TECHNICAL BRIEFING PAPER: HEALTH EFFECTS FROM EXPOSURE TO FIBROUS GLASS, ROCK WOOL, OR SLAG WOOL

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Executive Summary

The Agency for Toxic Substances and Disease Registry (ATSDR) prepared this briefing paper to provide support for public health decisions regarding residences close to the World Trade Center site that may have elevated levels of fibrous glass in air and settled dust. Fibrous glass is a name for manufactured fibers made of glass. Other names for fibrous glass are fiberglass and glass fibers. There are two types of fibrous glass: continuous filament glass and glass wool. Continuous filament glass is used to make fiberglass fabrics that reinforce plastics, foams, and other materials in boats, automobile bodies, and other products. Glass wool is the principal material in fiberglass insulation widely used in U.S. houses and buildings. Fibrous glass belongs to a larger group of materials called synthetic vitreous fibers. Rock wool and slag wool are also synthetic vitreous fibers. They are made from rock or slag (a by-product of smelting processes) by a process similar to that used to make glass wool. Like glass wool, rock wool and slag wool are used for thermal and sound insulation.

Air concentrations of fibers in workplaces producing or using materials made of fibrous glass or other synthetic vitreous fibers are generally below 0.1 fibers/cc for fibers with lengths greater than 5 µm and widths less than 5 µm. Higher concentrations have been measured when insulation materials were installed or removed in closed places. Indoor air concentrations of synthetic vitreous fibers have been estimated at 100 to 1,000 times less than concentrations in occupational workplaces producing or using materials made of fibrous glass or other synthetic vitreous fibers.

Occupational exposure to synthetic vitreous fibers has been associated with acute irritation of the skin, eyes, and upper respiratory tract. Possible health hazards from long-term exposure to airborne fibrous glass, rock wool, or slag wool include effects associated with occupational exposure to asbestos (lung scarring, lung cancer, and mesothelioma), but available evidence from epidemiologic and animal studies indicates that these materials are less potent than asbestos. Epidemiologic studies of fibrous glass, rock wool, and slag wool workers provide no consistent evidence for increased risks of mortality from nonmalignant respiratory disease, lung cancer, or pleural mesothelioma. Lung tissue scarring, lung tumors, and mesotheliomas have been observed in rodents exposed to glass wool, rock wool, or slag wool fibers by intratracheal, intrapleural, or intraperitoneal administration, but these lesions were not observed in several studies of rodents exposed to glass wool fibers by inhalation. Results from recent animal research suggest that glass wool, rock wool, and slag wool are less potent than asbestos in producing tissue scarring and tumors due, at least in part, to their relatively rapid rates of dissolution in lung tissue. At chronic exposure levels below currently recommended occupational exposure limits of 1 fiber/cc, elevated risks for developing nonmalignant or malignant respiratory disease are not expected.

The International Agency for Research on Cancer has most recently concluded (in 2001) that insulation glass wool, rock (stone) wool, and slag wool, as well as continuous filament glass, are *not classifiable as to carcinogenicity to humans* because of the inadequate evidence of carcinogenicity in humans and the relatively low biopersistence of these materials. As of April 2002, the monograph supporting the IARC conclusion has yet to be publicly released. The U.S. Department of Health and Human Services' National Toxicology Program concluded in 1994 and 2001 that glass wool (respirable size) *is reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals. The most recently recommended acceptable exposure levels of airborne fibrous glass in U.S. workplaces were adopted by the American Conference of Governmental Industrial Hygienists in 2001. The recommended Threshold Limit Values-Time-Weighted Averages (TLVs-TWAs) are 1 fiber/cc for continuous filament glass fibers, with an A4, *not classifiable as a human carcinogen*, designation, and

1 fiber/cc for glass wool, rock wool, slag wool, and special-purpose glass fibers, with an A3, *confirmed animal carcinogen with unknown relevance to humans*, designation.

Technical Briefing Paper: Health Effects From Exposure to Fibrous Glass, Rock Wool, or Slag Wool

Background and Environmental Exposures

Following the collapse of the World Trade Center, the U.S. Department of Health and Human Services (DHHS) collected air and dust samples inside and outside of selected residences around and near the World Trade Center site. One objective of this sampling was to determine if residents are being exposed to concentrations of materials that may be of public health concern. The samples were tested for asbestos, silica, gypsum, mica, fibrous glass, and calcite. Fibrous glass was detected in some of the air and dust samples. The Agency for Toxic Substances and Disease Registry (ATSDR), a DHHS agency, prepared this briefing paper to provide support for public health decisions regarding residences close to the World Trade Center site that may have elevated levels of fibrous glass in air and settled dust.

Fibrous glass is a name for manufactured fibers made from hot and liquid (molten) glass or sand. The molten material is allowed to cool and solidify so that fibers are formed. Other names for fibrous glass are fiberglass and glass fibers.

There are two general types of fibrous glass: continuous filament glass and glass wool (ACGIH 1997, 2001; IARC 1988; NIOSH 1977). Continuous filament glass fibers are made by pulling molten glass through small holes. Continuous filament glass fibers can be twisted together to form yarn that is used to weave fiberglass fabric. Fiberglass fabric reinforces plastics, foams, and other materials used in the manufacture of boats, automobile bodies, and other products. Most types of continuous filament glass fibers have large diameters (6-15 µm). Glass wool fibers are made by blowing or spinning molten glass through small holes. Glass wool fibers are widely used for thermal and sound insulation in commercial and residential buildings. Fiberglass insulation commonly used in many U.S. homes today is made from glass wool. Glass wool fibers typically have smaller diameters (1-10 µm) than continuous filament glass fibers.

