorganic oxides at high temperatures. All commercially important SVFs are silica-based and contain various amounts of other inorganic oxides. The non-silica components typically include, but are not limited to, oxides of alkaline earth, alkalis, aluminium, boron, iron and zirconium. SVFs have a broad variety of chemical compositions (**IARC**, 2002); (**SCOEL**, 2012).

The 2002 IARC review divided man-made vitreous fibres (MMVF – a synonym for SVF) into filaments and wools, then into subgroups, loosely based on raw materials, production process, and/or production application as described in Figure 1.

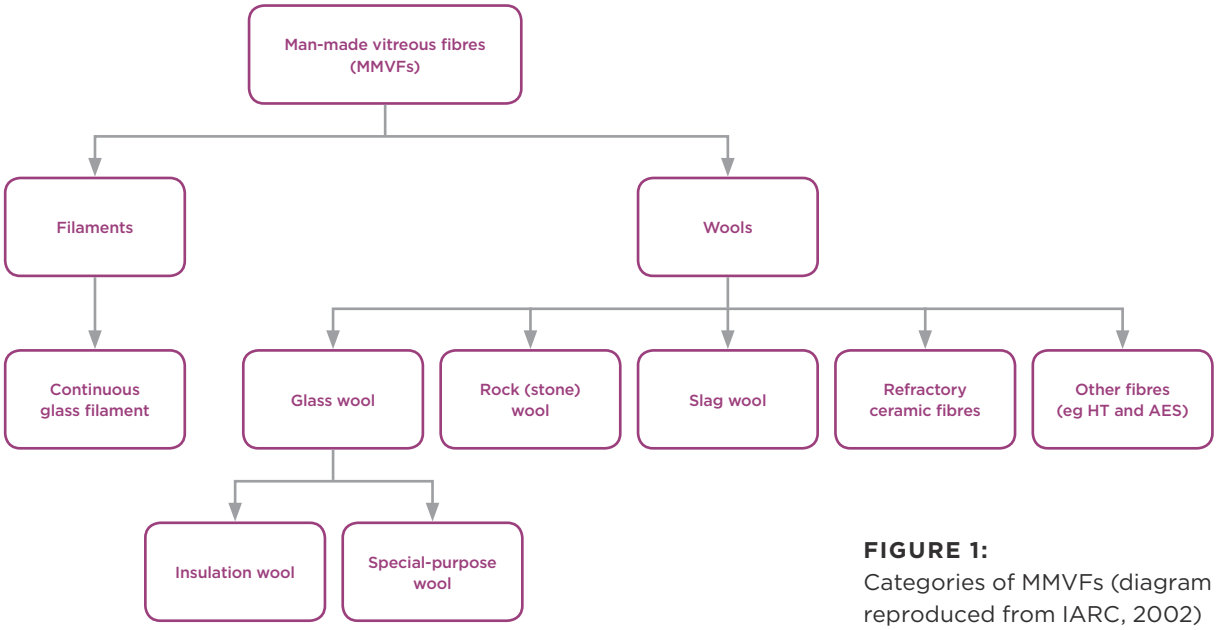

FIGURE 1:
Categories of MMVFs (diagram reproduced from IARC, 2002)

HT = high-alumina, low-silica wools; AES = alkaline earth silicate wools

The physical structure and chemical composition significantly impact the toxicological hazard profile and health risk characteristics of SVFs.

Physical structure

The fibre diameter and length determine if the fibre can be breathed into the nose or mouth (**inhalable particulate fraction**), or penetrate beyond the terminal bronchioles into the gas-exchange region of the lungs (alveoli) (**respirable particulate fraction**). As SVFs are amorphous (non-crystalline), they do not have cleavage planes that cause them to split lengthwise into fibres with smaller diameters (*c.f.* asbestos), but break across the fibre resulting in shorter fibres with the same diameter (IARC, 2002).

Physical structure influences leaching of the fibres and their reactions to mechanical stress (SCOEL, 2012).

Chemical composition

Leaching favours dissolution and disintegration of the fibre and it changes the surface characteristics of the fibre, such as specific surface area, surface charge, the presence of iron ions and the fibre dimensions. Fibre surface and fibre dimensions affect interactions with biological structures and the generation of reactive oxygen species (**ROS**) (SCOEL, 2012).

Synthetic vitreous fibres are non-crystalline and remain vitreous when used at temperatures below 500°C. At higher temperatures, they flow, melt or crystallise depending on their composition. High-silica and low-alkali metal oxide compositions such as refractory ceramic fibres, AES wools, and some rock (stone) wools will start to crystallise at temperatures above 900°C. The crystalline phases produced will depend on composition and temperature. Longer exposure times are required for fibre devitrification at lower temperatures (Brown *et al*., 1992; Laskowski *et al.*, 1994, references are cited in IARC, 2002). One such product, cristobalite, is classified by IARC as carcinogenic to humans (Group 1) (AIOH, 2016).

The 2006 NIOSH review defined SVFs and refractory ceramic fibres (RCFs) as follows:

> "SVFs include a number of manmade (not naturally occurring) fibers that are produced by the melting and subsequent fiberization of kaolin clay, sand, rock, slag, and other materials. The major types of SVFs are fibrous glass, mineral wool (slag wool, rock wool), and ceramic fibers (including RCFs). SVFs are also frequently referred to as manmade mineral fibers (MMMFs) or manmade vitreous fibers (MMVFs)."
>
> "RCFs are a type of SVF; they are amorphous synthetic fibers produced from the melting and blowing or spinning of calcined kaolin clay or a combination of alumina (Al_2O_3) and silicon dioxide (SiO_2). Oxides such as zirconia, ferric oxide, titanium oxide, magnesium oxide, calcium oxide, and alkalis may be added. The percentage of components (by weight) is as follows: alumina, 20% to 80%; silicon dioxide, 20% to 80%; and other oxides in smaller amounts. Like the naturally occurring mineral fibers, RCFs possess the desired qualities of heat resistance, tensile strength, durability, and light weight. On a continuum, however, RCFs are less durable (ie more soluble) than the least durable asbestos fiber (chrysotile) but more durable than most fibrous glass and other types of SVFs." (NIOSH, 2006)

European Union Regulations define two broad groups of SVFs, plus specific fibres, as outlined in Table 1 below:

INTERNATIONAL CHEMICAL IDENTIFICATION	HAZARD CLASS AND CATEGORY CODE(S)	NOTES
Mineral wool, with the exception of Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content greater than 18 % by weight	Carc. 2 Skin Irrit. 2	Q, R
Refractory Ceramic Fibres, Special Purpose Fibres, with the exception of Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+$ MgO+BaO) content less or equal to 18 % by weight	Carc. 1B Skin Irrit. 2	R

TABLE 1:
EU definitions of SVFs, extracted from Table 3.1 of EU Regulation 1272/2008

The 2011 **DECOS** review noted that the Chemical Abstract Service defined RCFs (CAS No. 142844-00-6) as fibres with a weight percentage composition variable between 20 and 80% in alumina, 20 and 80% in silica, and a low percentage of other oxides and with thermal resistance (DECOS, 2011).

This review also noted that the World Health Organization (**WHO**) considers a fibre to be a particle with a diameter of less than 3 µm and a length of more than 5 µm, which has a length/diameter aspect ratio of at least 3. Furthermore, the WHO considers fibres as respirable for humans when they have a mass median aerodynamic diameter (**MMAD**) of approximately 3.5 µm or less (**IPCS**, 1988; DECOS, 2011).

Carc. 2 Described in **EU** Regulation 1272/2008 as meeting Carc. Cat 3; R40 from Annex VI of EU Directive 67/548/EEC. Carc. Cat 3 means the substance is possibly carcinogenic to man, but the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance into Category 2. R40 means limited evidence of a carcinogenic effect.

Carc. 1B Described in EU Regulation 1272/2008 as meeting Carc. Cat 2; R49 from Annex VI of EU Directive 67/548/EEC. Carc. Cat 2 means the substance should be regarded as if it is carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of cancer, generally on the basis of appropriate long-term animal studies or other relevant information. R49 means may cause cancer by inhalation.

