

January 31, 2013

Dr. Mahmood A. Khwaja Sustainable Development Policy Institute (SDPI) #3 UN Boulevard Diplomatic Enclave-1, G-5 Islamabad, Pakistan

Dear Dr. Khwaja :

It has recently come to our attention that The Pakistan National Assembly's Standing Committee on Human Resource Development earlier this month decided to recommend a complete ban on the import and use of asbestos (all types). We respectfully submit that before pursuing this important decision that consideration be given to a comprehensive review of the current scientific evidence regarding the significant difference in risk between asbestos fiber types.

Please permit us to describe briefly our organization for the benefit of interested parties considering or participating in this process. The International Chrysotile Association (ICA) is an incorporated, non-profit organization whole membership from 21 countries includes national chrysotile associations and companies using chrysotile fibers in the manufacture of products. The purposes of ICA are:

- 1. To promote the worldwide safe and responsible use of chrysotile; this mandate is derived from Convention 162 of the International Labor Organization concerning Safety in the Use of Asbestos as approved in 1986;
- 2. To create a full awareness of potential health problems associated with the irresponsible use of chrysotile;
- 3. To disseminate and provide prompt information service to member associations and other parties covering medical, scientific and technical matters, both occupational and environmental;
- 4. To put forward the view of the international chrysotile industry and defend it from unwarranted attack.

We submit that it is critical in reaching an informed and objective decision to recognize the distinction between asbestos fiber types and their relative risks to health. As you know, «asbestos» is a generic name given to the fibrous variety of six naturally occurring minerals that have been used in commercial products. The minerals that can crystallize as asbestos belong to two groups: serpentine (chrysotile) and amphibole (crocidolite, amosite, anthophyllite, tremolite and actinolite). There is overwhelming scientific evidence proving that chrysotile presents a vastly smaller health risk than do amphibole fibers.

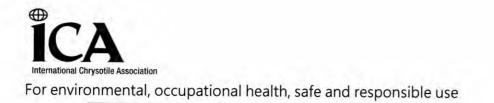
The number of scientific studies demonstrating that chrysotile can and is being used safely, i.e. at low exposures it does not present a detectable risk to health, is numerous. The most recent instance of a peerreviewed study of paramount relevance to your deliberations is entitled *«Health risk of chrysotile revisted»* and is published in Issue 2 of Volume 43 of Critical Reviews in Toxicology (February – March 2013). Its publication is now on-line and the link is : <u>http://informahealthcare.com/eprint/6vsT3NGwu953mmKegdgS/full</u>. We are forwarding a copy of this study herewith for your convenience and urge your and your colleagues' close attention to its contents. Two excerpts from the study's abstract are quoted below:

This review provides a basis for substantiating both kinetically and pathologically the differences between chrysotile and amphibole asbestos. Chrysotile which is rapidly attacked by the acid environment of the macrophage, falls apart in the lung into short fibers and particles, while the amphibole asbestos persist creating a response to the fibrous structure of this mineral.

The importance of the present and other similar reviews is that the studies they report show that low exposures to chrysotile do not present a detectable risk to health. Since total dose over time decides the likelihood of disease occurrence and progression, they also suggest that the risk of an adverse outcome may be low with even high exposures experienced over a short duration.

In addition, we invite your attention to a few other studies that underscore the major difference in health risk between chrysotile and amphiboles:

 The Biopersistence of Canadian Chrysotile Asbestos following Inhalation authored by David M. Bernstein, Rick Rogers and Paul Smith and published in the journal Inhalation Toxicology, Volume 15, Number 13, November 2003. The last sentence of the abstract states, «Taken in context with scientific literature to date, this report provides new robust data that clearly support the difference seen epidemiologically between chrysotile and amphibole asbestos.»