Glass wool and continuous filament fibers are included in a larger class of materials called synthetic vitreous fibers (also referred to as man-made vitreous fibers and previously called man-made mineral fibers) that includes rock wool, slag wool, and refractory ceramic fibers (ACGIH 1997, 2001; NRC

Subcommittee on Manufactured Vitreous Fibers, 2000; Hesterberg and Hart 2001). These materials are made similarly to glass wool, except that the respective starting materials are rock, slag (i.e., by-products of certain smelting operations), and clay. Rock wool and slag wool, like glass wool, are incorporated into thermal and sound insulation material (e.g., batts, blankets, ceiling tiles, and bulk blown-in material) used in buildings. Average diameters of rock wool and slag wool fibers are similar to those of glass wool (1-10 µm). Refractory ceramic fibers are used for high-temperature insulation purposes (e.g., in furnaces). They have average diameters in the range of 1-3 µm.

Synthetic vitreous fibers are generally less durable than asbestos fibers, but vary in durability due to differences in chemical composition. For example, dissolution rates in fluids of composition similar to lung fluids show the following order: glass and slag wools > rock wools > ceramic fibers and continuous filament fibers > chrysotile asbestos (ACGIH 2001).

Concentrations of fibrous glass (and other synthetic vitreous fibers) in air and dust samples are measured with the same techniques used to measure asbestos fibers and other inorganic fibers: phase contrast light microscopy, polarized light microscopy, and transmission electron microscopy (ATSDR 2001; IARC 1988; NIOSH 1994a). Air concentrations are usually measured in units of number of fibers per cubic centimeter (fibers/cc). Fibers are typically counted as particles with lengths greater than 5 µm and length:width ratios greater than or equal to 3:1 (NIOSH 1994a). Other counting rules define fibers as particles with lengths greater than 5 µm, widths less than 3, 3.5, or 5 µm, and length:width ratios greater than or equal to 5:1 (NIOSH 1977, 1994a, b). Under the light microscope, groups of synthetic vitreous fibers can often be distinguished from other fibers, such as asbestos fibers, based on morphological differences, but the identity of individual fibers can be difficult to discern based on morphology alone (Switala et al. 1994). To better distinguish the identity of fibers in air or dust samples, light microscopy can be augmented with other techniques such as energy-dispersive x-ray analysis with scanning or transmission electron microscopy and electron diffraction analysis with transmission electron microscopy (ATSDR 2001). Inhaled fibers with diameters in excess of 3-5 µm are generally defined as nonrespirable; when inhaled they are deposited in the upper respiratory tract and are not carried to lower regions of the respiratory tract where gas exchange occurs (see Appendix A for further discussion of *respirable fibers or particles*).

Based on a comprehensive review of U.S. data for exposure during the production or use of fibrous glass and other synthetic vitreous fibers, the International Agency for Research on Cancer (IARC 1988) concluded that workplace air concentrations were generally below 0.1 fibers/cc for fibers with lengths greater than 5 µm and widths less than 5 µm. In several studies, higher concentrations were measured when insulation materials were installed or removed in closed places. A more recent survey of workplace air concentrations of fibers with lengths >5 µm, widths <3 µm, and length:width ratios ≥5:1 (analyzed by phase contrast microscopy) reported ranges of mean concentrations of 0.006-0.12 fibers/cc for a number of operations in the manufacture of glass wool insulation and a mean of 0.13 fibers/cc (95% confidence interval of 0.1-0.16) for removing glass wool insulation from pipes and ceilings (Jacob et al. 1993). Analysis of tissue samples of autopsied lungs of 145 people who worked in U.S. synthetic vitreous fiber plants and 124 matched referents indicated that lung fiber counts (assayed by phase contrast microscopy) were 60% higher in the workers than referents (McDonald et al. 1990). Electron microscopic analysis indicated that fibers in the lung tissues were of several types (synthetic vitreous fibers, asbestos, and other types) and that no obvious excess of any one type was apparent.

IARC (1988) and the World Health Organization (WHO 1988) reported that data were limited on the concentration of glass fibers and other synthetic vitreous fibers in outdoor ambient air. Reported average concentrations were restricted to 0.0026 fibers/cc in a California study (Balzer 1976), and, in a German study (Hohr 1985), 0.00004 fibers/cc in rural air and 0.00017 fibers/cc in urban air. In a more recent study of ambient air collected from around a fiberglass manufacturing plant and from a rural area in Ohio, average respirable fiber concentrations (lengths >5 µm, widths <3 µm, and length:width ratios ≥5:1) were 0.00156 and 0.00148 fibers/cc, respectively (Switala et al. 1994). The concentrations ranged from nondetectable to 0.02318 fibers/cc for the manufacturing area, and from nondetectable to 0.04290 fibers/cc for the rural area. The detection limit of the phase contrast microscopic analysis was reported to be 0.00001 fibers/cc. Glass fibers accounted only for 0.22% and 0.08% of the fibers measured from the manufacturing and rural areas, respectively.

