World Trade Organization (WTO) measures affecting asbestos and products containing asbestos

Chronology

1996 : France announces its intention to ban all types of asbestos.

1997 : France implements its ban. Political and technical discussions. France maintains its position.

1998 : Canada challenges the French decree before the WTO, where France is represented by the European Communities.

1999 : In May and June, the WTO receives written and oral depositions from all parties. Brazil, Zimbabwe and the U.S. EPA request and obtain "Third Party" status. The WTO also receives letters from "Amici Curiae".

In July, the WTO decides to consult a group of international experts (from outside the two parties involved in the dispute).

November, the WTO receives the experts opinions on specific questions.

2000 : A preliminary report to the parties is expected in March, and the final report to the WTO Member States in April or May.

Arguments

Canada challenges the decree on the basis that the ban is a "technical regulation", i.e.: an unacceptably restrictive decree, unnecessary to achieve France's objective. Canada must demonstrate that France:

- cannot prove that banning will further reduce the risk to health than what was already achieved by its present regulation (0,6 f/ml);
- failed to scientifically support its health risk assessment;
- using chrysotile-only at low exposure levels, in high-density modern applications, represents a feasible and acceptably safe alternative to a complete ban.

France claims that there is no alternative but to completely ban in order to protect the health of its population.

Brazil and **Zimbabwe** position is based on "The Marrakech Declaration" (April 15, 1994), adopted at the time of the signature of the Uruguay Round Final Act, with special regard to developing countries. They argue that in imposing the ban, France did not take into account the special development, financial and trade needs of Brazil and Zimbabwe, and did not ensure that the ban did not create unnecessary obstacles to exports. The ban is inconsistent with France's obligations under the TBT (Technical Barrier to Trade) Agreement, art. 12.2 and 12.3.

The **U.S. EPA** (Environment Protection Agency) supports the French ban. Claims that it is the individual country's right to decide and judge what measures are necessary to protect the health of their population.

Comment : This position is inconsistent with the regulatory situation in the U.S. Appears to be a much delayed, frustrated response to having lost its battle to ban asbestos in the U.S. (Final Rule, October 18, 1991, reversing the ban)

<u>The French Decree</u>

Based mainly on an INSERM (French National Institute on Health and Medical Research) report :

- there is really no difference in pathogenecity between asbestos fibre types;
- there is no threshold of exposure to chrysotile below which there is no risk: there is still a residual risk, even at exposures as low as 0,1 f/ml;
- the concept of "controlled use" is not applicable;
- resorting to substitutes is safer.

Based also on recently published predicted high incidence of mesothelioma in the near future, most of it due to chrysotile exposure.

<u>Canada's Response</u>

a) On Fibre Types

The scientific records are numerous and almost totally unanimous in recognizing the difference in pathogenicity between asbestos fiber types (see Annex 1). Predictions of residual risk, even at very low exposure to chrysotile, are "calculated" from extrapolations from very high levels of exposure to mixtures of fibre types, using a "straight-line" dose response relationship.

Comment by Sir Richard Doll: *We have no real grounds for postulating that a linear relationship for lung cancer can be extrapolated back to the levels with which we are concerned in non-occupational settings.* (World Health Organization Scientific Publication No. 90, pp. 511-518, 1989)

b) On the Existence of a Threshold

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) of the DG XXIV of the European Union (February 1998) reports "a threshold implies the demonstration that an effect does not occur at or under a given dose level. The unequivocal demonstration of a negative effect is tantamount to impossible". The CSTEE adds that, given this inherent impossibility to prove a negative, "there may well be a `practical threshold´, such as would be suggested when a huge bulk of good scientific information consistently provides convincing suggestion of a lack of effect."

c) On substitutes

CSTEE Report (February 1998) :

"Conclusion that specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile is not founded".

"...acute and subacute toxicity data on the three substitute fibres are very meager and do not allow for a proper comparison with chrysotile".

"...there is a lack of epidemiological studies due to the relatively short time elapsed since onset of industrial uses of the substitute materials".

d) On the Feasibility of Controlled Use

Controlled use is a reality when :

- only chrysotile is used (threshold limit value of 1 f/ml time-weighed average);
- engineering controls and safe work practices are followed;
- dust monitoring is scrupulously conducted;
- medical surveillance programs are applied;
- workers awareness, information and training programs are conducted.

This results in adequate worker protection, because there is no measurable increased risk to health at this limit value (see Annex 2).