Skin Irrit. 2 Meaning from EU Regulation 1272/2008, as shown below:

Skin irritation category

CATEGORY	CRITERIA
Category 2: Irritant	1. Mean value of ≥ 2,3 – ≤ 4,0 for erythema/eschar or for oedema in at least two of three tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on three consecutive days after the onset of skin reactions 2. Inflammation that persists to the end of the observation period normally 14 days in at least two animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling or 3. In some cases where there is pronounced variability of response among animals, with very definiate positive effects related to chemical exposure in a single animal but less than the criteria above.

Q The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:
- a short term biopersistence test by inhalation has shown that the fibres longer than 20 **µm** have a weighted half-life less than 10 days
- a short term biopersistence test by intratrachael instillation has shown that the fibres longer than 20 µm have a weighted half-life less than 40 days
- an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity, or
- absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.

R The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter less than two standard geometric errors greater than 6 µm.

3.0
Exposures

Synthetic vitreous fibre exposure can occur in various industries, including manufacture of fibres, fibreglass, thermal insulation, acoustic insulation, filtration media, plastic reinforcement and furnace insulation.

Exposure to SVF can occur during the manufacture, installation and removal of SVF containing products. Demolition activities, particularly involving 'aged' SVFs subjected to high temperatures over prolonged periods, can lead to exposures with different hazard profiles from the same products during manufacture and installation.

The 2016 AIOH review noted for Australia, that:

> "While SMF is a stand-alone material it has also become an important replacement for asbestos in a variety of products where thermal insulation, acoustic insulation, or electrical or fire protection is required.
>
> Glass wool and rock wool represent the bulk majority of SMF use, being used extensively in thermal and acoustic building insulation products such as batts, boards, blankets, and sheets and loose fill for ceilings, walls and air-conditioning systems.
>
> Continuous glass filament is used as reinforcement in plastics and building products, and in industrial fabrics. Continuous glass filament is used as chopped strand and is often woven into yarn or mats for such applications as reinforcing in 'fibreglass-resin' boat hulls and decks, nose cones for aeroplanes, surfboards and motor vehicle bodies.
>
> A very small proportion of the market is occupied by the use of special purpose glass fibres such as E-glass and '475' glass. These special purpose glass fibres are used as acid battery separators and high-efficiency air filtration media.
>
> RCFs and high temperature performance AES blankets, boards and shapes are used primarily in industry as insulation for high-temperature applications such as furnaces, boilers and other heating equipment subjected to temperatures up to 1350°C. They are also used as insulation in aerospace, automotive and appliance industries, and in marine fire protection applications." (AIOH, 2016)

Statistics New Zealand 2016 data indicate that 60,780 New Zealand workers were working in the areas of:

- ceramic product manufacturing
- glass product manufacturing
- land development and site preparation services (includes demolition)
- building installation services and
- building completion services.

35,980 New Zealand workers were employed just in the ceramic product manufacturing; glass product manufacturing; and building installation services areas (Statistics New Zealand, 2017).

4.0 Health effects of SVF

IN THIS SECTION:

The toxicological hazard profiles of SVFs are significantly influenced by their physical structure and chemical composition.

Apart from dose, fibre dimensions and residence time in the lungs are the main factors that distinguish between SVFs that should be presumed to be carcinogenic to humans, and those that are not.

4.1 Non-Cancer

The 2001 American Conference of Governmental Industrial Hygienists (**ACGIH®**) review noted that continuous glass filaments, glass wool, rock wool and slag wool may produce irritation or itching in some workers due to mechanical effects of the fibres on the skin. They noted that irritation may also occur in the nose, upper respiratory tract and eyes, and that fibres in excess of 5 μm in diameter were most associated with mechanical irritation. (Heisel, E.B. et al, 1968; Fisher, B.K. et al, 1969; Possick, A.A. et al, 1970). Inhalation of glass wool fibres may also produce a temporary mechanical irritation of the nose and upper respiratory tract (Milby, T.H. et al, 1969; Newable, H.H. et al., 1976) (references cited in ACGIH®, 2001).

The 2001 ACGIH® review, in relation to skin and respiratory irritation of RCFs, noted:

> "RCFs may irritate the skin of workers in manufacturing facilities and of those who use RCFs. RCFs may cause temporary irritation of the upper respiratory tract among workers producing or using RCFs." (Trethowan, W.N. et al, 1995, reference cited in ACGIH®, 2001).

The 2016 AIOH review noted that it is well documented that SVFs can cause irritation of the eyes and skin. They can also irritate the upper respiratory tract (the nose and throat) and parts of the lung, causing sore throat, nasal congestion and cough (**NOHSC**, 1989a). The irritation caused by SVFs is by a mechanical action caused by a 'splinter' type effect from thicker fibres rather than an inflammatory response. These acute irritant effects are generally temporary (reference cited in AIOH, 2016).

The 2012 SCOEL review summarised several long-term dose response inhalation studies that had not been reviewed in the earlier 1995 DECOS review. In most studies inflammation of the lung and/or slight alveolar fibrosis was observed, but no pulmonary neoplasm or mesothelioma were reported:

FIBRE	SPECIES/DURATION	EXPOSURE (mg/m^3)	NOAEL	DECOS Ref*
MMVF10	Rats, 24 mo, 6h/d, 5d/w	3, 16, 30	3 mg/m^3 (25 **f/ml**)	1
MMVF11	Rats, 24 mo, 6h/d, 5d/w	3, 16, 30	3 mg/m^3 (25 f/ml)	1
MMVF10	Rats, 78 w, 6h/d, 5d/w	3, 16, 30, 45, 60	3 mg/m^3 (25 f/ml) (**LOAEL**)	1
MMVF10.1	Hamster, 13 w, 6h/d, 5d/w	3, 16, 30, 45, 60	3 mg/m^3 (25 f/ml) (LOAEL)	1
MMVF10a, MMVF33	Hamster, 78 w, 6h/d, 5d/w	30	Not determined	2
MMVF21	Rats, 104 w, 6h/d, 5d/w	3, 16, 30	3 mg/m^3	2
MMVF22	Rats, 104 w, 6h/d, 5d/w	3, 16, 30	3 mg/m^3 (30 f/ml)	2
MMVF21	Rats, 13-104 w, 6h/d, 5d/w	16, 30	Not determined	3
MMVF34/HT	Rats, 13-104 w, 6h/d, 5d/w	30	Not determined	3
TISMO	Rats, 24 mo, 6h/d, 5d/w	20, 60, 200 f/ml	20 f/ml	4
X607	Rats, 24 mo, 6h/d, 5d/w	200 f/ml (≈16 mg/m^3)	200 f/ml (LOAEL)	

TABLE 2:
SCOEL's 2012 Table 2 – Long term dose response inhalation studies not considered by DECOS (1995)

MMVF10 901 glass wool.

MMVF10.1 901 glass wool.

MMVF10a Typical building insulation fibre glass.

MMVF11 Certain Teed glass wool.

MMVF21 Traditional (rock) stone wool. HL 65 and 92 days (WHO, long fibres).

MMVF22 Slag wool.

MMVF33 Special application fibre glass.

MMVF34/HT Biosoluble rock wool fibre. HL 25 and 6 days (WHO, long fibres).

TISMO Potassium octatitanate fibres, HL ~ 6 months.

X607 Calcium-magnesium-silicate fibre (similar to CMS) (SCOEL, 2012).

mo Months.

h/d Hours per day.

w Weeks.

d/w Days per week.

HL Half-life.

* References quoted in DECOS, 2011:
1. Hesterberg et al., 1993.
2. McConnell et al., 1999.
3. Kamstrup et al., 2001.
4. Ikegami et al., 2004.

4.2 Cancer

Shannon, H.S. et al (1990) reported on a Canadian study involving a cohort of 1465 employees of a glass filament plant. The death experience *[sic]* of the workers was compared to that expected on the basis of Ontario death rates. There was no statistically significant excess of lung cancer (reference cited in ACGIH®, 2001).