- 2. Comparison of Calidria Chrysotile Asbestos U.S.A. to pure Tremolite: Inhalation Biopersistence and Histopathology Following Short-Term Exposure. Authored by David M. Bernstein, Jorg Chevalier and Paul Smith and published in the journal Inhalation Toxicology, Volume 15, Number 14, December 2003. The last sentence of the abstract states «As Calidria chrysotile has been certified to have no tremolite fiber, the results of the current study together with the results from toxicological and epidemiological studies indicate that the fiber is not associated with lung disease.»
- 3. The Biopersistence of Brazilian Chrysotile Asbestos following Inhalation authored by David M. Bernstein, Rick Rogers and Paul Smith and published in the journal, Inhalation Toxicology, Volume 16, Nos 11-12, 2004. The last sentence of the abstract states, «These results support the evidence presented by McDonald and McDonald (1997) that the chrysotile fibers are rapidly cleared from the lung in marked contrast to amphibole fibers which persist.»
- 4. Environmental and occupational health hazards associated with the presence of asbestos in brake linings and pads (1900 to present): A «State-of-the-art» review authored by Dennis J. Paustenback, Brent L. Finley, Elizabeth T. Lu, Gregory P. Brorby and Patrick J. Sheehan and published in Journal of Toxicology and Environmental Health, Part B, 7:33-110, 2004. The last sentence of the abstract states, «These studies indicated that these workers were historically exposed to concentrations of chrysotile fibers perhaps 10 to 50 times greater than those of brake mechanics, but the risk of asbestosis, mesothelioma and lung cancer, if any was not apparent, except for those workers who had some degree of exposure to amphibole asbestos during their careers.»

Yet another relevant reference that directly pertains to chrysotile and its sage use is a *«To Whom It May Concern»* document dated November 2010, authored by six international scientists, entitled *«On the Safety in Use of Chrysotile Asbestos»* and copy is attached. Its conclusions appear belows:

The latest scientific evidence published strongly supports the following views:

1. Chrysotile is significantly less hazardous than the amphibole forms of asbestos (e.g. crocidolite and amosite);

## 2. When properly controlled and used, chrysotile asbestos in the modern day high-density applications does not present risks of any significance to public and/or worker health.

As to chrysotile cement building materials, it is well known that they are dense, non-friable, durable and cost competitive. With the application of simple control measures, these products do not present any significant risk to workers, the general public or the environment. We enclose two documents: a study entitled A survey of the health problems associated with the production and use of high density chrysotile products (J.A. Hoskins and J.H. Lange) and a Chrysotile Cement Building Materials (brochure) that provide a comprehensive review of these high quality products that have benefited society for almost 100 years.

From the above comments and attachments, there is conclusive evidence that chrysotile cement building materials can and are being manufactured, installed and used safely. The same cannot be said that substitute fibers used as chrysotile substitutes. These substitute fibers are non-regulated, more expensive, less durable and, unlike the minimal risk associated with chrysotile, their potential risk to the health of workers in unknown. We believe that the producers/manufacturers of chrysotile substitutes bear the responsibility of providing sound, scientific evidence of the safety of these substitutes and should be held to the same standard of scrutiny as in the case of chrysotile fibers.

It is surely appropriate to underscore that an asbestos ban has NOT occurred in either Canada, China, India, Indonesia, Malaysia, Philippines, Russia, Sri Lanka, Thailand, Vietnam or the United States and other 129 countries Member States of the World Health Organisation (WHO). The overwhelming majority of bans have occurred within the European Union where political and economic issues are relevant. The attempt to ban most asbestos-containing products published in 1989 by the United States Environmental Protection Agency did not stand when scrutinized by a court of law. A ban of any product, or course, is the most burdensome of regulation and deserves to be weighed carefully. The U.S. EPA ban was challenged in the U.S. court system by a number of interested parties and the ban was overturned completely by the U.S. Court of Appeals for the Fifth Circuit on October 18, 1991. There were a number of reasons for this result including the fact that the U.S. EPA failed to prove an unreasonable risk existed from the use of products banned, that such action would actually «do more harm than good,» and the agency «failed to evaluate the harm that would results from increased risk of substitute products.» Enclosed is a summary of the current status of asbestos-containing products in the United States. And, it should be noted that asbestos cement products are authorized for manufacture and use. In conclusion, we are persuaded the scientific evidence is overwhelming which supports the safe and responsible use of chrysotile and that there is no basis for prohibiting its use in today's high density products.