WHO (1988) concluded that indoor air concentrations of glass fibers are generally 100-1,000 times less than concentrations in occupational environments. The conclusion was based on studies in which fiber concentrations were measured in indoor air samples from Danish schools and offices with ceiling boards containing fibrous glass or other synthetic vitreous fibers (Schneider 1986; Schneider et al. 1990). Mean air concentrations of manufactured fibers with lengths >10 µm and widths <3 µm (detected with phase contrast light microscopy) were reported to range from 0.000026 to 0.00021 fibers/cc. Samples of settled dusts collected from infrequently cleaned surfaces in the rooms were analyzed for fibers using polarized light microscopy. Reported mean concentrations of total manufactured inorganic fibers ranged from 5 to 43 fibers/cm^2 (Schneider et al. 1990). Reported average concentrations for "respirable" manufactured inorganic fibers (widths <3 μm) in settled dust samples were 20, 6, and 10 fibers/cm^2 for rooms in which the quality of cleaning was judged to be poor, medium, or good, respectively. Average concentrations for total manufactured inorganic fibers in settled dust samples from these rooms were 50.9, 19.4, and 26.4 fibers/cm^2, respectively.

Health Effects

Occupational exposure to materials made from fibrous glass, rock wool, or slag wool has been associated with acute irritation of the skin, eyes, and upper respiratory tract. Concern for long-term development of lung scarring (i.e., pulmonary fibrosis) and cancer has been raised because fibrous glass and other synthetic vitreous fibers, when disturbed, can release fibers that can become airborne, inhaled, and retained in the respiratory tract. Part of the concern comes from the knowledge that chronic occupational exposure to asbestos fibers can increase risks for pulmonary fibrosis, lung cancer, and pleural mesothelioma and that these effects take a long time to develop. The recent ATSDR (2001) *Toxicological Profile for Asbestos* provides more detailed information on health effects from asbestos fibers. In contrast to epidemiologic studies of asbestos-exposed workers, epidemiologic studies of fibrous glass workers provide no consistent evidence for increased risks of mortality from nonmalignant respiratory disease, lung cancer, or pleural mesothelioma. Tissue scarring and tumors have been observed in rodents exposed to glass wool, rock wool, or slag wool fibers by intratracheal instillation, by intrapleural implantation or injection, and by intraperitoneal injection, but these lesions were not observed in several studies of rodents exposed to inhaled glass wool fibers or in a few studies involving intraperitoneal injection of continuous filament fibers.

Greater potential for toxicity of inhaled inorganic fibers is associated with higher exposure concentrations, longer exposure durations, longer fiber lengths, greater fiber durability, and thinner fiber widths (see ATSDR 2001; Hesterberg and Hart 2001). Fibrous glass and other synthetic vitreous fibers differ from asbestos in two ways that may provide at least partial explanations for their apparent difference in toxicity. Because most synthetic vitreous fibers are not crystalline like asbestos, they do not split longitudinally to form thinner fibers. They also generally have less durability in biological tissues than asbestos fibers (see Appendix A for discussion of *pulmonary clearance of fibers*).

Irritation Effects. Occupational exposure to fibrous glass materials, including glass wool insulation and fiberglass fabrics, has been associated with acute skin irritation ("fiberglass itch") (Fisher and Warkentin 1969; Heisel and Hunt 1968; Koh et al. 1992; Petersen and Sabroe 1991; Possick et al. 1970; Stam-Westerveld et al. 1994), eye irritation (Longley and Jones 1966; Petersen and Sabroe 1991), and symptoms of upper respiratory tract irritation such as sore throat, nasal congestion, laryngeal pain, and cough (Milby and Wolf 1969; Petersen and Sabroe 1991). The skin irritation has been associated with glass wool fibers having diameters greater than 5 μm and becomes less pronounced with continued exposure (ACGIH 2001; Heisel and Hunt 1968; Stam-Westerveld et al. 1994). Symptoms of irritation of the upper respiratory tract have been mostly associated with unusually dusty workplace conditions (concentrations >1 fiber/cc) involving removal of fibrous glass materials in closed spaces without respiratory protection (ACGIH 2001; EPA 1980). The symptoms have been reported to disappear shortly following cessation of exposure. Similar symptoms of dermal and upper respiratory irritation may also occur in workers involved in the manufacture, application, or removal of insulation materials made from rock wool or slag wool (ACGIH 2001).

Cancer and Nonmalignant Respiratory Disease. Cross-sectional studies of populations working with fibrous glass materials have focused on the prevalence of respiratory symptoms through the administration of questionnaires, pulmonary function testing, and chest x-ray examinations (Clausen et al. 1993; Gross 1976; Hill et al. 1973; Hughes et al. 1993; Nasr et al. 1971; Weill et al. 1983; Wright 1968). In general, these studies reported no consistent evidence for increased prevalences of adverse respiratory symptoms, abnormal pulmonary functions, or chest x-ray abnormalities; however, one study reported altered pulmonary function (decreased forced expiratory volume in one second) in a group of Danish insulation workers compared with a group of bus drivers (Clausen et al. 1993). Such studies, while informative, do not account for workers who had ceased exposure before the study.

