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UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

OPTS - 62036

WRITTEN REPLY COMMENTS

GOVERNMENT OF CANADA

OCTOBER 17, 1988

**WRITTEN REPLY COMMENTS
GOVERNMENT OF CANADA**

The following written reply comments represent the considered views of the Government of Canada regarding the Environmental Protection Agency's (EPA's) proposed rule to ban and phase-out asbestos. A review of all the evidence presented by the EPA in support of its proposed rule has been undertaken. The Government of Canada remains of the view that the EPA has not demonstrated the existence of substantial net benefits from its proposed asbestos ban and phase-down rule.

During the recent cross-examination hearings, an EPA official admitted that the alternative being considered for the final rule was not yet formulated (Transcript, September 19, Augustyniak p. 1404) thus, it remains difficult for the Government of Canada to state, with precision, specific concerns about the final rule. We offer however, the following comments for your consideration.

First, EPA's ultimate decision concerning asbestos will, in our opinion, be a signal to industry regarding the manner in which the U.S. Government plans to deal with hazardous materials. While banning a substance may be regarded as the simplest solution to a complex problem, it can set an unwarranted precedent. This would be particularly distressing if the action were to be taken on emotional or subjective grounds rather than on the most current, generally accepted scientific evidence.

In the recent cross-examination hearings, it was disconcerting for Canada to hear the following:

- a) several EPA officials indicated that there remains no differentiation as to the potency of the various asbestos fibre types (chrysotile, crocidolite, amosite and the other 3). Such conclusions are inconsistent with the international consensus, and the balance of scientific evidence as is reflected in a quote from the British Journal of Industrial Medicine: "The existing evidence is convincing that continued failure to differentiate between fibre types by governmental regulatory agencies... is difficult to justify." (Hughes, et al, 1987, p. 172); and
- b) EPA officials also stated that the results of 2 recent NIOSH studies on controlling brake repair emissions through engineering controls were disregarded (Transcript, September 20, pp. 1534-1540). Given that 92% of EPA's alleged

lives saved by its proposal pertain to brake repair workers, further investigation into engineering controls, especially in light of the NIOSH finding, is clearly warranted. The Government of Canada contends, along with the United Kingdom, the European Economic Community, and the vast majority of the international, scientific community that the risks associated with the low levels of airborne asbestos (chrysotile) fibres in controlled occupational environments are minimal.

Based on the above, Canada can only conclude, with concern, that the numerous expert technical submissions to the EPA respecting its evidence have not been seriously reviewed nor analyzed. In fact, it was stated by EPA officials that nothing in EPA's occupational or non-occupational RIA estimates had been amended, added to, or changed as a result of technical submissions received by the EPA (Transcript, September 20, pp. 1494-1495). Given all the effort put forward by experts to present the most current information available to the EPA, Canada is disturbed by such comments.

Secondly, on a policy issue, the Government of Canada reaffirms to the U.S. Environmental Protection Agency, that there is no question that it is the right, indeed the duty of governments to act in a manner so as to protect the health of its citizens, and the health and safety of its workers. Governments however, are expected to apply a consistent and uniform approach to rulemaking. Environmental regulatory actions are best derived when they are based on the analysis of the most objective, scientific evidence available. Fortunately, in the case of asbestos, consistency in regulation is readily achievable because of the abundant scientific and medical evidence available. Indeed, asbestos is probably the most studied industrial material in use.

Current data, which explain why the controlled-use approach has gained such broad acceptance internationally, combined with the improvements in the workplace resulting from occupational health and safety and labour regulations, has led the Government of Canada and others, such as the European Economic Community, to believe that through the enforcement of appropriate regulations to rigorously control exposure, the risks associated with exposure to chrysotile (white) asbestos in mining, milling, product manufacture, installation, transportation and handling can be reduced to acceptable levels.

A controlled-use rule from the EPA would be consistent with the International Labour Organization's (ILO) Convention #162 on Safety in the Use of Asbestos. This Convention, unanimously approved in 1986 by 124 countries including the United States, now ratified by three countries, comes into force as an international instrument on June 16, 1989. As one of the fundamental purposes of the ILO is to guide countries, particularly important for the developing world, and to introduce harmonized regulations that afford optimal and feasible protection to workers for hazards associated with the workplace, confusion would surely result if the EPA stated the need for a ban after the United States, as part of the ILO, supported the controlled-use of asbestos and its products.