We hope that our comments above and the attachments hereto will be helpful. Please let us know should you have questions or if we can be of any further assistance.

Sincerely,

Jean-Marc Leblond

Chairman

International Chrysotile Association

Attachments:

- 1. Health risk of chrysotile revisited
- 2. Inhalation Toxicology, Volume 15, Number 13, November 2003 (Canada)
- 3. Inhalation Toxicology, Volume 15, Number 14, December 2003 (Calidria, U.S.A.)
- 4. The Toxicological Response of Brazilian Chrysotile Asbestos
- 5. On the Safety in use of Chrysotile Asbestos, November 2010
- 6. Chrysotile cement Building Materials, brochure
- 7. Review of EPA's attempt to ban most asbestos-containing products in the USA, January 2013
- 8. Review of the differences between chrysotile and amphibole asbestos, August. 2009
- 9. Recent studies published on chrysotile fibers (1998-2005)
- 10. Compendium of articles and scientific studies published on chrysotile fibers (2006-2011)

http://informahealthcare.com/txc ISSN: 1040-8444 (print), 1547-6898 (electronic)

Crit Rev Toxicol, 2013; 43(2): 154–183 © 2013 Informa Healthcare USA, Inc. DOI: 10.3109/10408444.2012.756454 informa healthcare

#### **REVIEW ARTICLE**

### Health risk of chrysotile revisited

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#### Abstract

This review provides a basis for substantiating both kinetically and pathologically the differences between chrysotile and amphibole asbestos. Chrysotile, which is rapidly attacked by the acid environment of the macrophage, falls apart in the lung into short fibers and particles, while the amphibole asbestos persist creating a response to the fibrous structure of this mineral. Inhalation toxicity studies of chrysotile at non-lung overload conditions demonstrate that the long (>20 µm) fibers are rapidly cleared from the lung, are not translocated to the pleural cavity and do not initiate fibrogenic response. In contrast, long amphibole asbestos fibers persist, are quickly (within 7 d) translocated to the pleural cavity and result in interstitial fibrosis and pleural inflammation. Quantitative reviews of epidemiological studies of mineral fibers have determined the potency of chrysotile and amphibole asbestos for causing lung cancer and mesothelioma in relation to fiber type and have also differentiated between these two minerals. These studies have been reviewed in light of the frequent use of amphibole asbestos. As with other respirable particulates, there is evidence that heavy and prolonged exposure to chrysotile can produce lung cancer. The importance of the present and other similar reviews is that the studies they report show that low exposures to chrysotile do not present a detectable risk to health. Since total dose over time decides the likelihood of disease occurrence and progression, they also suggest that the risk of an adverse outcome may be low with even high exposures experienced over a short duration.

#### **Table of Contents**

Abstract
Introduction
The differences in serpentine and amphibole asbestos 155
In-vitro biodurability
The relevance of early inhalation toxicology studies
toxicity:
Non-overload studies that evaluate the toxicity of chrysotile 161
Chronic inhalation toxicity studies
Sub-chronic inhalation toxicity studies
Shorter term inhalation toxicity studies
What do the toxicology studies indicate? 162
Epidemiology studies
Evaluation of epidemiology studies considered in earlier
evaluations
chrysotile exposure
Fiber lung burdens: Charleston, South Carolina, and
Quebec
Discussion of the predominately chrysotile epidemiology
studies:
Chrysotile epidemiological cohort studies
Chrysotile high density cement studies

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Chrysotile studies not specifically of cement products1	73
Chrysotile epidemiological reviews	74
Use and exposures in the past and today	75
Discussion	76
Conclusion	77
Declaration of Interests	77
References	78

#### Introduction

Recent scientific studies have contributed to a more complete understanding of the health risk from chrysotile asbestos as used today in high-density products. Key to understanding this is the differentiation of exposure, dose and response of the serpentine mineral chrysotile in comparison to the amphibole asbestos types such as crocidolite, tremolite and amosite. This paper reviews scientific studies identified as chrysotile only or predominately chrysotile and discusses how the newer toxicological and epidemiological data provide a convergence in the understanding of the risk from chrysotile.

