

Observation

THE ASBESTOS DILEMMA: II. THE BAN

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This article reviews the history of legal steps which led to conflicting regulatory approaches to the use of asbestos between the EU, the US and the rest of the world. Particular attention is paid to the EU ruling out the use of all types of asbestos. The author criticises how the Scientific Committee on Toxicity, Ecotoxicity and the Environment of the European Commission altered their own opinion within as short a time as seven months, and points out the weaknesses of the scientific justification for the EU ban. With equal criticism the author addresses the weak scientific rationale on which Collegium Ramazzini founds its call for an immediate and total international ban of the mining and use of all types of asbestos.

KEY WORDS: *chrysotile, EPA ban, EU ban, international total ban*

LEGAL STEPS LEADING TO THE BAN

The EPA's Asbestos Ban and Phase-out Rule (1) was enacted in 1989, prohibiting all use of asbestos in the US. In 1991, the US Court of Appeals for the Fifth Circuit revoked the ruling (2). The main justification of the withdrawal was that EPA had not analysed other "less burdensome" options to achieve the acceptable level of risk, did not produce sufficient proof for the justification of the ban, and therefore did not prove to have chosen "the least burdensome reasonable option", as requested by the US Toxic Substances Control Act. EPA had not evaluated the potential risks associated with substitute materials, some of which are carcinogenic. The Court particularly criticized the EPA's decision to prohibit the production and the use of asbestos-cement pipes for water supply, as it had not assessed the possible risks of polyvinyl chloride and ductile iron that would be used as substitutes which, even according to EPA, may cause cancer mortality. The Court also criticized EPA for not having assessed the risk of the use of automobile brakes without asbestos; the Court concluded that there was convincing evidence that brakes without asbestos could significantly increase the number of traffic fatalities. The Court also expressed its opinion

that the decision to ban the use of asbestos paper and some other roofing materials on the ground of causing one statistical death in a period of 13 years is a nonsense if this risk is compared, e.g., with the fact that every year, one person in the US dies from swallowing a toothpick. The Court also deemed unacceptable the EPA's readiness to spend 23.7 million dollars for saving less than 1/3 of a statistical life in 13 years, the price that has never been accepted to support a safety regulation. In 1991, the Commission of European Communities issued the Directive 659 prohibiting the marketing and use of all amphibole fibres and of products containing amphibole fibres (3). It also prohibited the use of 14 categories of chrysotile products, permitting, however, the continuation of the use of the most important chrysotile products - asbestos cement, friction materials and insulating or sound proofing materials of greater density than 1 g/cm³ (Table 1).

In 1999, the European Commission extended the 1991 Directive 659 to the marketing and the use of the remaining chrysotile (4), thus banning the use of all the types of asbestos in member-states by the year 2005. The amended Annex to the Directive is in Table 2.

Table 1 Annex to Directive 76/769/EEC as amended by the Commission of the European Communities in 1991, prohibiting the placing on the market and use of amphibole fibres and 14 categories of chrysotile fibres

<p>6.1. Crocidolite, CAS No 12001-28-4</p> <p>Amosite, CAS No 12172-73-5</p> <p>Anthophyllite asbestos, CAS No 77536-67-5</p> <p>Actinolite asbestos, CAS No 77536-66-4</p> <p>Tremolite asbestos, CAS No 77536-68-6</p>	<p>6.1. The placing on the market and use of these fibres and of products containing these fibres intentionally added shall be prohibited.</p>
<p>6.2. Chrysotile, CAS No 12001-29-5</p>	<p>6.2. The placing on the market and use of products containing this fibre shall be prohibited for:</p> <ul style="list-style-type: none"> (a) toys; (b) materials or preparations intended to be applied by spraying; (c) finished products which are retailed to the public in powder form; (d) items for smoking such as tobacco pipes and cigarette and cigar holders; (e) catalytic filters and insulation devices for incorporation in catalytic heaters using liquefied gas; (f) paints and varnishes; (g) filters for liquids. <p>By way of derogation, this prohibition will not apply to filters for medicinal use until after 31 December 1994;</p> <ul style="list-style-type: none"> (h) road surfacing material where the fibre content is greater than 2%; (i) mortars, protective coatings, fillers, sealants, jointing compounds, mastics, glues, decorative powders and finishes; (j) low density insulating or soundproofing materials (density less than 1 g/cm³); (k) air filters and filters in transport distribution and utilization of natural gas and town gas; (l) underlays for plastic floor and wall coverings; (m) textiles finished in the form intended to be supplied to the end use unless treated to avoid fibre release. <p>By way of derogation, this prohibition will not apply to diaphragms for electrolysis processes until after 31 December 1998;</p> <ul style="list-style-type: none"> (n) roofing felt.