There are several cohort mortality and nested case-control studies of groups of workers engaged in the production of fibrous glass or other synthetic vitreous fibers in the United States (Bayliss et al. 1976; Buchanich et al. 2001; Chiazze et al. 1992, 1993, 1995, 1997; Enterline and Henderson 1975; Marsh et al. 1990, 2001a, 2001b, 2001c; Morgan et al. 1981; Watkins et al. 1997), Europe (Boffetta et al. 1999;

Sali et al. 1999; Saracci et al. 1984; Simonato et al. 1986, 1987), Canada (Shannon et al. 1984, 1987, 1990), and Italy (Bertazzi et al. 1986). The studies have focused on determining if occupational exposure to fibrous glass or other synthetic vitreous fibers is associated with increased risk for death from nonmalignant or malignant respiratory disease or mesothelioma. A number of reviews of the fibrous glass cohort mortality and case-control studies concur that the studies provide inadequate evidence for the carcinogenicity of fibrous glass in humans (ACGIH 1997; Hesterberg and Hart 2001; IARC 1988, 2001; Lee et al. 1995; NIOSH 1977; NRC Subcommittee on Manufactured Vitreous Fibers 2000; Wilson et al. 1999).

In the most recent reports of the largest ongoing U.S. study, the 1942-1992 mortality experience of 32,110 workers from 10 fiberglass manufacturing plants was evaluated (Buchanich et al. 2001; Marsh et al. 2001a, 2001b, 2001c). This evaluation is part of the larger ongoing study of 17 plants manufacturing either fiberglass (glass wool or continuous filament glass) or rock wool and slag wool. The authors reported that the study has provided no consistent evidence of a relationship between synthetic vitreous fiber exposure and mortality from malignant respiratory disease (including mesothelioma) or non-malignant respiratory disease, but that a small overall excess risk for respiratory system cancer was found in both fibrous glass workers and rock wool/slag wool workers. Small, but statistically significantly increased standardized mortality ratios (SMRs) for respiratory system cancer were reported for the whole cohort from the 10 fiberglass plants using either national [SMR = 1.16; 95% confidence interval (CI) 1.08-1.24] or local (SMR = 1.06, 95%CI 1.00-1.14) reference mortality rates (Marsh et al. 2001a). However, in a nested case-control analysis, smoking was strongly associated with respiratory system cancer mortalities, but duration of employment or time since first employment were not. In addition, no patterns or statistically significant trends were found for increasing risk for respiratory system cancer mortality with increasing measures of exposure (i.e., years of employment, cumulative exposure measured as fibers/month-cc, or average exposure intensity measured as fibers/cc), with or without adjustment for potential confounding by smoking (Marsh et al. 2001a).

In another large ongoing study involving a number of European plants producing rock wool, slag wool, glass wool, or continuous filament glass, small increased risks for lung cancer and for combined oral, pharyngeal, and laryngeal cancer were recently reported in both the rock wool/slag wool and glass wool subcohorts, but the increases were not statistically significant (Boffetta et al. 1999). Mortality rates from nonmalignant respiratory disease or other nonneoplastic diseases also were not statistically significantly elevated compared with national mortality rates (Sali et al. 1999).

Increased incidences of tissue scarring (i.e., fibrosis) and tumors (e.g., lung tumors, mesotheliomas, sarcomas, or abdominal cavity tumors) have been observed in studies of rodents exposed to glass wool, rock wool, or slag wood by intratracheal instillation (Pott et al. 1984a, 1987), by intrapleural implantation or injection (Fraire et al. 1994; Monchaux et al. 1981; Stanton et al. 1977; Wagner et al. 1976, 1984), and by intraperitoneal injection (Pott et al. 1976, 1984b, 1987; Smith et al. 1987). These lesions were not observed in several studies of rodents exposed by inhalation (Hesterberg et al. 1993; Le Bouffant et al. 1984, 1987; Lee et al. 1981; McConnell et al. 1984, 1994; Muhle et al. 1987; Smith et al. 1987; Wagner at al. 1984) or in a few studies involving intraperitoneal injection of continuous filament glass fibers (Pott et al. 1987). IARC (1988) and Infante et al. (1994) noted that most of the inhalation studies had limitations such as less-than-lifetime exposure durations, small number of animals, lack of survival data, failure to report fiber dimensions, or exposure levels less than those producing maximum tolerated doses. More recent inhalation studies with hamsters reported that exposure to MMVF10a, a glass wool fiber displaying rapid dissolution in the lung, caused only a reversible pulmonary inflammatory reaction without fibrosis or a tumorigenic response (McConnell et al. 1999). In contrast, MMVF33, a more biopersistent glass wool fiber, caused mild pulmonary and pleural fibrosis and mesothelioma, and amosite asbestos, a fiber that does not dissolve in the lung, caused more pronounced fibrotic and mesothelioma responses (McConnell et al. 1999). The different responses to these three inorganic fibers occurred at exposure levels (250-300 fibers/cc, 6 hours/day, 5 days/week for 78 weeks; fibers with diameters <3 μm and lengths >5 μm) that produced equivalent amounts of long fibers (≥ 20 μm) deposited in the lungs immediately after 6 hours of exposure (McConnell et al. 1999).