The Asbestos Institute
January 2000

APPENDIX 1

REVIEW OF THE EVIDENCE PUBLISHED AFTER 1976 POINTS TO THE DEFINITE DIFFERENCES IN BIOLOGICAL EFFECTS AND POTENCIES OF CHRYSOTILE ASBESTOS AND THE AMPHIBOLE VARIETIES

There are no less than 25 reports from human studies alone, and they are presented here under two separate sub-headings:

a/ Mortality and morbidity data

•**Wagner, J.C., Newhouse, M.L., Corrin, B., Rossiter, C.E.and Griffiths, D.M. (1988).** Correlation between fibre content of the lung and disease in East London asbestos factory workers. British Journal of Industrial Medicine 45(5):305-308.
"We believe therefore that chrysotile is the least harmful form of asbestos in every respect and that more emphasis should be laid on the different biological effects of amphibole and serpentine asbestos fibre".

•**Kleinerman, J. (1988).** The pathology of asbestos related lung disease. Proceedings, The Fleischner Society, Eighteenth Annual Symposium on Chest Disease, Montréal, Canada, 16-18 May, pp. 33-46.
"Most asbestos workers who develop mesothelioma are exposed to amphibole asbestos. Few mesotheliomas are found in workers exposed to chrysotile... The tremolite exposure is considered to play a major role in the development of the mesotheliomas in these cases".

•**Dunnigan, J. (1988).** Commentary: Linking chrysotile asbestos with mesothelioma. American Journal of Industrial Medicine 14:205-209.
Overview of evidence showing unlikeliness of link of mesothelioma with chrysotile exposure. Epidemiological studies from USA (Weiss, McDonald and Fry, Dement), from Britain (Newhouse, Thomas, Acheson) are analysed, and lung burden studies (Pooley, Wagner, Jones, A.D. McDonald) are also pointed to.

•**Hughes, J.M., Weill, H. and Hammad, Y.Y. (1987).** Mortality of workers employed in two asbestos cement manufacturing plants. British Journal of Industrial Medicine 44(3):161-174.
Mortality of 6,931 employees of two asbestos cement factories was studied. In one of them (plant 2), crocidolite was used along with chrysotile. There were 10 cases of mesothelioma in this study, 8 of whom from the plant 2. The case-control analysis found a significant relation between risk of mesothelioma and proportion of time spent in the area of making a/c pipes where crocidolite was used.

•**Gardner, M.J. and Powell, C.A. (1986).** Mortality of asbestos cement workers using almost exclusively chrysotile fibre. Journal of the Society of Occupational Medicine 36(4):124-126.
Three studies are reviewed of asbestos-cement workers using almost exclusively chrysotile in Great Britain and in Sweden. No asbestos-related mortality in meaningful excess of expected was found. The authors state: "This is in contrast with most studies of workers making similar products from mixed fibres containing mainly chrysotile but also amphiboles, crocidolite and amosite".

•**Berry, G. and Newhouse, M.L. (1983).** Mortality of workers manufacturing friction materials using asbestos. British Journal of Industrial Medicine 40(1):1-7.
Study of 13,400 workers (friction materials) showing no mesothelioma when chrysotile only was used, but 10 mesotheliomas when crocidolite was also used.

•**Thomas, H.F., Benjamin, I.T., Elwood, P.C. and Sweetnam, P.M. (1982).** Further follow-up study of workers from an asbestos cement factory.
British Journal of Industrial Medicine 39(3):273-276.
Study of 1,970 a/c workers, showing no case of mesothelioma over 40-year period when chrysotile only was used, but 2 mesotheliomas when crocidolite was used during a 2-year period.
•**McDonald, A.D. and Fry, J. (1982).** Mesothelioma and fibre type in three american asbestos factories - Preliminary report.
Scandinavian Journal of Work, Environment and Health 8 (Supplement 1):53-58.
Study of yarns, cloth and packings, and also gaskets manufacturing, showing only 1 case of mesothelioma / 2,341 workers when almost exclusively chrysotile was used, and 18 cases / 1,429 workers when mixed fibre types were used.

• **Acheson, E.D., Gardner, M.J., Pippard, E.C. and Grime, L.P. (1982).** Mortality of two groups of women who manufactured gas masks from chrysotile and crocidolite asbestos: a 40-year follow-up.
British Journal of Industrial Medicine 39(4):344-348.
Study of gas mask workers showing no case of mesothelioma when chrysotile only was used, and 5 cases / 757 workers using crocidolite.