The ACGIH® concluded for continuous glass filament fibres:

> "Respirable and nonrespirable continuous filament glass fibres should be listed with the A4 designation, Not Classifiable as a Human Carcinogen, because there are inadequate data to classify the agent in terms of its carcinogenicity in humans and/or animals." (ACGIH®, 2001)

In relation to glass wool fibres, the 2001 ACGIH® review stated:

> "A number of epidemiologic studies have assessed the health effects of workers engaged in the production of glass wool fibres. These have been carried out in the United States, Europe and Canada by numerous investigators employing a variety of experimental designs (primary cohort and nested case-control designs). A detailed synthesis of the epidemiologic literature on the risk of respiratory system cancer from glass fibres concluded that, "taken together, the data indicate that among those occupationally exposed, glass fibers do not appear to increase the risk of respiratory system cancer" (Lee, I.-M. et al., 1995). The United States, European, and Canadian studies have also found no increased risk of mesothelioma among glass wool manufacturing workers." (Reference cited in ACGIH®, 2001.)

A cohort mortality study of more than 16,000 U.S. production workers, involving 14,185 who had worked at 11 plants producing glass fibres throughout the United States, 5,606 deaths were analysed:

> "For the workers engaged in the production of glass wool, lung cancer mortality was slightly elevated, but the excess was not statistically significant with local rates as the comparison group (standardized mortality rate [SMR] = 106.7)." "No relationship was found between lung cancer and duration of exposure or with cumulative exposure" (Marsh, G.M. et al, 1990, reference cited in ACGIH®, 2001).

In a Canadian study:

> "2557 glass wool production workers showed a statistically significant increase in lung cancer mortality (SMR = 176; 95% confidence interval = 128-311) using Ontario mortality rates for comparison. These numbers were based on only 21 lung cancer deaths, a relatively small number compared to other studies in Europe and the United States. The authors concluded that the "interpretation of these data remains difficult because the SMRs by length of exposure and time since first worked were not consistent with a causal relationship" (Shannon, H.S. et al, 1987, reference cited in ACGIH®, 2001).

The 2001 ACGIH® review noted that epidemiological studies do not consistently show a relationship between exposure to glass fibres and non-malignant respiratory disease:

> "Hughes et al. carried out a survey of 1259 workers engaged in the production of glass fibers in five U.S. plants. The authors compared the prevalence of selected respiratory symptoms, smoking history, pulmonary function testing and chest X-ray. The study showed no adverse effects of exposure to glass fibers including chest X-ray changes" (Hughes, J.M. et al, 1993, reference cited in ACGIH®, 2001).

In relation to special-purpose glass fibres, the 2001 ACGIH® review noted:

> "An inhalation study of one type of special-purpose glass fibers (MMVF 33), sponsored by the North American Insulation Manufacturers Association (NAIMA), resulted in the induction of mesothelioma after 6 months of exposure. NAIMA filed a Section 8(e) notification under the Toxic Substances Control Act of the U.S. Environmental Protection Agency (EPA)." (NAIMA Section 8(e) notification, reference cited in ACGIH®, 2001.) "This was the first indication that one of the special-purpose glass fibers may induce mesothelioma." (ACGIH®, 2001)

The ACGIH® concluded for glass wool, special-purpose fibers, and rock/slag wool fibers:

> "Glass wool, special-purpose fibers, and rock/slag wool fibers are carcinogenic by unusual routes of exposure to test animals (eg intrapleural and intraperitoneal injection and possibly intratracheal injection). These routes of administration are not considered relevant to worker exposure. Available epidemiologic studies do not confirm or support an increased risk of cancer in exposed humans. The evidence suggests that the agent is not likely to cause cancer in humans except under unlikely routes of exposure. Accordingly, an A3, Animal Carcinogen with Unknown Relevance to Humans, notation is recommended for these types of fibers" (ACGIH®, 2001).

The 2001 ACGIH® review did not describe studies in humans involving potential carcinogenic effects of RCF, however based on animal inhalation studies of RCF, recommended an A2 designation, Suspected Human Carcinogen, for this type of fibre (ACGIH®, 2001).

The 2012 SCOEL review summarised the mode of action of fibre carcinogenesis:

> "Inhalation of man-made vitreous fibres (MMVF) leads to both inflammatory and fibrotic processes, as well as expression of genes linked to cell proliferation and antioxidant defense in a dose-related fashion. These processes are associated with the activation of alveolar macrophages, lymphocytes, polymorphonuclear cells, mast cells, and fibroblasts and the release of a number of cellular mediators (eg tumour necrosis factor α (TNFα), interleukin-1α (IL-1α), interleukin-6 (IL-6), and basic fibroblast growth factor (bFGF) and the upregulation of protooncogenes). Injury to alveolar epithelial cells is followed by hyperplasia and hypertrophy and occasionally by neoplastic transformation resulting in tumourigenesis. Fibre activated macrophages and other inflammatory cells generate reactive oxygen species (ROS) (eg O_2-•, H_2O_2, and NO (Wang et al 1999 a)). The hydroxyl radical (O_2-•), peroxynitrite, and nitronium ions may also be formed. ROS can also originate from redox reactions occurring at the fibre surface (eg by fibre iron catalysis) leading finally to generation of O_2-•.

> These oxidants induce oxidative stress in the target cells (Baan and Grosse 2004; Driscoll 1996; Fubini 1996; Kamp et al 1992; Martin et al 1998; Mossman and Churg 1998; Oberdörster and Lehnert 1991; Saffiotti 1998; Staruchova et al 2008; Tsuda 1997; Wang et al 1999a, b; Zhu et al 1998)". (references cited in SCOEL, 2012).
>
> "These processes, being the underlying mechanism of fibre carcinogenicity, are considered to have a threshold. Cellular antioxidative systems including superoxide dismutase (SOD), catalase, and glutathione-S-transferase-dependent systems, protect against cellular injury and DNA damage as long as the release of ROS is not sufficient to overwhelm this defence (Howden and Faux 1996; Marks-Konzcalik et al 1998; Oberdörster 1997). Consequently, the lung is able to deal with a considerable number of fibres without detectable molecular or pathogenic events, which has been shown in epidemiologic and experimental studies (Mossman and Churg 1998)." (references cited in SCOEL, 2012).

RCFs

The 2011 DECOS review noted that:

> "Overall, the investigations on the association between occupational exposure to RCFs and cancer development in humans are insufficient to draw a definite conclusion" (DECOS, 2011).

In 2011 SCOEL summarised several long-term inhalation studies with RCFs in test species conducted since 1988:

> "In a long-term inhalation study with 4 types of RCF in rats at about 200 f/ml each, a statistically significant increase in the incidence of lung tumours and a few mesotheliomas were observed. Chrysotile asbestos was used as a positive control (Mast et al 1995a). In hamsters exposed to about 250 f/ml, no increase of lung tumours but a significant increase in the incidence of mesotheliomas was observed (McConnell et al 1995).
>
> In more recent studies the fibres were rat respirable (geometric mean diameter about 1 µm or less) with a large portion of long fibres (50% of the fibres had an arithmetic mean length of 20 µm) and representative for workplace exposure (Hesterberg et al 1993). Moreover, aerosolization and exposure by nose only inhalation have been improved (Hesterberg and Hart 2001).
>
> Two long-term inhalation studies in rats exposed to RCF have been performed. One using a concentration of 30 mg/m^3 (approximately 190 WHO-fibres/ml. WHO definition: length >5 µm, diameter <3 µm, ratio length/diameter <3:1 *[sic]*) using 4 different types of RCF (RCF-1-4) (Mast et al 1995a) and a succeeding study using the same protocol (5 days/wk and 6 h/day for 104 weeks) at doses of 3, 9, or 16 mg/m^3 RCF-1, which corresponded to 26, 75 and 120 WHO fibres/ml (Mast et al 1995b).
> The studies have been re-evaluated and summarized by Mast et al (2000b).
> To prepare rodent respirable fibre samples the commercial RCF was extensively milled and the animals were exposed to a fraction of a relatively high particle to fibre ratio of about 25% by weight and 10 particles per fibre (Turim and Brown 2003).