The association of asbestos exposure with disease dates from the turn of the twentieth century (McDonald & McDonald, 1996). The report by Wagner et al. (1960), reporting on 33 cases of mesothelioma, which the authors stated were primarily from the crocidolite mining area in the

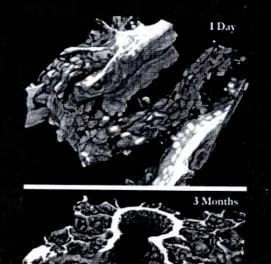
#### Keywords

Amphibole asbestos, cement products, chrysotile, epidemiology, health risk, inhalation toxicology, mining

#### History

Received 22 March 2012 Revised 19 November 2012 Accepted 21 November 2012 ISSN: 0895-8378 INHTE5 15(13) 2003

# Inhalation Toxicology



Volume 15, Number 13 November 2003

NOW 14 ISSUES PERYEAR

> Donald E. Gardner Editor-in-Chief

Taylor&Francis healthsciences BSN: 0895-8378 INHTE5 15(14) 2003

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Volume 15, Number 14 December 2003 Donald E. Gardner Editor-in-Chief

Taylor&Francis healthsciences Inhalation Toxicology, 18:313-332, 2006 Copyright C Taylor and Francis Group, LLC ISSN: 0895-8378 print / 1091-7691 online DOI: 10.1080/08958370500515871



### The Toxicological Response of Brazilian Chrysotile Asbestos: A Multidose Subchronic 90-Day Inhalation **Toxicology Study with 92-Day Recovery to Assess Cellular and Pathological Response**

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Inhalation toxicology studies with chrysotile asbestos have in the past been performed at exceedingly high doses without consideration of fiber number or dimensions. As such, the exposures have exceeded lung overload levels, making quantitative assessment of these studies difficult if not impossible. To assess the cellular and pathological response in the rat lung to a wellcharacterized aerosol of chrysotile asbestos, a 90-day subchronic inhalation toxicology study was performed using a commercial Brazilian chrysotile (CA 300). The protocol was based on that established by the European Commission for the evaluation of synthetic vitreous fibers. The study was also designed to assess the potential for reversibility of any such changes and to permit association of responses with fiber dose in the lung and the influence of fiber length. Wistar male rats were randomly assigned to an air control group and to 2 CA 300 exposure groups at mean fiber aerosol concentrations of 76 fibers  $L > 20 \ \mu m/cm^3$  (3413 total fibers/cm<sup>3</sup>; 536 WHO fibers/cm<sup>3</sup>) or 207 fibers  $L > 20 \ \mu$ m/cm<sup>3</sup> (8941 total fibers/cm<sup>3</sup>; 1429 WHO fibers/cm<sup>3</sup>). The animals were exposed using a flow-past, nose-only exposure system for 5 days/wk, 6 h/day, during 13 consecutive weeks (65 exposures), followed by a subsequent nonexposure period lasting for 92 days. Animals were sacrificed after cessation of exposure and after 50 and 92 days of nonexposure recovery. At each sacrifice, subgroups of rats were assessed for the determination of the lung burden; histopathological examination; cell proliferation response; bronchoalveolar lavage with the determination of inflammatory cells; clinical biochemistry; and for analysis by confocal microscopy. Through 90 days of exposure and 92 days of recovery, chrysotile at a mean exposure of 76 fibers  $L > 20 \ \mu m/cm^3$  (3413 total fibers/cm<sup>3</sup>) resulted in no fibrosis (Wagner score 1.8 to 2.6) at any time point. The long chrysotile fibers were observed to break apart into small particles and smaller fibers. In vitro modeling has indicated that these particles are essentially amorphous silica. At an exposure concentration of 207 fibers  $L > 20 \ \mu m/cm^3$  (8941 total fibers/cm3) slight fibrosis was observed. In comparison with other studies, chrysotile produced less inflammatory response than the biosoluble synthetic vitreous fiber CMS. As predicted by the recent biopersistence studies on chrysotile, this study clearly shows that at that at an exposure concentration 5000 times greater than the U.S. threshold limit value of 0.1 f(WHO)/cm3, chrysotile produces no significant pathological response.