•**McDonald, A.D. and McDonald, J.C. (1978).** Mesothelioma after crocidolite exposure during gas mask manufacture.
Environmental Research 17(3):340-346.
Exposure to crocidolite in making war-time military gas-masks in Québec led to accumulation of 9 cases of mesothelioma out of 56 deaths (16%). High amounts of crocidolite (and some chrysotile) were found in their lungs. This compares with incidence of mesothelioma, 0.26% of deaths in the Québec (chrysotile) mines.

•**Weiss, W. (1977).** Mortality of a cohort exposed to chrysotile asbestos.
Journal of Occupational Medicine 19(11):737-740.
Study showing no case of mesothelioma in millboard and paper manufacturing when chrysotile only is used.

b/ Analysis of mineral lung content

•**Wagner, J.C., Newhouse, M.L., Corrin, B., Rossiter, C.E.R. and Griffiths, D.M. (1988).** Correlation between fibre content of the lung and disease in East London asbestos factory workers.
British Journal of Industrial Medicine 45(5):305-308.
The lungs from 36 past workers of an asbestos factory using chrysotile, crocidolite, and amosite were examined. Crocidolite and amosite lung contents were strongly associated with asbestosis, and with mesothelioma, whereas no such correlation was evident with chrysotile and mullite.

•**Wagner, J.C., Moncrieff, C.B., Coles, R., Griffiths, D.M. and Munday, D.E. (1986).**
Correlation between fibre content of the lungs and disease in naval dockyard workers.
British Journal of Industrial Medicine 43(6):391-395.
Study showing increasing amounts of amphiboles in lung tissue with increasing severity of asbestosis, but no increase of chrysotile.

•**Churg, A. (1985). Malignant mesothelioma in British Columbia in 1982.**
Cancer 55(3):672-674.
Study showing a 300-fold increase of amphiboles in lung tissue of mesothelioma cases, but no difference with general population with regard to chrysotile lung content.

•**Churg, A. (1988).** Chrysotile, tremolite, and malignant mesothelioma in man.
Chest 93(3):621-628.
Churg maintains that of 53 cases of mesothelioma ever reported as caused by chrysotile, in fact 51 may be attributed to contamination by tremolite, crocidolite and/or amosite.

•**Jones, J.S.P., Roberts, G.H., Pooley, F.D., Clark, N.J., Smith, P.G., Owen, W.G., Wagner, J.C., Berry, G. and Pollock, D.J. (1980).** The pathology and mineral content of lungs in cases of mesothelioma in the United Kingdom in 1976.
In Biological Effects of Mineral Fibres, J.C. Wagner Editor, Vol. 1, International Agency for Research on Cancer, IARC Scientific Publications No. 30, Lyon:187-199.
Study in U.K. showing that patients with mesothelioma have a far greater number of amphiboles in their lungs, but same amount of chrysotile when compared to controls.

•**McDonald, A.D. (1980).** Mineral fibre content of lung in mesothelial tumours: - Preliminary report.
Biological Effects of Mineral Fibres, J.C. Wagner Editor, Vol. 2, International Agency for Research on Cancer, IARC Scientific Publications No. 30, Lyon:681-685.
Same observation as above for patients with mesothelioma in North America.

•**Churg, A. (1982).** Asbestos fibres and pleural plaques in a general autopsy population.
American Journal of Pathology 109(1):88-96.
Study showing that patients with pleural plaques have a 50-fold increase of amphiboles compared to chrysotile.

•**Wagner, J.C., Berry, G. and Pooley, F.D. (1982).** Mesothelioma and asbestos type in asbestos textile workers: a study of lung contents.
British Medical Journal 285:603-606.
In an asbestos textile factory that utilized mainly chrysotile with some crocidolite, less chrysotile and more crocidolite fibre were found in the lungs of 12 persons who had died of mesothelioma than in the lungs of controls without mesothelioma.

•**Wagner, J.C., Pooley, F.D., Berry, G., Seal, R.M.E., Munday, D.E., Morgan, J. and Clark, N.J. (1982).** A pathological and mineralogical study of asbestos-related deaths in the United Kingdom in 1977.
The Annals of Occupational Hygiene, Inhaled Particles V, 26(1-4):423-431.
Study showing a 100 fold increase of amphiboles in lung tissue, but similar amounts of chrysotile in referred pneumoconiosis patients.