> In the study using the three different exposure concentrations of 3, 9, or 16 mg/m^3 of RCF-1, pulmonary clearance was considered to be unaffected for most of the exposure period at 3 mg/m^3. No observable clinical signs were seen at all doses while time-and dose-dependent increases in lung weight and in lung to body weight ratio occurred at all exposure levels. These increases became statistically significant at 16 mg/m^3. Histopathological evaluation of lung tissue was started after 3 months of exposure. At this time dose-related influx of fibre-containing macrophages, minimal fibre-containing microgranulomas at the bronchoalveolar junction and early bronchiolization was seen with a minimal progression of the effects over time. At 3 mg/m^3 these changes were considered to be minimal to mild within the 1 to 4 grading of lung fibrosis scale of Wagner. The effects correlated with the fibre lung burden (Mast et al 1995b). SCOEL notes that this 24 months inhalation study in rats resulted in a **LOAEC** of minimal effects in the rat-lung in a at *[sic]* 3 mg/m^3 RCF-1, which is equivalent to 26 fibres/ml.
>
> When studying the 3 different types of RCF that represented types of rodent respirable fractions of typical RCF compositions rats were exposed to a single concentration of 200 WHO fibers/ml for 24 months. An additional group has been exposed to RCF 4. High incidence of exposure-related pulmonary neoplasms (bronchoalveolar adenomas and carcinomas) were observed with RCF 1-3, not with RCF-4. A small number of mesotheliomas were observed in each of the fibre exposure groups (Mast et al 1995a). Using the same experimental design hamsters exposed to 30 mg/m^3 (260 f/ml) for 18 mo developed lung fibrosis, a significant number of pleural mesotheliomas (42/102) but no primary lung tumours (McConnell et al 1995)" (references cited in SCOEL, 2011).

1. In a 2014 review, Greim et al, argued that RCF and rock wool have similar airborne fibre dimensions and biopersistence, and therefore the authors considered it likely that the fibres would have similar toxicology (Greim et al, 2014):

> "Chronic nose-only inhalation bioassays indicated that RCF exposure in rats increased the incidence of lung cancer and similar exposures resulted in mesothelioma in hamsters, but these studies may have been compromised by overload. Epidemiological studies in the US and Europe showed an association between exposure and prevalence of respiratory symptoms and pleural plaques, but no interstitial fibrosis, mesotheliomas, or increased numbers of lung tumors were observed. As the latency of asbestos induced mesotheliomas can be up to 50 years, the relationship between RCF exposure and respiratory malignances has not been fully determined. Nonetheless, it is possible to offer useful perspectives. RCF and rock wool have similar airborne fiber dimensions and biopersistence. Therefore, it is likely that these fibers have similar toxicology. Traditional rock wool has been the subject of numerous cohort and case control studies. For rock wool, IARC (2002) concluded that the epidemiological studies did not provide evidence of carcinogenicity. Based on analogies with rock wool (read across) *[sic]*, it is reasonable to believe that increases in lung cancer or any mesotheliomas are unlikely to be found in the RCF-exposed cohort" (Greim et al, 2014).

The 2016 AIOH review noted that:

> "The amorphous fibres in high performance temperature SMF (RCF and the new generation HT alkaline earth glass wool) that has been subjected to temperatures exceeding ~1100°C for a long period (months to years in industrial applications) has the potential to undergo a phase change to a mix of mullite (synthetic alumino silicate) and cristobalite (a crystalline form of silica) (Gantner, 1986; Holroyd et al 1988). Low/moderate performance mineral wools simply melt at these temperatures and there is no phase change. The form of cristobalite found in the high temperature conversion of the HT fibres has a highly disordered micro-crystalline structure. Cristobalite is classified by IARC as carcinogenic to humans (Group 1) (IARC, 1997). However, when these after-use devitrified cristobalite containing fibres were tested in long-term animal inhalation studies they were found not to cause micro fibrosis in the lung or excess lung tumours, whereas the same fibres which had not been subject to high temperature and phase change induced micro fibrosis and lung cancers in the animals (ECFIA, 2011)" (references cited in AIOH,2016).

SVFs

The 2012 SCOEL review summarised:

> "The life time studies in rats on rock wool and slag wool as well as insulation fibre glass (and of TISMO[1]) did not reveal carcinogenic effects. Recent evaluations of the epidemiological studies of workers exposed to respirable rock wool and glass wool fibres (Lipworth et al 2010) and glass wool fibres (NTP 2010) support these data. Lipworth et al (2010) who conducted a systemic review and meta-analysis of lung and neck cancers in epidemiological studies of workers exposed to rock wool and glass wool concluded: "Despite a small elevation of the **RR**" [relative risk] "for lung cancer among MMVF production workers, the lack of excess risk among end users, the absence of any dose-risk relation, the likelihood of detection bias, and the potential for residual confounding by smoking and asbestos exposure argue against a carcinogenic effect of MMVF, rock wool, or glass wool at this time. Similar conclusions apply to head and neck cancer." (References cited in (SCOEL, 2012).

4.3 Absorption, distribution, metabolism and excretion

The 2012 SCOEL review noted that:

> "The uptake of fibres into the body takes place via the respiratory tract. Transport and deposition of the fibres in the airways are determined by their aerodynamic behaviour. The fibre size, their chemical composition and the deposited dose in the lung define their retention kinetics. Fibres may be deposited in the respiratory airways by: impaction, sedimentation, interception and diffusion. The fate of deposited fibres within the respiratory system depends on both the site of deposition and the characteristics of the fibre. The main mechanisms of fibre clearance include mucociliary movement in the nasopharyngeal and tracheobronchial regions and alveolar macrophage phagocytosis in the alveolar region with subsequent removal towards the mucoliary escalator. In addition to these mechanisms, chemical dissolution and leaching, swelling and breakage, can occur" (SCOEL, 2012).

[1] TISMO: potassium octatitanate fibres.

The 2016 AIOH review noted that bio-persistence of the fibres is considered an important factor in indicating the potential toxicity of fibres:

> "Bio-persistence is a complex interaction between fibre solubility and the natural clearance mechanisms in the lung. The fibre composition, length and diameter affect the rate of solubility and clearance. For longer fibres preferential element dissolution (particularly silicon) results in internal weakening of the amorphous fibre structure and subsequent transverse breakage to shorter fibres, which are subject to phagocytosis and removal. Clearance of deposited fibres is a multi-stage mechanism, with fibres shorter than the size of macrophages (15 μm) being totally phagocytised, and longer fibres partly engulfed then removed by either the mucocilliary system or temporary storage in the lymph nodes. In-vitro and in-vivo investigations have shown that amphibole asbestos is less soluble and more bio-persistent than RCF, which in turn is less soluble and more bio-persistent than old style glass wool and Rockwool. Both moderate and high temperature newer style AES wools of specific chemical composition when tested were found to be more soluble and less bio-persistent than their old style SMF counterparts. These findings of bio-persistence are reflected in the regulatory approach taken in the EEC and carried forward into an Australian classification system." (AIOH, 2016)

4.4 AIOH evaluation and rationale

The 2016 AIOH review of synthetic mineral fibres (SMFs) concluded that:

> "The AIOH recognises the improved information on the epidemiological studies on SMF manufacturing workforce made since the 1989 NOHSC Technical Report and agrees with the reclassification of carcinogenicity made by IARC (2002). AIOH also agrees with the system of testing and classification (Nota Q) that is operating in the EEC in regard to old style fibres, RCF and new generation low bio-persistent fibres.
>
> The AIOH position is that forms of SMF deemed as non-carcinogens according to IARC (2002) and EEC Note Q testing (NOHSC 1999) are deemed as being not hazardous according to Safe Work Australia classification.
>
> While the above considerations relate to potential carcinogenic risk, the issue of primary 'tickling' irritation of the upper respiratory tract, which is felt when elevated levels of thicker fibres are inhaled, and mechanical 'splinter type' irritation of the skin and eyes after contact with fibres and lumps of SMF still needs to be addressed.
>
> As a minimum, guidance material along the line of that currently available in some industry sectors, an SDS needs to be provided to the users to assist them in handling and protective procedures, which will minimise potential for such irritation."
>
> "In contrast the forms of SMF such as RCF and special purpose fibreglass that do not meet the above criteria, these should remain classified as hazardous." (AIOH, 2016)

4.5 SCOEL evaluation and rationale

The 2011 SCOEL review of refractory ceramic fibres (RCF) concluded that:

> "Occupational exposure to RCFs is associated with adverse respiratory effects as well as skin and eye irritation and may pose a carcinogenic risk based on the results of chronic animal inhalation studies. In these studies, exposure to RCFs produced an increased incidence of mesotheliomas in hamsters and lung cancer in rats. Mesotheliomas and sarcomas in rats and hamsters have also been induced after intrapleural and intraperitoneal implantation of RCFs. Intratracheal instillation induced lung tumours in rats. Epidemiologic studies have found no association between occupational exposure to airborne RCFs and an excess rate of pulmonary fibrosis or lung cancer". (SCOEL, 2011)

4.6 DECOS evaluation and rationale

The 2011 Dutch Expert Committee on Occupational Safety (DECOS) evaluation of the carcinogenicity and genotoxicity of refractory ceramic fibres (RCF) summarised:

> "The number of observational studies reporting on possible associations between occupational exposures to refractory ceramic fibres and cancer development in humans is limited. Overall, available data are insufficient to draw a conclusion whether RCF is carcinogenic to humans."
>
> "Several animal carcinogenicity studies have been performed using rats or hamsters, which were exposed to various types of RCFs by various routes of exposure. Positive findings on lung tumour development were reported after whole-body and nose-only exposure. RCFs were also able to induce formation of pleural mesotheliomas after nose-only exposure or intrapleural injections; and, abdominal mesotheliomas after intraperitoneal injections. However, not all studies were clearly positive. Also, interpretation of some results was restricted, due to limited reporting, or due to the presence of additional risk factors. Overall, however, the Committee concludes that data show carcinogenic activity in animals".
>
> "The Committee considers the induction of chronic inflammation as the most plausible mechanism of carcinogenic action of RCFs. In addition, it is unlikely that RCFs possess stochastic genotoxic properties via direct production or reactive oxygen species, due to their very low iron content." (DECOS, 2011)

The 2011 DECOS evaluation concluded with a recommendation for the classification of RCFs:

> "The Committee concludes that refractory ceramic fibres are presumed to be carcinogenic to man, and recommends classifying these fibres in category 1B. Based on the currently available data, the Committee assumes that the fibres act by a non-genotoxic mechanism." (DECOS, 2011)

On a technical note, the 2011 DECOS evaluation characterised an important inter-species difference:

> "It is also a factor to take into account when extrapolating animal data to humans, because between rodents and humans distinct differences exist in respiratory tract and lung size, lung and macrophage anatomy, and geometry. For instance, fibres with a diameter of more than 3.5 µm and an aspect ratio of more than 10 are not deposited in the alveoli of rats and hamsters, whereas in humans, fibres with an aerodynamic diameter of 5 µm can still reach the alveoli. Based on models in which rodents and humans inhaled a same concentration, it is furthermore estimated that approximately 2.2% of fibres with an aerodynamic diameter of 2 µm are deposited in the alveolar region of the lungs of rats, whereas in humans it is estimated to be approximately 23%, a ten-fold difference. If these differences are not taken into account, the human risk in developing cancer is underestimated when using animal data for quantitative risk assessment." (DECOS, 2011)

4.7 NIOSH evaluation and rationale

The 2006 NIOSH review of RCFs concluded that:

> "In addition to the main determinants of fiber toxicity (dose, dimension, and durability), other factors such as elemental composition, surface area, and composition can also influence the toxicity of the fiber. Thus, it is difficult to predict a fiber's potential for human toxicity based solely on in vitro or in vivo tests. Based on consideration of these factors, the major findings from the RCF animal and human studies are as follows:
>
> – Toxicologic evidence from experimental inhalation studies indicates that RCFs are capable of producing lung tumors in laboratory rats and mesotheliomas in hamsters [Mast et al. 1995a,b; McConnell et al. 1995]. However, interpreting these studies with regard to RCF potency and its implication for occupationally exposed human populations is complicated by the issue of coexposure to fibers and nonfibrous respirable particulate.
> – The durability of RCFs contributes to the biopersistence of these fibers both in vivo and in vitro [Bellmann et al. 1987; Scholze and Conradt 1987; Lockey and Wiese 1992].
> – Cytotoxicity and genotoxicity studies indicate that RCFs
> - are capable of inducing enzyme release and cell hemolysis [Wright et al. 1986; Fujino et al. 1995; Leikauf et al. 1995; Luoto et al. 1997],
> - affect mediator release [Morimoto et al. 1993; Ljungman et al.1994; Fujino et al. 1995; Leikauf et al. 1995; Hill et al. 1996; Cullen et al. 1997; Gilmour et al. 1997; Luoto et al. 1997; Wang et al. 1999],
> - may decrease cell viability and inhibit proliferation [Yegles et al. 1995; Okayasu et al. 1999; Hart et al. 1992] – affect cell viability and proliferation [Hart et al. 1992], and
> - may induce free radicals, micronuclei, polynuclei, chromosomal breakage, and hyperdiploid cells [Brown et al. 1998; Dopp et al. 1997; Hart et al. 1992].
> – Exposure monitoring results indicate that airborne fibers measured in both the manufacturing and end-use sectors of the RCF industry have dimensions that fall within the thoracic and respirable size ranges [Esmen et al. 1979; Lockey et al. 1990; Cheng et al. 1992].

- Epidemiologic studies of workers in the RCF manufacturing industry report an association between increased exposures to airborne fibers and the occurrence of pleural plaques, other radiographic abnormalities, respiratory symptoms, decreased pulmonary function, and eye and skin irritation [Lemasters et al. 1994, 1998; Lockey et al. 1996; Trethowan et al. 1995; Burge et al. 1995]. Current occupational exposures to RCFs have not been linked to decreases in pulmonary function of workers [Lockey et al. 1998].
- Worker exposure to airborne fiber in the RCF industry over the past 20 years or more have decreased substantially, reportedly as the result of increased hazard awareness and the design and implementation of engineering controls [Rice et al. 1997; Maxim et al. 1997].

These observations warrant concern for the continued control and reduction of occupational exposures to airborne RCFs." (References cited in NIOSH, 2006).

5.0 Exposure standards and guidance values in use around the world

IN THIS SECTION:

Table 3 below shows the synthetic vitreous fibre exposure standards from around the world, as published by the Institute for Occupational Safety and Health of the German Social Accident Insurance (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung, 2017).

JURISDICTION OR BODY	FIBRES, MAN MADE VITREOUS (AMORPHOUS) FIBRES	REFRACTORY CERAMIC FIBRES	CINDER WOOL FIBRES, SLAG	CONTINUOUS FILAMENT GLASS FIBRES	GLASS WOOL FIBRES	ROCK WOOL FIBRES, MINERAL WOOL FIBRES
Australia		0.5 f/ml [R] 2 mg/m^3	2 mg/m^3 [IC]	2 mg/m^3 [IC]	2 mg/m^3 [IC]	2 mg/m^3 [IC]
Belgium	1 f/m^3	0.5 f/cm^3	1 f/cm^3		10 mg/m^3	1 f/cm^3
Canada – Ontario		0.5 f/cm^3	1 f/cm^3 [R]	1 f/cm^3 [R]	1 f/cm^3 [R]	1 f/cm^3 [R]
Canada – Quebec		1 f/cm^3	1 f/cm^3		2 f/cm^3 1 f/cm^3 [E] 10 mg/m^3 [E]	1 f/cm^3
Denmark		1 f/cm^3	1 f/cm^3		1 f/cm^3	1 f/cm^3
Finland		0.2 mg/cm^3 [R]		5 mg/m^3 [I] 1 f/cm^3		
France		0.1 f/cm^3	1 f/cm^3		1 f/cm^3	1 f/cm^3
Germany (AGS)		0.1 f/cm^3 [RA] 0.01 f/cm^3 [B]				
Hungary		1 f/cm^3	1 f/cm^3		1 f/cm^3	1 f/cm^3
Japan – JSOH		1 f/cm^3		1 f/m^3	1 f/cm^3	1 f/cm^3
New Zealand		1 f/ml [F] 5 mg/m^3 [F]	1 f/ml [RF] 5 mg/m^3 [F]	1 f/ml [RF] 5 mg/m^3 [IF]	1 f/ml [RF] 5 mg/m^3 [IF]	1 f/ml [R] 5 mg/m^3 [I]
People's Republic of China			3 mg/cm^3 [I]			3 f/cm^3 [I]
South Korea		0.2 f/cm^3 [R]				10 mg/m^3
Spain		0.5 f/cm^3			1 f/cm^3	
Sweden	1 f/m^3	0.2 f/m^3			1 f/cm^3	1 f/cm^3
Switzerland		0.25 f/cm^3			0.5 f/cm^3	0.5 f/cm^3