Received 16 September 2005; accepted 16 November 2005.

This study was sponsored by a grant from SAMA Mineração de Amianto LTDA. Brazil.

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AIA NA

November 2010

### TO WHOM IT MAY CONCERN

### ON THE SAFETY IN USE OF CHRYSOTTLE ASBESTOS

It must be recognized that past, uncontrolled use of all the commercial types of asbestos has left a sad legacy of disease and death as a result of carelessness in handling these mimerals, especially in the workplace and sometimes in the general population.

Yet, over the last 50 years, the world production has not declined. The world production in 1960 was around 2M tonnes, and still amounted to 2M tonnes in 2009. However, while the world production in the early 60s included all major types (chrysotile, crocidolite and crocidolite), the production of the amphibole varieties (crocidolite and amosite) has ceased since the 1987 and 1992 respectively. Unfortunately, because of procrastination by some governments in implementing regulation of amphiboles, the remaining amphiboles invontories were allowed to be used in some factories up to the mid 90s. In addition, due to the large use in past years of amphiboles by some countries, a significant background level of amphibole asbestos remains. Due to the characteristic long latency associated with onset of asbestos-related cancer, especially with mesothelioma, a high incidence of this particular cancer of the pleura may be foreseen in those industries for the next two or three decades.

The carcinogenic potency of amphibole asbestos has been established both epidemiologically and texicologically, leading to it being no longer used in commerce. In 1989, a group of international experts convened by the World Health Organization (WHO) in Oxford (UK) had recommended that these asbestos varieties should be prohibited immediately, and that the use of chrysotile should be controlled and regulated at a permissible exposure limit of 1 fiber/ml in the workplace.

Today, the remaining practical concern is whether chrysotile can be produced and used safely, and if indeed this regulation carries a reasonable assurance that workers are adequately protected. Based upon current science, the short answer to this question is that in absence of amphiboles, the use of chrysotile at current Québec permissible exposure limits in the workplace carries no epidemiologically and clinically detectable increase in risk. Indeed, a number of recent scientific studies published in peer-reviewed journals have come to this conclusion (see Annex). From these published studies, it can be seen that safety in the use of chrysotile is not a simple wish, but a resility. The International Labour Organization (ILO) has issued a « Code of Practices » entitled « Safety in the Use of Asbestos », which addresses all pertinent issues regarding the modern and responsible use of asbestos.

(This Code of Practice is available by downloading it from : http://www.ike.ong/safework/normative/codes/lang-on/docName--WCMS\_107843/indes.htm)

Erosion of surface deposits over millennia means that chrysotile is a ubiquitous component of the particulate matter in the air. The WHO (1986) estimates the background exposure to chrysotile as between 0.01 and 0.001 fiber per milliliter of air. The risk to health from this background exposure is, for all practical purposes, non existent. Industrial and other

## Chrysotile Cement Building Materials

Safe, durable, and cost competitive, these products also offer many benefits to developing countries which have a large and growing need for dependable and affordable housing

For more than 80 years chrysotile fibre has been combined with cement to produce a wide range of cost-effective and durable high performance building and construction materials. The products range from traditional low-cost corrugated sheets to today's more sophisticated roofing, cladding and extruded products available in a variety of designer colors and textures.