•**Gylseth, B., Mowe, G. and Wannag, A. (1983).** Fibre type and concentration in the lungs of workers in an asbestos cement factory.
British Journal of Industrial Medicine 40(4):375-379.
The predominant asbestos type used in a Norwegian asbestos-cement factory (1942-1980) has been chrysotile (91.7%), with small admixture of amosite (3.1%), crocidolite (4.1%) and anthophyllite (1.1%). In the lungs of workers who had died of mesothelioma (4) or of lung cancer (3), the percentage of chrysotile fibres was 0%-9% whereas the corresponding proportion for the amphiboles was 76% and 99%.

•**Rowlands, N., Gibbs, G.W. and McDonald, A.D. (1982).** Asbestos fibres in the lungs of chrysotile miners and millers - A preliminary report.
The Annals of Occupational Hygiene, Inhaled Particles V, 26(1-4):411-415.
Lung samples from 47 workers of chrysotile mines in Québec who had died of various causes not related to asbestos were studied. Similar quantities of chrysotile and tremolite were found although tremolite admixture to chrysotile ore is extremely small. It indicates that tremolite persisted in the lungs while chrysotile was dissolved.

•**McDonald, A.D., McDonald, J.C. and Pooley, F.D. (1982).** Mineral fibre content of lung in mesothelial tumours in North America.
The Annals of Occupational Hygiene, Inhaled Particles V, 26(1-4):417-422.
99 case-control pairs of lung tissue specimens were examined from persons who had died of mesothelioma in North America. High content of amosite was found in 26 cases and 8 controls, and high content of crocidolite in 15 cases and 5 controls, while content of chrysotile was equal in cases and controls.

•**Gibbs, A.R., Jones, J.S.P., Pooley, F.D., Griffiths, D.M. and Wagner, J.C. (1989).** Non-occupational malignant mesotheliomas.
In Non-Occupational Exposure to Mineral Fibres, Eds. J. Bignon, J. Peto and R. Saracci. WHO/IARC Scientific Publications No. 90, Lyon:219-228.
The mineral content of the lungs from 84 cases of malignant pleural mesothelioma was estimated by electron microscopy and energy-dispersive X-ray analysis. These cases were chosen because the history of asbestos exposure was absent, indirect or ill-defined. The chrysotile counts in the lungs from these mesothelioma cases were similar to those in controls an in a previous series of mesotheliomas in which the majority had had direct exposure to asbestos. These findings confirm those of previous studies indicating that amphiboles are more important than chrysotile in the causation of malignant mesothelioma. The results confirm that some mesotheliomas develop in the absence of asbestos exposure. "It is possible that chrysotile might potentiate the effects of amphiboles, but we believe that it has either no potential (or a very low one) for mesothelioma induction on its own".

•**Albin A, Pooley FD, Strömberg U, Attewell R, Mitha R and Welinder H (1994)**
Retention patterns of asbestos fibres in lung tissue among asbestos cement workers.
A study which showing different kinetics for amphibole and chrysotile fibres in human lung tissue. Amphibole fibre concentrations increase with duration of exposure, whereas chrysotile concentrations do not. The authors indicate that their study supports a former finding of a possible adaptive clearance of chrysotile, and conclude that their findings "support the hypothesis that adverse effects are associated rather with the fibres that are retained (amphiboles), than with the ones being cleared (largely chrysotile)."

APPENDIX 2

HEALTH EXPERIENCE OF WORKERS AT VERY LOW EXPOSURE LEVELS TO CHRYSOTILE ONLY

•**Berry, G. and Newhouse, M.L. (1983).** Mortality of workers manufacturing friction materials using asbestos.
British Journal of Industrial Medicine 40(1):1-7.
A mortality (1942-1980) study carried out in a factory producing friction materials, using almost exclusively chrysotile. Compared with national death rates, there were no detectable excess of deaths due to lung cancer, gastrointestinal cancer, or other cancers. The exposure levels were low, with only 5% of men accumulating 100 fibre-years/ml. The authors state: "The experience at this factory over a 40-year period showed that chrysotile asbestos was processed with no detectable excess mortality".