Recommendations and Regulations

A scientific working group of 19 experts from 11 countries convened by IARC in October 2001 reviewed a new IARC monograph on man-made (i.e., synthetic) vitreous fibers. The monograph was prepared because considerable epidemiologic and toxicolgic research had been conducted since the previous IARC (1988) assessment of these materials. As of April 21, 2002, the monograph had not been published, and the *List of IARC Evaluations* on IARC's Web site (see Appendix B) had not been updated to reflect the new classifications for these materials. As reported in an IARC (2001) press release, the new monograph and the working group concluded that epidemiologic studies published since a previous IARC (1988)[1] assessment provide no evidence of increased risks of lung cancer or of mesothelioma from occupational exposure during the manufacture of synthetic vitreous fibers and inadequate evidence overall of any excess cancer risk (IARC 2001). Insulation glass wool, rock (stone) wool, slag wool, and continuous filament glass were classified in Group 3, *not classifiable as to carcinogenicity to humans* because of the inadequate evidence of carcinogenicity in humans and the relatively low biopersistence of these materials. Refractory ceramic fibers and certain special-purpose glass wools not used as insulating materials were classified in Group 2B*, possibly carcinogenic to humans,* because of their relatively high biopersistence. The U.S. Department of Health and Human Services' National Toxicology Program (1994, 2001) concluded that glass wool (respirable size) *is reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals.

Several recommendations have been made for setting acceptable occupational exposure limits for U.S. workers exposed to fibrous glass (see Appendix B for comparison of recommendations and regulations for fibrous glass and other synthetic vitreous fibers with asbestos).

The most recent recommendations come from the American Conference of Governmental Industrial Hygienists (ACGIH 2001), which adopted Threshold Limit Values-Time-Weighted Averages (TLVs-TWAs) of 1 fiber/cc for continuous filament glass fibers, with an A4, *not classifiable as a human*

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[1] Previously, IARC (1988) had concluded that glass wool, rock wool, and slag wool were *possibly carcinogenic to humans* (Group 2B) based on inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals, and that continuous filament glass is *not classifiable as to carcinogenicity to humans* (Group 3) based on inadequate evidence of carcinogenicity in humans and experimental animals. See Appendix B.

carcinogen, designation, and 1 fiber/cc for glass wool fibers, rock wool, slag wool, and special-purpose glass fibers with an A3, *confirmed animal carcinogen with unknown relevance to humans*, designation. A TLV-TWA of 0.2 fibers/cc was adopted for refractory ceramic fibers with an A2, *suspected human carcinogen*, designation. These recommendations are for fibers with length >5 µm and length:width ratios ≥3:1. They are expected to protect workers from irritation of the upper respiratory tract and any possible long-term respiratory health effects. ACGIH designated continuous filament glass fibers as A4 because several intrapleural implantation studies did not induce mesotheliomas or other tumors in rats, and two intraperitoneal injection studies also were negative. Glass wool was given the A3 designation because carcinogenic responses in animals have only been observed following routes of exposure (intrapleural, intraperitoneal, and intratracheal injection or implantation) not considered relevant to worker exposure. The A2 designation was recommended for refractory ceramic fibers because carcinogenic responses have been observed in animal inhalation experiments, but available epidemiologic studies provide insufficient evidence to confirm or support increased cancer risk in exposed humans.

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) currently has no specific Permissible Exposure Limit (PEL-TWA) for occupational exposure to fibrous glass, but regulates synthetic vitreous fibers by the PELs-TWAs for general particulate dusts of 15 mg/m^3 for total particulate dusts, and 5 mg/m^3 for respirable particulates. In 1992, OSHA proposed an 8-hour PEL-TWA of 1 fiber/cc for respirable fibrous glass in general, construction, maritime, and agricultural industries (ACGIH 1997). The North American Insulation Manufacturers Association, the National Insulation Association, the Insulation Contractors Association of America, and OSHA established a voluntary Health and Safety Partnership Program for fiberglass and mineral wool in May 1999 (Jeffress 1999; Mentzer 1999; OSHA 1999). The program established a voluntary PEL-TWA of 1 fiber/cc for glass wool, rock wool, and slag wool. It also recommended that dust respirators certified by the National Institute for Occupational Safety and Health (NIOSH) be worn when the PEL is exceeded and during specific tasks generating airborne dusts.

In 1977, NIOSH established a Recommended Exposure Limit (REL-TWA) of 3 fibers/cc for fibrous glass fibers having diameter less than or equal to 3.5 µm and length greater than or equal to 10 µm determined as a time-weighted average for up to a 10-hour workshift in a 40-hour workweek. NIOSH noted that it did not consider fibrous glass to be a substance like asbestos that produces cancers as a result of occupational exposure and noted that small diameter fibrous glass fibers "seem to be considerably less hazardous than asbestos." NIOSH (1977) also set a REL-TWA of 5 mg/m^3 for total fibrous glass particulates, noting that it considered the hazard potential of glass fibers with diameters greater than 3.5 µm "to be greater than that of nuisance dust, but less than that of coal dust or quartz."

Conclusions

Reversible acute irritations of the skin, eyes, and upper respiratory tract are well known health hazards associated with direct dermal and inhalation exposure to fibrous glass, rock wool, or slag wool in construction and manufacturing workplaces. The wearing of protective clothing and respiratory equipment has been recommended to prevent these health hazards (and possible chronic health hazards) when airborne concentrations of fibers exceed recommended occupational exposure limits of 1 fiber/cc (ACGIH 2001; Jeffress 1999; Mentzer 1999; OSHA 1999).