Table 2 A part of the Annex to Directive 76/769/EEC as amended in 1999

<p>6.1. Crocidolite, CAS No 12001-28-4</p> <p>Amosite, CAS No 12172-73-5</p> <p>Anthophyllite asbestos, CAS No 77536-67-5</p> <p>Actinolite asbestos, CAS No 77536-66-4</p> <p>Tremolite asbestos, CAS No 77536-68-6</p>	<p>6.1. The placing on the market and use of these fibres and of products containing these fibres added intentionally shall be prohibited.</p>
<p>6.2. Chrysotile, CAS No 12001-29-5</p>	<p>6.2. The placing on the market and use of this fibre and of products containing this fibre added intentionally shall be prohibited. However, Member States may except diaphragms for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner. The Commission will review this derogation before 1 January 2008.</p>

POSITION OF THE SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT ON HUMAN HEALTH RISKS FROM CHRYSOTILE (FEBRUARY 1998)

The Directorate General III (Industry) of the European Commission commissioned the Environmental Resources Management (ERM) of Oxford, England to make an analysis of the latest evidence that a change in the risk assessment for chrysotile is necessary. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) of the Commission was requested to assess this analysis. The assessment of SCTEE was intended to be the basis for the Commission's decision as to whether a change of the Directive 659 of 1991 was necessary. The following are the main points of the SCTEE report (5):

- The ERM report provides no new evidence which indicates that a change in the risk assessment for chrysotile is appropriate.
- There is a substantial body of information on chrysotile albeit at high exposure levels. Neither epidemiology nor the animal data is sufficient to identify the nature of the dose-response

relationship at the low doses which reflect current exposure in Europe. Consequently, it is not possible to be certain whether or not there is a true threshold dose for lung carcinogenesis or mesothelioma.

- The ERM statement that the main fibrous alternatives to chrysotile asbestos are polyvinylalcohol, cellulose and para-aramid fibres is not complemented by adequate information on the technical performance of these materials which render them main alternatives. ERM acknowledges that little research has been carried out on hazards and risks posed by candidate substitutes to chrysotile. Nevertheless, it is concluded that each of these types of fibre is likely to pose less of a risk than chrysotile. In fact, ...the report provides no criteria for comparing hazards and risks (at the same level of technical performance) of chrysotile, MMMFs and other substitute fibres.
- For the substitute materials, with the exception of vitreous fibres, there is no significant epidemiology base to judge the human health risks. The conclusion that specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile, is not well founded.

- The SCTEE recommends a proper evaluation of public, occupational and para-occupational health risks posed by the candidate substitutes.
- Major concerns on the general quality of the ERM analysis include the following: 1. It is based on materials submitted by member-states. This has led to a preponderance of nonscientific material and submissions by interest groups in the list of references. 2. No active and systematic effort has been made in order to trace the available scientific literature. 3. It is based on reviews prepared by others. 4. In many points it is unclear whether remarks referred to any type of asbestos or specifically to chrysotile."

Clearly, the SCTEE assessment of the ERM's analysis is negative, generally concluding that data on health effects of candidate substitutes are scarce, that there are insufficient data to evaluate the dose-response relationship at the current low exposures of chrysotile, and that there is no scientific basis for the conclusion that specific substitute materials pose a significantly lower risk to human health than chrysotile.

OPINION ON CHRYSOTILE ASBESTOS AND CANDIDATE SUBSTITUTES (SEPTEMBER 1998)

In September 1998, only eight months after the first assessment, the SCTEE issued a new, completely different assessment of the same ERM analysis (6). Follow the main points of the second assessment which summarise their change of opinion:

- "- Chrysotile is a proven carcinogen and there is not sufficient evidence that it acts through nongenotoxic mechanism. Thus a cautionary approach is that there is no threshold for the carcinogenic effect of this agent. Regarding the candidate substitutes (i.e., cellulose, PVA, p-aramid fibres), there is neither evidence of carcinogenicity nor reliable toxicological information for identifying no effect levels, if any.
- No epidemiological studies or observations in humans of long term effects of p-aramide or PVA have been reported... in scientific literature probably ...because of the limited number of person-year-observations.
- A recent review summarizes published studies on 4 cohorts of workers exposed to cellulose fibres.