JURISDICTION OR BODY	FIBRES, MAN MADE VITREOUS (AMORPHOUS) FIBRES	REFRACTORY CERAMIC FIBRES	CINDER WOOL FIBRES, SLAG	CONTINUOUS FILAMENT GLASS FIBRES	GLASS WOOL FIBRES	ROCK WOOL FIBRES, MINERAL WOOL FIBRES
The Netherlands		0.54 f/cm^3				
AIOH[F]		0.5 f/ml [R] 2 mg/m^3 [IG]	2 mg/m^3 [I]	2 mg/m^3 [I]	2 mg/m^3 [I]	2 mg/m^3 [I]
SCOEL[F]		0.3 f/ml [R]	1 f/ml [R]	1 f/ml [R]	1 f/ml [R]	1 f/ml [R]
NIOSH[F]		0.5 f/ml [R]	0.5 f/ml [R]	3 f/ml [R] 5 mg/m^3 [I]	3 f/ml [R] 5 mg/m^3 [I]	3 f/ml [R] 5 mg/m^3 [I]
OSHA[F]		0.5 f/ml [R]	5 f/ml [R] 15 mg/m^3 [I]	5 f/ml [R] 15 mg/m^3 [I]	5 f/ml [R] 15 mg/m^3 [I]	5 f/ml [R] 15 mg/m^3 [I]
ACGIH®[F]		0.2 f/ml [R]	1 f/ml [R]	1 f/ml [R] 5 mg/m^3 [I]	1 f/ml [R]	1 f/ml [R]

TABLE 3: Eight-hour TWA exposure standards for SVFs from around the world

[R] Respirable fraction.

[I] Inhalable fraction.

[A] Proposed tolerable cancer risk.

[B] Proposed preliminary acceptable cancer risk.

[C] See Safe Work Australia criteria.

[D] Microfibres.

[E] continuous filament total dust.

[F] Not cited by GESTIS.

[G] Those RCFs deemed as non-carcinogenic according to IARC (2002) and Note Q testing.

The only organisations which had information publicly available as to how and why they set these occupational exposures standards or guidance values were ACGIH®, AIOH, SCOEL and NIOSH.

5.1 New Zealand

WorkSafe's WESs for man-made mineral fibres (synthetic mineral fibres); synthetic mineral fibres (man-made mineral fibres); fibrous glass dust; glass, fibrous or dust; mineral wool fibres have been unchanged since adoption in 1994.

The toxicological literature reviewed indicates that synthetic vitreous fibres cannot be considered as a single group with a single hazard profile, based on occupational exposure assessments and studies in test species. It should be noted that due to the extensive and developing range of SVFs, many have not been comprehensively tested.

The latest reviews by AIOH (2016), DECOS (2011) and SCOEL (2011 and 2012) concluded that SVFs could be divided into: (a) those fibres classified as carcinogens; (b) those fibres not classifiable; and, (c) those fibres classified as not carcinogenic. The ACGIH® has not reviewed SVF since 2001. At that time they recommended cancer classifications of A2 (Suspected Human Carcinogen), A3 (Animal Carcinogen with Unknown Relevance to Humans), and A4 (Not Classifiable as a Human Carcinogen) for various SVFs as discussed above in section 4.2.

FIBRE	SVF CARCINOGENICITY CLASSIFICATION	NOTES	ORGANISATION
MMVFs	Suspected of being carcinogenic (EU 2)	Notes Q, R[2]	EU Reg 1272/2008 (Consolidated 2015)
	Not classifiable as to their carcinogenicity (IARC 3)		IARC (2002)
RCFs	Presumed human carcinogen (EU 1B)	Note R	EU Reg 1272/2008 (Consolidated 2015)
	Genotoxic carcinogens for which a practical threshold is supported (SCOEL GrpC)		SCOEL (2011)
	Presumed human carcinogen (EU 1B)	Note R	DECOS (2011)
	Possibly carcinogenic to humans (IARC 2B)		IARC (2002)
Special-purpose glass fibres (eg E-glass; '475')	Possibly carcinogenic to humans (IARC 2B)		IARC (2002)

TABLE 4: SVF carcinogenicity classifications from other organisations

In many cases SVFs may be classified as not carcinogenic because they meet criteria in Notes Q or R in EU Regulation 1272/2008 (Consolidated, 2015).

[2] EU Reg 1272/2008 (Consolidated 2015) – see Notes to Table 1.

5.2 ACGIH®

As stated above, the ACGIH® has not reviewed SVF since 2001.

In their 2001 review, ACGIH® recommended:

- a TLV-TWA of 1 f/cc for respirable continuous glass filament to "minimize the potential for workers to experience the effect of mechanical irritation to the skin and mucous membranes. For nonrespirable, continuous glass filament particles, a TLV-TWA of 5 mg/m^3, measured as inhalable aerosol, is recommended. This exposure level is also designed to minimize skin and mucous membrane irritation." (ACGIH®, 2001)
- A TLV-TWA of 1 f/cc for glass wool, rock wool and slag wool. "The TLV® is designed to minimize skin and mucous membrane irritation." (ACGIH®, 2001)
- A TLV-TWA of 1 f/cc for special-purpose glass fibres. They note that the paucity of data for these fibres makes it difficult to establish a TLV®. The TLV® is "designed to minimize skin and mucous membrane irritation." (ACGIH®, 2001)
- A TLV-TWA of 0.2 f/cc for RCFs. "RCFs are considered intermediate in toxicity between the other SVFs and asbestos fibers, probably being closer to the latter than the former in terms of potential human toxicity." "Although the available data are incomplete, 0.2 f/cc is considered at this time to be a cautious number that should be sufficiently protective for malignant and non-malignant health effects among exposed individuals." (ACGIH®, 2001)

5.3 AIOH

The 2016 AIOH review of synthetic mineral fibres (SMFs) concluded that:

"The exposure standard applicable to these 'non-hazardous' forms of SMF, which was based on respirable fibres (presumably on the basis of controlling previous concerns of potential risk of fibrosis and lung cancer), is not particularly applicable since the carcinogenic and fibrotic risk has been deemed exonerated via the various recent studies. Except in the manufacture and application of some non-bonded forms, almost all of the air monitoring data suggests that airborne levels of SMF in manufacture and use of bonded product are well below the exposure standard of 0.5 respirable fibres/ml. Based on risk assessment, reference to existing task-specific exposure data, and the fact that most of the fibre product has a larger than respirable fibre diameter, in the majority of instances air monitoring of respirable fibre levels will not provide a meaningful value on which to assess compliance with safe handling procedures so as to minimise irritation. A more relevant approach to minimising irritancy should be adopted where risk assessment determines the application of a gravimetric exposure standard such as the existing complementary exposure standard of 2 mg/m^3 of inhalable dust."

"Particular attention should be paid to control procedures during the demolition and repair of plant which contains RCF and other nonfibrous silicate insulation materials, which may have been subjected to high temperatures in excess of 1000°C, so as to prevent possible overexposure to excess levels of airborne embrittled fibres and cristobalite formed in the bulk non-fibrous refractories." (AIOH, 2016)

> "The AIOH recognises that due to changes in the carcinogenic classification of some forms of SMF, the existing exposure standard based on respirable fibre numbers (0.5 f/ml) is not particularly appropriate to reflect the impact of upper respiratory tract irritation and hence a standard based solely on inhalable mass (2 mg/m^3) may be more appropriate for the low-bio-persistent forms of SMF. The existing WES (0.5 f/ml) should remain for some of the old forms of SMF such as RCF." (AIOH, 2016)

The review recommended:

> "A standard to limit exposure to no more than 2.0 mg of SMF in each cubic metre of air is recommended for the inhalable low-bio-persistent forms of SMF. A standard of 0.5 fibres in each millilitre of air should be used for some of the old forms of SMF such as RCF." (AIOH, 2016)

Note: The standard recommended by the AIOH for inhalable low bio-persistent forms of SMF is equivalent to 2.0 mg/m^3 'inhalable dust'.