Possible health hazards from long-term exposure to airborne fibrous glass, rock wool, or slag wool include effects associated with occupational exposure to asbestos (lung scarring, lung cancer, and mesothelioma), but available evidence from epidemiologic and animal studies indicates that these materials are less potent than asbestos. Epidemiologic studies of fibrous glass, rock wool, and slag wool workers provide no consistent evidence for increased risks of mortality from nonmalignant respiratory disease, lung cancer, or pleural mesothelioma. Lung tissue scarring, lung tumors, and mesotheliomas have been observed in rodents exposed to glass wool, rock wool, or slag wool fibers by intratracheal, intrapleural, or intraperitoneal administration, but these lesions were not observed in several studies of rodents exposed by inhalation to glass wool fibers. Most synthetic vitreous fibers are less durable in lung tissue than asbestos. This difference is thought to be key in explaining the difference in potency. At chronic exposure levels below currently recommended occupational exposure limits of 1 fiber/cc, elevated risks for developing nonmalignant or malignant respiratory disease are not expected.

Appendix A: Definitions of Terms Used To Discuss Health Effects From Inhaled Fibers

Asbestiform: A habit of crystalline aggregates displaying the characteristics of asbestos: groups of separable, long, thin, strong, and flexible fibers often arranged in parallel in a column or in matted masses (Veblen and Wylie 1993; Zoltai 1979, 1981). See definition of *mineral*. Mineralogists call asbestiform amphibole minerals by their mineral name followed by “asbestos.” Thus, asbestiform tremolite is called tremolite asbestos.

Asbestos: A group of highly fibrous minerals with separable, long, thin fibers often arranged in parallel in a column or in matted masses (Veblen and Wylie 1993; Zoltai 1979, 1981). Separated asbestos fibers are generally strong enough and flexible enough to be spun and woven, are heat resistant, and are chemically inert (Veblen and Wylie 1993). See definitions of *fibrous* and *mineral*.

Currently, U.S. regulatory agencies, such as the Environmental Protection Agency (EPA) and OSHA, recognize six asbestos minerals: the serpentine mineral, chrysotile; and five asbestiform amphibole minerals, actinolite asbestos, tremolite asbestos, anthophyllite asbestos, amosite asbestos (also known as asbestiform cummingtonite-grunerite), and crocidolite asbestos (also known as asbestiform riebeckite) (ATSDR 2001; OSHA 1992; Vu 1993). Proposals have been made to update asbestos regulations to include other asbestiform amphibole minerals such as winchite asbestos and richterite asbestos (Meeker et al. 2001; Wylie and Verkouteren 2000).

Asbestosis: Interstitial fibrosis of the pulmonary parenchyma tissue in which asbestos bodies (fibers coated with protein and iron) or uncoated fibers can be detected (American Thoracic Society 1986). Pulmonary fibrosis refers to a scar-like tissue in the lung that does not expand and contract like normal tissue. This makes breathing difficult. Blood flow to the lung may also be decreased, and this causes the heart to enlarge. People with asbestosis have shortness of breath, often accompanied by a persistent cough. Asbestosis is a slow-developing disease that can eventually lead to disability or death in people who have been exposed to high levels of asbestos over a long period. Asbestosis is not usually of concern to people exposed to low levels of asbestos. For more information, see the ATSDR (2001) *Toxicological Profile for Asbestos.*

Fiber: Any slender, elongated particle or mineral structure. For the purposes of counting fibrous glass fibers or other synthetic vitreous fibers in air samples, the NIOSH (1994a) 7400B counting rule is often used: length >5 µm, width <3 µm, and length:width ratio ≥5:1. The ACGIH (2001) TLV-TWAs for synthetic vitreous fibers are for "respirable" fibers with length >5 µm, and length:width ratios ≥3:1 (see Appendix B). For the purposes of counting asbestos fibers in air samples, regulatory agencies commonly count particles that have lengths ≥5 µm and length:width ratios ≥3:1 as fibers (NIOSH 1994a; counting rule 7400A). For detecting asbestos fibers in bulk building materials, particles with length:width ratios ≥5:1 are counted as fibers (NIOSH 1994b).

Fiber-year/mL: Epidemiologic studies of groups of workers exposed to airborne inorganic fibers commonly express exposure in cumulative exposure units of fiber-year/mL or fiber-year/cc. This exposure measure is calculated by multiplying a worker's duration of exposure (measured in years) by the average air concentration during the period of exposure (measured in number of fibers/mL of air or fiber/cc). The units are reported sometimes as fiber/month-cc or fiber/year-cc.

Fibrosis, pulmonary interstitial: Scar-like tissue that develops in the lung parenchymal tissue in response to inhalation of dusts of certain types of substances such as asbestos and silica.

Fibrous: Having the slender elongated shape of a fiber. In mineralogy, fibrous refers to a mineral habit with crystals that look like fibers (Zoltai 1981). A mineral with a fibrous habit is not asbestiform if the fibers are not separable and are not long, thin, strong, and flexible (Veblen and Wylie 1993; Zoltai 1979; 1981).

Mesothelioma: Cancer of the thin lining surrounding the lung (the pleura) or the abdominal cavity (the peritoneum). Mesotheliomas are rare cancers in general populations. Mesotheliomas annually accounted for an average of 1.75 deaths per million in the U.S. general population for the period 1987-1996 (NIOSH 1999). For U.S. white males (the U.S. group with the highest mortality rate), the rates were 3.61 per million in 1987 and 2.87 per million in 1996 (NIOSH 1999). See the ATSDR (2001) *Toxicological Profile for Asbestos* for more information. Increased risk for mesotheliomas has been associated with occupational exposure to asbestos (ATSDR 2001), but not with employment in the manufacture of fibrous glass, rock wool, or slag wool (Marsh et al. 2001b).