•**Newhouse, M.L. and Sullivan, K.R. (1989).** A mortality study of workers manufacturing friction materials: 1941-86.
British Journal of Industrial Medicine 46(3):176-179.
The previous study has been extended by seven years. The authors confirm that there was no excess of deaths from lung cancer or other asbestos related tumours, or from chronic respiratory disease. After 1950, hygienic control was progressively improved at this factory, and from 1970, levels of asbestos have not exceeded 0.5-1.0 f/ml. The authors conclude: "It is concluded that with good environmental control, chrysotile asbestos may be used in manufacture without causing excess mortality".

•**Thomas, H.F., Benjamin, I.T., Elwood, P.C. and Sweetnam, P.M. (1982).** Further follow-up study of workers from an asbestos cement factory.
British Journal of Industrial Medicine 39(3):273-276.
In an asbestos-cement factory using chrysotile only, 1,970 workers were traced, and their mortality experience was examined. There was no appreciably raised standardised mortality ratio (SMR) for the causes of death investigated, including all causes, all neoplasms, cancer of the lung and pleura, and cancers of the gastrointestinal tract. The authors indicate: "Thus the general results of this mortality survey suggest that the population of the chrysotile asbestos-cement factory studied are not at any excess risk in terms of total mortality, all cancer mortality, cancers of the lung and bronchus, or gastrointestinal cancers".

•**Weill, H., Hughes, J. and Waggenspack, C. (1979).** Influence of dose and fibre type on respiratory malignancy risk in asbestos cement manufacturing.
American Review of Respiratory Disease 120(2):345-354.
An investigation on 5,645 asbestos-cement manufacturing workers, showing no raised mortality resulting from exposure for 20 years to chrysotile asbestos at exposure levels equal to or less than 100 MPPC.years (corresponding to approximately 15 fibres/ml.years). The authors state: "...However, the demonstration that low cumulative and short-term exposures did not produce a detectable excess risk for respiratory malignancy may be of assistance in the development of regulatory policy, because a scientifically defensible position based on these data is that there are low degrees of exposure not associated with a demonstrable excess risk".

•**Ohlson, C.-G. and Hogstedt, C. (1985).** Lung cancer among asbestos cement workers. A Swedish cohort study and a review.
British Journal of Industrial Medicine 42(6):397-402.
A cohort study of 1,176 asbestos-cement workers in a Swedish plant using chrysotile asbestos showing no excess related mortality at exposures of about 10-20 fibres/ml.years.

•**Gardner, M.J., Winter, P.D., Pannett, B. and Powell, C.A. (1986).** Follow up study of workersmanufacturing chrysotile asbestos cement products.
British Journal of Industrial Medicine 43:726-732.
A cohort study carried out on 2,167 subjects employed between 1941 and 1983. No excess of lung cancers or other asbestos-related excess death is reported, at mean fibre concentrations below 1 f/ml, although higher levels had probably occurred in certain areas of the asbestos-cement factory.

MOST RECENTLY AVAILABLE EVIDENCE.

McDonald, JC, Liddell, DK, Dufresne, A. and McDonald, AD (1993)
The 1891-1920 birth cohort of Quebec chrysotile miners and millers: mortality 1976-88
Brit. J. Ind. Med. 50: 1073-1081
This study is undoubtedly the largest cohort of asbestos workers ever studied and followed for the longest period is that of the miners and millers of the chrysotile mines in Québec. The cohort, which was established in 1966, comprises some 11,000 workers born between 1891-1920 and has been followed ever since. Optimal use was made of all available dust measurements to evaluate for each cohort member his exposure in terms of duration, intensity and timing. Findings on mortality have been published on five occasions, and the most recent report provides an update of the results of analysis of mortality for the period 1976-1988 inclusive. One of the central findings of this update is that over several narrow categories of exposure up to 300 mpcf.y, the SMRs for lung cancer fluctuated around unity, with no evidence of trend, and increased steeply above that exposure level. Still more recently, the same authors confirmed their original findings with a mortality update up to 1992:

Liddell, FDK, McDonald, AD and McDonald, JC (1997)
The 1891-1920 birth cohort of Quebec chrysotile miners and millers: depelopment from 1904 and mortality to 1992

In terms of present day mandated or recommended exposure levels for chrysotile, and whatever hesitations one might have in converting mpcf to f/ml, even by applying a conservative conversion factor of 1 mpcf ~ 3 f/ml, the above mentioned references including this update provide strong support for the recommendation from the "Group of Experts" convened by the WHO (Oxford, 1989) of a TLV of 1 f/ml for chrysotile asbestos.