Excesses of cancer death were reported in some of the studies.

- To the knowledge of the SCTEE no cases of lung fibrosis have been reported among workers exposed to either ...p-aramid, cellulose or PVA fibres. In fact, the medium and long term effects of each of these three agents on the lung function have been investigated to a limited extent.
- Dermatoses may occur in workers exposed to p-aramid, at an unknown frequency.
- As for cellulose fibres, a study on workers in a soft paper mill production unit exhibited excess mortality from chronic obstructive pulmonary disease and asthma, with no excess of cancer deaths. Workers in this unit also exhibited a decrease in lung vital capacity and residual pulmonary volume.
- In rats, chrysotile produced mesotheliomas and lung carcinomas after inhalation and mesotheliomas after intrapleural administration. For most of these experiments, it is not known whether and to which extent the chrysotile, which was administered to animals, was contaminated with amphiboles.
- No adequate long term carcinogenicity experiment with either cellulose or PVA fibres has been reported in the published literature.
- The toxicity of cellulose fibres has recently been reviewed. These fibres were found to be toxic to mouse macrophages in vitro, as shown by the release of lactic dehydrogenase. Cellulose fibres have been shown to be as effective as chrysotile in stimulating macrophages to release inflammogenic substances, such as interleukin-1, and were more effective than asbestos in stimulating the release of prostaglandins. Cellulose powder instilled into rat lung produced a persistent granulomatous response.
- Very little information is available on the pulmonary toxicity of PVA fibres in laboratory animals.
- P-aramid was inactive in gene mutation tests in bacteria in mammalian cells. No adequate evaluation of genotoxicity can be done. No data have been found for polyvinylalcohol and for cellulose fibres.
- Conclusions: No evidence of fibre-caused cancer occurrence in men is available for any of the three candidate substitutes. Admittedly, for cellulose fibres, this may reflect limitations in the design of the underlying studies, whereas the lack of epidemiological studies on PVA and p-aramid may

be due to the relatively short time elapsed since the onset of industrial uses of these materials.

- Acute and subacute toxicity data on the three substitute fibres are very meagre and do not allow for a proper comparison with chrysotile, with the possible exception of p-aramid, which in experiments in rats was shown to cause less inflammation and cellular proliferation than chrysotile given at similar doses. In vitro, the ability of cellulose to induce certain inflammation-related changes seems greater than that of chrysotile".

After reporting the serious lack of toxicological data for all three candidate substitute fibres, the SCTEE concluded:

"Both for the induction of lung and pleural cancer and lung fibrosis and for other effects, it is unlikely that either cellulose, PVA, or p-aramid fibres pose an equal or greater risk than chrysotile asbestos".

As can be assessed from the parts of their report preceding their conclusions and even from parts of the Conclusions, the SCTEE final evaluation is not supported by sufficient scientific evidence.

The last sentence of the SCTEE report makes it clear that the Committee also felt that way: "SCTEE also strongly recommends expansion of research in the areas of toxicology and epidemiology of the substitute fibres". It is a strange recommendation after having recommended the substitution of these fibres for chrysotile asbestos. It is out of line with the ILO recommendation in the Convention Concerning Safety in the Use of Asbestos (7) "The replacement of asbestos or of certain types of asbestos or products containing asbestos by other materials or products or the use of the alternative technology, should be scientifically evaluated by a competent authority as harmless or less harmful".

SCIENTIFIC JUSTIFICATION FOR THE NEW DIRECTIVE

The EU scientific justification for the amendment to the Directive 659 on the basis of the ERM and the SCTEE reports is summarised below (8):

- No threshold level of exposure has been identified below which chrysotile does not pose carcinogenic risks and (on the basis of available information) substitutes are available for the majority of current uses of chrysotile and they are likely to pose less of a risk to health than chrysotile.

- It may be appropriate, *in the absence of definitive information*, to assume that there is no safe dose of chrysotile.
- The conclusion that specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile, *might eventually prove to be correct*.
- *More data should be gathered* on the risks of the main substitutes so that they could better compare the risks with chrysotile.
- The expansion of research in the areas of toxicology and epidemiology of substitute fibres as well as in the technology of the development of new, thicker (less respirable) fibres is recommended."