5.4 SCOEL

The 2012 SCOEL review of man-made mineral fibres (MMMF) concluded that:

> "SCOEL considers properly conducted inhalation studies, preferentially in rats, using fibres of rat respirable size which upon long term exposure did not induce carcinogenic effects as the best basis for setting an **OEL**. Fibres longer than 5 µm, shorter than 100 to 200 µm, of a diameter less than 3 µm with a length/diameter ratio of at least 3:1 are considered respirable. Such studies have been performed with fibres of glass wool, rock wool, slag wool and calcium-magnesium-silicate (Table 3). In all these studies, inflammation and subsequent fibrosis of the lung have been the critical effects. In the two-year exposure studies in rats, NOAELs within the narrow range of 25 to 30 fibres/ml of inhaled air have been determined.
>
> "For fibres with insufficient data to derive a specific OEL, SCOEL proposes a general OEL of 1 fibre/ml. This value is derived as described before: Considering the uncertainties to extrapolate from LOAEL to NOAEL, the uncertainties of interspecies-extrapolation and possible intrinsic differences in fibre toxicity, the conservative assessment factors of 20 and 10, respectively, have been applied. The resulting values range between 1.3 and 3 (see Table 3). Based upon this information the lowest value of 1.3 fibres/ml for glass wool fibres is adjusted to a general OEL of 1 fibre/ml, which corresponds to about 0.1 mg/m^3 (Schneider 1987). This OEL is applicable to MMMF without indication of carcinogenicity and the characteristics: length >5 µm, diameter D <3 µm and a ratio L:D >3:1 (WHO fibres). For the fibres listed in Tables 2 and 3, for which NOAELs can be derived, SCOEL will propose specific OELs (see eg MMVF10, SCOEL 2000)" (SCOEL, 2012).

FIBRES	NOAEL RESPIRABLE fibres/ml	LOAEL RESPIRABLE fibres/ml	VALUES DERIVED BY APPLYING AFS RESPIRABLE fibres/ml	ASSESSMENT FACTOR (AF)
MMVF10 (glass wool) Rat, 2 years	25		2.5	10
MMVF10 (glass wool) Rat, 78 w		25	1.25	20[4]
MMVF10.1 (glass wool) Hamster, 13 w		25	1.25	20[4]
MMVF11 (glass wool) Rat, 2 years	25		2.5	10
MMMF21 (rock wool) Rat 2 years	30		3	10
MMMF22 (slag wool) Rat, 2 years	30		3	10
X607[3] Rat, 2 years		200	10	20[4]

TABLE 5:
SCOEL 2012 Table 3 – NOAELs/LOAELs and levels of man-made mineral fibres derived by applying assessment factors (AF) according to DECOS (1995) (SCOEL, 2012)

The 2011 Scientific Committee on Occupational Exposure Limits (SCOEL) for Refractory Ceramic Fibres stated:

> "The epidemiological studies in the US and in Europe showed an association between exposure and increased prevalence of respiratory symptoms and conditions such as dyspnoea, wheezing, chronic cough, decreases in pulmonary function, and skin, eye, and upper respiratory tract irritation. These findings, which primarily reflect workers employed before 1980, did not persist with analysis of follow-up production years and accumulated RCF exposure from initial pulmonary function tests. More recent exposures from the late 1980s until 2004 had no deleterious impact on the longitudinal trend of **FVC** and **FEV_1**. During this time the RCF workplace concentrations constantly decreased below 1 f/ml. Since about 1993 the concentrations ranged around 0.2 f/ml in RCF fibre manufacture facilities and decreased from about 0.4 to 0.3 f/ml in customer facilities. So far none of these studies provide information at what concentration the pulmonary effects are no longer seen. The common presence of other non-fibrous dust further complicates the evaluation of effects and their dose-responses at specific RCF workplace exposures. However, the studies indicate that the exposures since the late 1980s neither had deleterious impact on the lung function, nor diagnosed pleural plaques or mesothelioma. These exposures ranged from approximately 1 fibre/ml to below the limit of detection (Rice et al 1997).

[3] X607: Calcium-magnesium-silicate fibre.

[4] Factor 20 to consider LOAEL.

> Pulmonary function provides sensitive parameters to evaluate the effects of RCF exposure (see studies in workers in the US: Lockey et al., 1998, 2002; LeMasters et al., 1998; McKay 2010). The first cross-sectional pulmonary function study reported statistically (but not clinically) significant decrements in FVC and FEV1 for workers in the highest exposure category (> 60 fibres-months per cc) compared to those in the lowest exposure category (≤15 **f-m/cc**), but later studies reported no significant decline in lung function in a longitudinal analysis of male workers providing pulmonary function tests over seven years.
>
> Upon request the authors of the McKay et al. (2010) study provided the following additional information:
>
> - the average cumulative exposure among all workers in the > 60 **f-mo/ml** group was 147.9 f-mo/ml, and
> - when sorted by chronological age, those workers at age 60 in the > 60 f-mo/ml group experienced an average cumulative exposure of 184.8 f-mo/ml.
>
> Assuming a 45 years exposure the average cumulative exposures of 147.9 and 184.8 f-mo/ml, respectively, result in an average fibre concentrations of 0.27 and 0.34 f/ml. Considering these values as no observed adverse effect levels SCOEL proposes an OEL of 0.3 f/ml.
>
> From the available information it is concluded that the genotoxic effects observed in the different studies are secondary so that RCFs are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported." (References cited in SCOEL, 2011.

As discussed in more detail above, the 2012 SCOEL review of MMMF recommended:

> "For fibres with insufficient data to derive a specific OEL, SCOEL proposes a general OEL of 1 fibre/ml. ... This OEL is applicable to MMMF without indication of carcinogenicity and the characteristics: length >5 µm, diameter D <3 µm and a ratio L:D >3:1 (WHO fibres). For the fibres for which NOAELs can be derived, SCOEL will propose specific OELs (see eg MMVF10, SCOEL 2000)." (SCOEL, 2012)

The 2011 SCOEL review of RCFs further recommended, for RFCs, an OEL of 0.3 f/ml. They concluded that the genotoxic effects observed in the different studies are secondary so that RCFs are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported.

5.5 NIOSH

The 2016 NIOSH review of RCFs recommended:

> "Recognizing that RCFs are carcinogens in animal studies and given the limitations in deriving an exposure value that reflects no excess risk of lung cancer or mesothelioma for humans, NIOSH recommends that every effort be made to keep exposures below the **REL** of 0.5 f/cm^3 as a TWA for up to 10 hr/day in a 40-hr work-week. These efforts will further reduce the risk for malignant respiratory disease and protect workers from conditions and symptoms deriving from irritation of the respiratory tract, skin, and eyes." (NIOSH, 2006)

"This recommended exposure limit (REL) is intended to reduce the risk of lung cancer, mesothelioma, and other adverse respiratory health effects (including irritation and compromised pulmonary function) associated with excessive RCF exposure in the workplace. Limiting exposures will also protect workers' eyes and skin from the mechanical irritation associated with exposure to RCFs." (NIOSH, 2006)

"Risk assessment analyses using data from chronic inhalation studies in rats indicate that the excess risk of developing lung cancer when exposed to RCFs at a TWA of 0.5 f/cm^3 for a working lifetime is 0.073 to 1.2/1,000. However, on the basis of the assumptions used in the risk analyses, NIOSH concludes that this risk estimate is more likely to underestimate than to overestimate the risk to RCF-exposed workers. Reduction of the RCF TWA concentration to 0.2 f/cm^3 would reduce the risk for lung cancer to 0.03 to 0.47/1,000." (NIOSH, 2006)

6.0 Analytical methods for the assessment of airborne SVF

IN THIS SECTION:

There are various sampling methods for assessing airborne exposure to SVF.

6.1 Inhalable fraction

The most appropriate analytical method is to measure inhalable dust gravimetrically, according to AS 3640: 2009 – *Workplace atmospheres – Method for sampling and gravimetric determination of inhalable dust* (Standards Australia, 2009). A competent person should then make a professional judgement, based on knowledge of the workplace, the processes used and the work that workers perform, as to whether or not it is likely that the dust making up the sample is predominantly SVF dust, and whether it is likely that its airborne concentration is approaching or exceeds the WES.