Mineral: Any naturally occurring, inorganic substance with a crystalline structure. Naturally occurring, inorganic substances without a crystalline structure (such as amorphous silica) are called mineraloids (Veblen and Wylie 1993).

Parenchyma: The cells or tissue that confer the distinctive function of a gland or organ; for example, the lung parenchyma. The major lung parenchymal abnormality associated with exposure to asbestos is the development of scar-like tissue referred to as pulmonary interstitial fibrosis. Pulmonary interstitial fibrosis shows as widespread opaque areas (opacities) in a chest x-ray that are not present in a normal chest x-ray.

Pleura: A thin lining or membrane around the lungs or chest cavity. This lining can become thickened or calcified in asbestos-related disease. Pleural abnormalities associated with exposure to asbestos include pleural plaques, pleural thickening or calcifications, and pleural effusion (see ATSDR 2001 *Toxicological Profile for Asbestos*). Pleural abnormalities have not been a frequent observation in chest x-ray studies of workers involved in the manufacture of fibrous glass, rock wool, or slag wool (Clausen et al. 1993; Gross 1976; Hill et al. 1973; Hughes et al. 1993; Nasr et al. 1971; Weill et al. 1983; Wright 1968).

Pulmonary clearance of fibers: Clearance of particles or fibers deposited in the lower lung (see definition for *respirable fibers or particles*) involves engulfment (i.e., phagocytosis) by cells called alveolar macrophages. Fiber-containing macrophages are transported to the mucociliary escalator where they can be cleared to the throat. Results from animal studies and studies of lung tissue from fiber-exposed human subjects indicate that fibers with lengths longer than the diameter of macrophage cells (about 12-20 μm) are not cleared from the lower lung until they dissolve or transversely break, because of the inability of macrophages to fully engulf them (Hesterberg and Hart 2001; Hesterberg et al. 1996; Lippmann 1994). The dissolution and transverse breakage of fibers within cells or interstitial fluids is an important feature of the mechanism by which the lung clears respired fibers (Bernstein et al. 1996; Hesterberg and Hart 2001; Hesterberg et al. 1996; Lippmann 1994). Rates of dissolution of different types of fibers in lung fluid have been inversely correlated with abilities to produce cytotoxicity, lung fibrosis, and cancer (Lippmann 1994).

Respirable fibers or particles: Fibers or particles that can be inhaled into the lower lung where gas exchange occurs.

The aerodynamic diameter of a particle is a key determinant of its respirability. The formula for aerodynamic diameter (DA) is DA = $1.3 \times p^{1/2} \times d^{5/6} \times L^{1/6}$, where p=particle density; d=actual diameter; and L=length (Hesterberg and Hart 2001; Stober 1972). The formula shows that length is much less important than actual diameter in determining aerodynamic diameter. Consistent with this are observations that long fibers with very small diameters can be transported into the lower lung. Asbestos fibers longer than 100 µm have been detected in human (Morgan and Holmes 1980; Timbrell 1972) and rat lungs (Morgan et al. 1978).

Fibers or particles with aerodynamic diameters >3-5 µm are expected to be predominantly deposited in the upper airways and not transported to the lower lung (Morgan et al. 1980; Oberdörster 1994). Fibers and particles deposited in the upper airways are quickly cleared to the throat by mucociliary action. Based on a review of the literature on particle deposition in the human lung, ACGIH (2001) published an algorithm predicting the collection efficiency of particles of varying aerodynamic diameters. The algorithm predicts that inhalation exposure to particles of uniform aerodynamic diameters of 1, 5, 6, or 10 µm would lead to the following mass percentages being deposited in the lower lung: 97%, 30%, 17%, or 1%.

Synthetic vitreous fibers: Fibers that are manufactured from molten sand, glass, basalt rock, slag (a by-product of certain smelting processes), or clay. The terms *synthetic vitreous fibers, man-made vitreous fibers, or manufactured vitreous fibers* have replaced the earlier term *man-made mineral fibers*, because these fibers are not naturally occurring and do not have a crystalline structure like naturally occurring mineral fibers such as asbestos fibers. See definitions for *asbestos*, *fiber*, *mineral*, and *respirable fibers or particles*.

Glass wool, rock wool, slag wool, and refractory ceramic fibers are made by spinning or blowing the respective molten starting materials of sand or glass, rock, slag, and clay. Continuous filament glass fibers are made by pulling the molten material through small holes.

Appendix B: Comparison of Recommendations and Regulations for Inorganic Fibers

Cancer Assessments

U.S. Department of Health and Human Services, National Toxicology Program (NTP 1994, 2001)

Asbestos: *known to be a human carcinogen*, based on sufficient evidence of carcinogenicity in humans
Glass wool (respirable size): *reasonably anticipated to be a human carcinogen*, based on sufficient evidence of carcinogenicity in experimental animals [originally listed in the *7th Report on Carcinogens* (NTP 1994), but not changed since then in the *8th and 9th Reports on Carcinogens*]
Refractory ceramic fibers: listed as ceramic fibers (respirable size) in the *7th Report on Carcinogens* as *reasonably anticipated to be a human carcinogen*, and the listing remains the same in the *8th and 9th Reports on Carcinogens*.
Continuous filament glass, rock wool, slag wool: not listed or assessed in the *9th Report on Carcinogens* (NTP 2001)

International Agency for Research on Cancer (IARC)

Asbestos: Group 1, *carcinogenic to humans*, based on sufficient evidence of carcinogenicity in humans (IARC 1987)

Man-made vitreous fibers: In 2001, IARC convened a scientific working group of 19 experts from 11 countries to review a new monograph on man-made vitreous fibers that will replace the previous IARC (1988) monograph on these materials. However, as of April 21 2002, the monograph had not been published, and the *List of IARC Evaluations* on IARC's Web site (http://193.51.164.11/monoeval/grlist.html) had not been updated to reflect the new classifications noted below.