The wording obviously reflects the hesitancy and the uncertainty of the SCTEE with respect to their own conclusions. The phrases, such as "in the absence of definitive information", "might eventually prove to be correct", "more data needed for better comparing the risks", and "on the basis of available information", are indicative of their own doubts.

CALL FOR AN INTERNATIONAL BAN AND THE COMMENT ON THE CALL

The Collegium Ramazzini called for an immediate ban on all asbestos mining and use, "which must be international in scope and must be enforced in every country of the world" (9, 10). According to the Collegium: "1. asbestos is an occupational and environmental hazard of catastrophic proportions for which safer substitutes exist, 2. 'controlled use' is not possible, 3. early indication that chrysotile might be less dangerous than other forms of asbestos have not been supported, and 4. the strictest occupational exposure limits in the world for chrysotile asbestos (OSHA: 0.1 f/ml of air) are estimated to be associated with life-time risks of 5 per 1,000 for lung cancer and 2 per 1,000 for asbestosis".

A number of papers do not support the approach of the Collegium Ramazzini (11-15).

With reference to points 1 and 2, the Collegium provides no data to support the statement that safer substitutes exist and that the 'controlled use' of asbestos is not possible. As for the 3rd point, by saying that early indications that chrysotile might be less dangerous have not been supported [giving as reference the IPCS Environmental Health Criteria 203 (16)], the Collegium distorts the content of the Criteria.

In fact, there is a statement in the Evaluation of the Criteria Document that endorses the evaluation of the previous IPCS Criteria Document 53 from 1986 which addressed all types of asbestos, including chrysotile (17): "The risk of mesothelioma in chrysotile-exposed workers is less than that in workers exposed to crocidolite or amosite". As for the 4th point, the reference to the strictest occupational exposure limit in the world for chrysotile is wrong, as the exposure limit (OSHA) concerns all types of asbestos and not chrysotile alone. Besides, the OSHA exposure limit is based on the data obtained from the production and use of asbestos insulation, which mainly involve amphiboles whose unit risk, even according to EPA [Table 3 in (21)], is considerably higher than that of chrysotile (K_L amosite 430, K_L chrysotile 2.3 or 9.8).

The Collegium's choice of supportive literature clearly shows that it deliberately overestimates the risks of chrysotile, disregarding the majority of published asbestos risk assessments (including those with subjects exposed mainly to chrysotile asbestos). It mainly relies on the papers by Selikoff and co-workers (18-20) investigating the consequences of exposure to obviously more hazardous amphiboles (21) and on one cohort study of textile workers (22) with an extraordinarily high slope of exposure-response relationship which is 10-30 times higher than in chrysotile miners (21). Obviously, the Collegium intentionally omitted the largest cohort study ever of Canadian chrysotile miners by McDonald and co-workers. It is unacceptable that not a single reference to McDonald and co-workers has been made, although this group has published the greatest number of papers on chrysotile asbestos exposure in the world literature (see references 47-53 in 21). It is clear that the mining industry must be a useful source of information for asbestos risk assessment because it produces fibres for all the other asbestos industries. It has been shown (15, 23) that risks of asbestosis, lung cancer and mesothelioma are 15-50 times lower in chrysotile than in amphibole miners. The same has also been shown for nonoccupational exposure (12, 24). It is clear that risk assessment of chrysotile exposure must be based on subjects exposed to this type of asbestos and not predominantly to amphiboles. Even the K_L data of EPA [presented in Table 3 of the first part of this paper (21)] clearly show the difference in unit risks between chrysotile and amphiboles.

Referring to the paper by Camus and co-workers (12), the Collegium emphasised that a recent study of women residing in communities in Canadian

asbestos mining areas showed a sevenfold increase in death rate from pleural cancers, but intentionally ignored the finding reported in the same paper that no excess of lung cancers among residents of the same mining towns was found, and that even the quoted number of mesotheliomas is at least 20 times lower than that which would be calculated using the EPA model (11).

The two most comprehensive asbestos risk reviews issued by the US Health Effects Institute (HEI) and Institut National de la Santé et de la Recherche Médicale (INSERM) (25, 26) showed that excess lung cancers, pleural mesotheliomas, and peritoneal mesotheliomas in mainly amphibole industries are 3, 12, and 30 times more frequent, respectively than in chrysotile industries for an equal number of expected cases.