Using this method an air sample is collected onto a pre-weighed membrane filter using an inhalable dust sampling train set at a flow rate of 2 L of air per minute. Following exposure of the filter for an appropriate period of time, the filter is re-weighed and the dust concentration calculated based on the mass of dust present and the volume of air that has been filtered. The detection limit of this method will depend on the equipment used, but should be of the order of 10 **µg** per sample.

This would allow a minimum concentration of 0.01 mg of inhalable dust per cubic metre of air to be quantified over a collection period of 8 hours.

6.2 Respirable fraction

The most appropriate analytical method is to measure respirable dust gravimetrically, according to AS 2985: 2009 – *Workplace atmospheres – Method for sampling and gravimetric determination of respirable dust* (Standards Australia, 2009). A competent person should then make a professional judgement, based on knowledge of the workplace, the processes used and the work that workers perform, as to whether or not it is likely that the dust making up the sample is predominantly SVF dust, and whether it is likely that its airborne concentration is approaching or exceeds the WES.

Using this method an air sample is collected onto a pre-weighed membrane filter using a respirable dust sampling train set typically at a flow rate of 2.2 or 2.5 L of air per minute. Following exposure of the filter for an appropriate period of time, the filter is re-weighed and the dust concentration calculated based on the mass of dust present and the volume of air that has been filtered. The detection limit of this method will depend on the equipment used, but should be of the order of 10 µg per sample.

This would allow a minimum concentration of as low as 0.01 mg of respirable dust per cubic metre of air to be quantified over a collection period of 8 hours.

6.3 Determination of airborne fibre concentration

The most appropriate analytical method to determine the airborne concentration of fibres is one of the membrane filter methods, as used for the analysis of asbestos fibres. One such method is the Guidance Note on the Membrane Filter Method for Estimating Airborne Asbestos Fibres (2nd Edition), as published by the Australian National Occupational Health and Safety Commission (NOHSC, 2005). Using the membrane filter method, respirable airborne fibre concentrations of as low as 0.02 fibres/ml can typically be quantified.

It is noted that this method is based on counting fibres that satisfy very specific geometric criteria – those with a diameter of less than 3 µm, a length of more than 5 µm, and with a length/diameter aspect ratio of at least 3. These dimensions are consistent with the respirable fibre in which the Australian exposure standard is expressed (NOHSC, 1988). Use of the 'guidance note' method will not identify SVF specifically, as other respirable fibres such as asbestos and organic fibres will also potentially meet these geometric criteria.

Scanning electron microscopy (SEM) is one method that can be used for identifying SVF.

7.0
Discussion and recommendation

Based on the aforementioned documentation, WorkSafe does not consider its current WES-TWA of 1 respirable fibre/ml air and 5 mg/m^3 inhalable dust for man-made mineral fibres (synthetic mineral fibres); synthetic mineral fibres (man-made mineral fibres); fibrous glass dust; glass, fibrous or dust; mineral wool fibres, to be adequate to manage health risks from inhalation exposure.

It is proposed that WorkSafe:

1. Adopt a WES-TWA for synthetic vitreous fibres (SVFs) classified as carcinogenic, for example RCFs, special-purpose glass fibres and biopersistent SVFs of:
   - 0.03 mg/m^3 [0.3 f/ml] (respirable fraction) and
   - 0.1 mg/m^3 [1 f/ml] (inhalable fraction); and
2. Adopt a WES-TWA for synthetic vitreous fibres (SVFs) classified as not carcinogenic (eg those meeting criteria in Notes Q or R in EU Regulation 1272/2008) of:
   - 0.1 mg/m^3 [1 f/ml] (inhalable fraction).

The proposed WES-TWA for SVFs classified as carcinogenic is based on the risk assessment and recommendations in SCOEL (2011), and supported by those of AIOH (2016) and NIOSH (2006).

The proposed WES-TWA for SVFs classified as not carcinogenic is based on the risk assessment and recommendations in SCOEL (2012).

Appendices

IN THIS SECTION:

Appendix 1: Glossary

TERM	MEANING
ACGIH®	The American Conference of Governmental Industrial Hygienists (ACGIH®) is a 501(c)(3) charitable scientific organization, established in 1938, that advances occupational and environmental health. Examples of this include their annual edition of the TLVs® and BEIs® book and Guide to Occupational Exposure Values.
AES	Alkaline earth silicates.
AIOH	Australian Institute of Occupational Hygienists, Inc.
cm	Centimetre, or one hundredth of a metre.
DECOS	Dutch Expert Committee on Occupational Standards.
EU	European Union.
FEV1 or FEV_1	Volume that has been exhaled at the end of the first second of forced expiration.
f/cm³ or f/cc	Fibres per cubic centimetre of air, equivalent to f/ml (see below).
f/ml	fibres per ml air: fibre concentration in air.
f-m/cc	fibre-months per cubic centimetre of air: cumulative fibre exposure.
f-mo/ml	fibre-months per ml air: cumulative fibre exposure.
FVC	Forced vital capacity: the determination of the vital capacity from a maximally forced expiratory effort (ie the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible).
IARC	The International Agency for Research on Cancer – an agency of the World Health Organisation, whose mission is to coordinate and conduct research on the causes of human cancer and to develop scientific strategies for cancer prevention and control.
Inhalable particulate fraction	Inhalable particulate fraction is that fraction of dust that can be breathed into the nose or mouth. Particulate size: mostly < 100 µm, 50% cut point. For sampling purposes the inhalable dust is to be collected according to the method set out in AS 3640-2009: Workplace Atmospheres – Method for Sampling and Gravimetric Determination of Inhalable Dust. (*cf.* Respirable fraction) (Also referred to as: inhalable particulate matter)
IPCS	International Programme for Chemical Safety.
LOAEC	Lowest Observed Adverse Effect Concentration.
LOAEL	Lowest Observed Adverse Effect Level.
m³	Cubic metre.
mg	Milligram or one thousandth of a gram.
mg/m³	Milligrams of substance per cubic metre of air.
ml	Millilitre, or thousandth of a litre. 1 ml = 1 cm³.
MMAD	Mass median aerodynamic diameter is the diameter at which 50% of the particles by mass are larger and 50% smaller.
MMMF	Man-made mineral fibre.
MMVF	Man-made vitreous fibre.
NIOSH	The National Institute for Occupational Safety and Health (NIOSH) is the United States federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services.

TERM	MEANING
NOAEL	No Observed Adverse Effect Level.
NOHSC	National Occupational Health and Safety Commission – Australia.
OEL	Occupational Exposure Limit.
RCF	Refractory ceramic fibre.
REL	Recommended Exposure Limit.
Respirable particulate fraction	Respirable particulate fraction is that fraction of inhaled airborne particles that can penetrate beyond the terminal bronchioles into the gas-exchange region of the lungs (alveoli). Particulate size: mostly < 4 µm, 50% cut point. For sampling purposes the respirable dust samples are to be collected according to the method set out in the Standards Australia publication AS 2985-2009: Workplace Atmospheres – Method for Sampling and Gravimetric Determination of Respirable Dust. (cf. Inhalable fraction) (Also referred to as: respirable particulate matter).
ROS	Reactive oxygen species.
RR	Relative risk.
SCOEL	The Scientific Committee on Occupational Exposure Limits is a committee of the European Commission, established in 1995 to advise on occupational health limits for chemicals in the workplace within the framework of Directive 98/24/EC, the chemical agents directive, and Directive 90/394/EEC, the carcinogens at work directive.
SMF	Synthetic mineral fibre.
SMR	Standardised Mortality Ratio. The SMR is the (total observed deaths in a study population x 100) ÷ (total expected deaths in the study population).
SVF	Synthetic vitreous fibre.
WES	Workplace Exposure Standard – WESs are values that refer to the airborne concentration of substances, at which it is believed that nearly all workers can be repeatedly exposed to, day after day, without coming to harm. The values are normally calculated on work schedules of five shifts of eight hours duration over a 40 hour week. A New Zealand term.
WES-TWA	The average airborne concentration of a substance calculated over an eight-hour working day. A New Zealand term.
WHO	World Health Organisation.
µm	Micrometre, or millionth of a metre.
µg	Microgram, or millionth of a gram.

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