As reported in an IARC (2001) press release, the new monograph and the working group concluded that epidemiologic studies published since the previous IARC (1988) assessment provide no evidence of increased risks of lung cancer or of mesothelioma from occupational exposure during the manufacture of man-made vitreous fibers and inadequate evidence overall of any excess cancer risk. The following new classifications were assigned:
Insulation glass wool, rock (stone) wool, and slag wool, and continuous filament glass: Group 3, *not classifiable as to carcinogenicity to humans* because of the inadequate evidence of carcinogenicity in humans and the relatively low biopersistence of these materials;
Refractory ceramic fibers and certain special-purpose glass wools not used as insulating materials: Group 2B, *possibly carcinogenic to humans,* because of their relatively high biopersistence.

The previous IARC (1988) assessment made the following classifications: glass wool: Group 2B, *possibly carcinogenic to humans*, based on inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals; continuous filament glass: Group 3, *not classifiable as to carcinogenicity to humans*, based on inadequate evidence of carcinogenicity in humans and experimental animals (IARC 1988); rock wool: Group 2B, *possibly carcinogenic to humans*, based on limited evidence of carcinogenicity in humans and limited evidence of carcinogenicity in experimental animals; slag wool: Group 2B, *possibly carcinogenic to humans*, based on limited evidence of carcinogenicity in humans and inadequate evidence of carcinogenicity in experimental animals; refractory ceramic fibers: Group 2B, *possibly carcinogenic to humans*, based on no data on carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.

U.S. EPA Integrated Risk Information System (IRIS) (EPA 2001)

Asbestos: Group A, *human carcinogen,* based on adequate evidence in humans and animals.
Inhalation unit risk = 0.23 per fiber/mL; No oral slope factor
Glass wool, continuous filament glass, rock wool, slag wool: No cancer assessments on IRIS

Refractory ceramic fibers: Group B2, *probable human carcinogen*, based on no data on carcinogenicity in humans and sufficient evidence of carcinogenicity in animal studies

Occupational Recommendations or Regulations

American Conference of Governmental Industrial Hygienists (ACGIH)

Asbestos: TLV-TWA, 0.1 fibers/cc, A1, *confirmed human carcinogen* (fibers counted as particles with length >5 µm and length:width ratio ≥3:1 using phase contrast microscopy) (ACGIH 1998)

Synthetic vitreous fibers: (fibers counted as particles with length >5 µm, and length:width ratio ≥3:1 using phase contrast microscopy) (ACGIH 2001)

Glass wool fibers, rock wool, slag wool, and special-purpose glass fibers: TLV-TWA, 1 fiber/cc, A3, *confirmed animal carcinogen with unknown relevance to humans*

Continuous filament glass fibers: TLV-TWA, 1 fiber/cc, A4, *not classifiable as a human carcinogen*. TLV-TWA, 5 mg/m^3 (measured as inhalable particulates), A4, *not classifiable as a human carcinogen*

Refractory ceramic fibers: TLV-TWA 0.2 fibers/cc, A2, *suspected human carcinogen.*

National Institute for Occupational Safety and Health (NIOSH)

Asbestos: REL-TWA, 0.1 fibers/cc (fibers >5 µm long), as an occupational carcinogen (NIOSH 1992)

Fibrous glass: REL-TWA, 3 fibers/cc, for fibrous glass fibers with diameters ≤3.5 µm and length ≥10 µm and REL-TWA of 5 mg/m^3 for total fibrous glass particulates (NIOSH 1977). NIOSH (1992) notes the recommendations extend to fibrous glass (including glass fibers and glass filaments) and mineral wool (including mineral rock wool and slag wool).

Refractory ceramic fibers: No REL-TWAs for these materials have been set (NIOSH 1992)

Occupational Safety and Health Administration (OSHA)

Asbestos: PEL-TWA, 0.1 fibers/cc for fibers >5 µm long and length:width ratio ≥3:1 (OSHA 2001)

Man-made vitreous fibers: No specific PEL for glass wool, continuous filament glass, rock wool, slag wool, or refractory ceramic fibers is set. These materials are regulated under the PELs-TWAs of 15 mg/m^3 for total particulate dusts and 5 mg/m^3 for respirable particulates (ACGIH 1997).

Fiberglass and mineral wool: The North American Insulation Manufacturers Association, the National Insulation Association, the Insulation Contractors Association of America, and OSHA established a voluntary Health and Safety Partnership Program for fiberglass and mineral wool in May 1999 (Jeffress 1999; Mentzer 1999; OSHA 1999). The program established a voluntary PEL-TWA of 1 fiber/cc for glass wool, rock wool, and slag wool. It also called for the wearing of NIOSH-certified dust respirators when the PEL is exceeded and during specific tasks.

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