Rickards (27) reported that the current controlled occupational exposure is practically 1,000 times lower than in the past. In other words, workers who are now exposed to chrysotile run at least 1,000 times lower lifetime risk than those who were exposed to the mixture of asbestos fibres in the past. This translates into 1-5 per 100,000, or the estimation 20-100 times lower than that of the Collegium Ramazzini (14).

Camus is very reserved about the Collegium's argument that there are safer substitutes (14) and refers to opposing evidence in papers showing that PVA and p-aramid (kevlar fibres), and cellulose are more biopersistent than chrysotile, that p-aramid fibres induced fibrosis and mesothelioma in animal studies, and that cellulose produced cytotoxic effects.

CONCLUSIONS

The asbestos dilemma continues. Or rather, the chrysotile dilemma, as the amphiboles are no longer an issue, except for the tremolite asbestos as an impurity in chrysotile.

Although the dose-response relationship has been clearly established for diseases associated with the pure chrysotile such as fibrosis, lung cancer, and mesothelioma, there is a disagreement regarding the dose-response curve at low doses. Some authors believe that the dose-response relationship for chrysotile is a threshold phenomenon while others strongly oppose this proposition. The issue becomes even more complex, as the unit risks

(expressed as the increase in lung cancer risk per unit of cumulative exposure) vary widely among different types of exposure (16): by far the greatest cancer risk is associated with the textiles (0.01–0.03), considerably lower are the risks associated with the production of asbestos cement (0.0003–0.007), the manufacture of friction materials (0.0005–0.0006), and chrysotile mining (0.0006–0.0017). The relative risks of lung cancer in relation to cumulative exposure in chrysotile textile workers were shown to be 20–30 times steeper than those in chrysotile mining, production of friction materials or in chrysotile cement product manufacture. In asbestos cement production, the standard mortality rates from lung cancer in groups exposed almost exclusively to chrysotile were not found to be significantly increased; in the manufacture of friction materials for brakes and clutches there was practically no relationship between the relative risk and exposure. In chrysotile miners and millers, the increase in the relative risk was found only in heavy cumulative exposure or in exposure to chrysotile contaminated with tremolite. Relevant studies claim that there is a practical threshold of exposure below which no measurable health effect should be expected (21).

This does not mean that chrysotile does not pose a risk to human health. Exposure to chrysotile has caused cancers, but the current cancers are the consequence of high exposure of 30–50 years ago. Whether chrysotile will cause these events in future, and to what extent, depends on the current types and levels of exposure which are incomparably lower.

Unfortunately, there is a general mistrust between those who support the 'amphibole hypothesis' and those who oppose it. Scientists are divided in two practically irreconcilable groups. Suspicions have been expressed that some scientific findings have been conditioned by financial support from asbestos producing industries or countries, while others have raised the question whether findings supporting the total ban of all types of asbestos are free from the influence of those industries or countries that produce and export non-asbestos substitute materials.

The call for an eventual ban of all types of asbestos is at least partly motivated by the just interest for protecting human health from a recognized carcinogen. However, the insistence to immediately replace it by substitutes of unknown toxicity and, particularly, of unknown risk to human health, raises suspicion of hidden motives. The EU decision to ban asbestos, in spite of the lack of scientific support by their own Scientific Committee, must have been

politically motivated. Eventually, it might prove to be a good decision, but there is no defensible basis for it until the potential substitutes are objectively evaluated. At the moment, Europe faces a situation similar to that of the US EPA in 1991 when the Court of Appeals for the Fifth District revoked their Ban and Phase-out Rule.

As for Croatia, let me summarise what I recently wrote in a paper entitled "The Time to Get Ready for the Problems Caused by Airborne Fibres?" (28). In view of Croatia's intention to join the European Union, there is no doubt it will have to adopt the EU legislation, including, of course, the asbestos ban. This raises the following questions: 1. Should the country pass a phase-out rule on asbestos to be applied by the year 2005 (EU enforcement deadline), although it will not become the member of EU by that time? 2. Should it already give more consideration to the possible risks related to the use of other airborne fibres and should the corresponding exposure thresholds be introduced for such fibres? 3. Should definitions of regulated health-related airborne fibres be adopted and the method for their sampling and concentration determination standardized? 4. Should the exposure thresholds also be passed for carcinogenic fibres, and if so, should there be a difference in the approach to genotoxic and epigenetic fibres? 5. Should Croatia adopt the ILO recommendation that only substances proven to be less harmful to human health should be introduced as asbestos substitutes?

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