Chrysotile cement building materials are dense and non-friable. The chrysotile fibre is encapsulated in the cement, preventing the release of fibres. With the application of simple control measures, these products do not present any significant risk to workers, the general public or the environment

### REVIEW OF EPA'S ATTEMPT TO BAN MOST ASBESTOS-CONTAINING PRODUCTS IN THE UNITED STATES OF AMERICA

(January 2013)

On October 18, 1991, the U.S. Court of Appeals, for the Fifth Circuit, struck down the Environmental Protection Agency's (EPA) 1989 rule that would have, by 1996, banned nearly all uses of asbestos in the United States. In short, the Court concluded that "EPA failed to muster substantial evidence to support its rule," and that the rule, therefore, is "vacated." Earlier, in 1975, EPA had banned the use of asbestos as sprayed insulation in structures. The principal basis for this ban was due to the friable nature of this use and is unlike the current, non-friable uses of asbestos.

In its 57-page 1991 decision the Court "concluded that EPA has presented insufficient evidence to justify its asbestos ban." The Court stated that its conclusion was based on "the failure of EPA to consider all necessary evidence" and "to give adequate weight to statutory language requiring it to promulgate the least burdensome, reasonable regulation required to protect the environment adequately." The Court found EPA's support for a ban under the Toxic Substances Control Act (TSCA) deficient in several ways.

First, after noting that a ban -"the death penalty alternative" - is "the most burdensome of all possible" rules under TSCA, the Court held EPA had failed "to explore in more than a cursory way the less burdensome alternatives to a total ban." EPA failed, the Court stated "to calculate the costs and benefits" of "cach regulatory option," as it is required to do to determine whether "any other regulation...would achieve an acceptable level of risk."

Second, the Court found EPA had failed "to evaluate the harm that will result from increased use of substitute products," many of which, the Court noted, contained carcinogens. As a result, said the Court, the ban "actually may increase the risk of injury Americans face."

Third, the Court held EPA had failed by "basically ignoring the cost side of the TSCA equation" to meet the statutory requirement to "balance the costs of its regulation against their benefits." The Court noted that "EPA's willingness to argue (for) spending \$23.7 million to save less than one-third of a life reveals that its economic review of its regulations, as required by TSCA, was meaningless."

# REVIEW of the differences between chrysotile and amphibole asbestos



August 2009

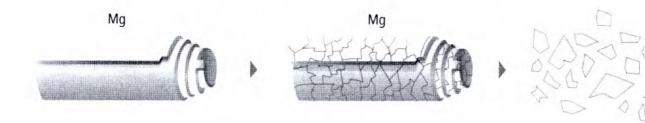
"Asbestos" is not a mineral in itself. It is a collective term given to a group of minerals whose crystals occur in fibrous forms. The term "asbestos" was adopted for commercial identification.

The six minerals commonly referred to as asbestos come from two distinct groups of minerals. One group is known as serpentines (chrysotile, white asbestos); while the other group is the amphiboles (amosite, brown asbestos; crocidolite, blue asbestos; anthophyllite; tremolite; and actinolite). While both are all silicate minerals, the two groups are chemically and mineralogically distinct.

#### CHRYSOTILE

Chrysotile is a sheet silicate which is formed as a very thin rolled sheet as illustrated in Figure 1. The sheet is about 8 angstroms thick (0.8 nanometers thick). It is composed of a sandwich of magnesium and silica. In the lung, the acid environment of the macrophage scavenger cell quickly breaks apart the sheet structure causing the fiber to decompose into small pieces (Figure 2). These pieces can then be readily cleared from the lung. If the fiber is swallowed and ingested it is attacked by the even stronger acid environment (hydrochloric acid, pH 2) in the stomach. 6

Figure 1 - Chrysotile



# RECENT STUDIES PUBLISHED ON CHRYSOTILE FIBERS

COMPENDIUM OF ARTICLES AND SCIENTIFIC STUDIES PUBLISHED ON CHRYSOTILE FIBRES (2006 – 2011)