Thirdly, an important consideration in rulemaking is the cost to society. Although Canada continues to question the numbers referenced in EPA's case, the EPA documents nevertheless indicated that: "...most of the overall cost per cancer avoided figures are in the \$20 million to \$40 million range..." (RIA, Volume 1, p. 83) with an overall range "...from a low of \$7.7 million per case avoided... to a high of about \$58.4 million per case avoided" (ibid). An EPA rule, we suggest, based on such cost figures, would place an unwarranted burden not only on your society, but also on other countries. However, if the EPA were to support the prevailing scientific view concerning fibre potency, the cost of the proposed rule would increase likely by an order of magnitude. The Government of Canada, and undoubtedly other countries as well, are concerned about the precedence established by such an expensive regulatory measure, especially when a less costly and more realistic option, like controlled-use, has not been considered.

Fourthly, the Government of Canada remains concerned that the principles that the EPA has used for evaluating asbestos substitutes are not used for evaluating the different asbestos fibre types (chrysotile, crocidolite, amosite, tremolite, etc.). EPA experts considered the potency of the man-made and natural fibres which could be considered substitutes for asbestos, but these same experts stated that: "...it is generally difficult to definitively assess the relative biological activity and pathogenicity of nonasbestos fibres in comparison to asbestos because of limited data bases" (Health Hazard Assessment of Nonasbestos Fibres, p. 2). The Government of Canada is concerned that a ban on asbestos will be interpreted by industry as a license to indiscriminately use substitutes. Such a license would essentially be based on convenience and lack of information, rather than on scientific data indicating that substitutes are less hazardous to humans than asbestos. Research

results based solely on data from animal studies are not sufficient to warrant either a good or a bad report-card. This is confirmed by J.C. Wagner's own testimony about his own animal injection studies:

"Our view that chrysotile, if uncontaminated is probably a material causing little disease is not accepted by many workers although the number of converts is increasing. We have provided the major evidence for the innocence of chrysotile to humans. But our experiments suggested that chrysotile is both fibrogenic and carcinogenic. Dr. Pooley is now undertaking a major study into both original samples that we used in our studies, and those fibres retained in the lungs, and preliminary results suggest that we were using contaminated fibre". (Cancer: 57; 1905-1911 (1986)).

This testimony is important to consider and to contrast with Dr. V. Vu's concerns about the sufficiency of epidemiological data when unsubstantiated by animal study data as is reflected by her statement: "...we looked at the evidence from the epidemiology, and we also have to reconcile (it) with the animal data which show otherwise.... So there is conflicting results in epidemiology and animal data." (Transcript, September 19, pp. 1298; 1327-1330).

Lastly, the following quote from a paper presented at the recent VII International Pneumoconiosis Conference (Aug. 23-26, 1988) in Pittsburgh is worth reflecting upon.

"Asbestos-related disease in 90 original employees of a filter paper plant using exclusively crocidolite (1951-1970) were followed up to 1987. Of this group, there were 34 with asbestosis with 8 deaths; 8 have died of lung cancer, and 10 mesotheliomas were found. In a nearby paper plant using exclusively chrysotile (1962 up to the present), 90 employees employed for over 20 years were followed. Only 2 cases of minimal asbestosis were found, and no cases of mesotheliomas or lung cancer were found." ("Asbestos-Related Disease in Crocidolite and Chrysotile Filter Paper Plants", E.A. Gaensler).

In addition, at the above mentioned conference, results of several studies presented appear to further support the hypothesis that crocidolite is more potent than chrysotile in the induction of asbestos-related disease. As we have reiterated on a number of occasions regarding the potency of various fibre types, we consider that it would not be inappropriate for the EPA to consider these results in the context of its risk assessment for "asbestos".

The Government of Canada submits that the proposed rule, if issued on the basis of the EPA's documentation, will place the United States in a position inconsistent with the international community, the majority of which have accepted the philosophy of controlled-use. Moreover, EPA's own evidence suggests that the rule will result in negative net benefits for United States' citizens. This would seem to be contrary to the "public interest" responsibility of regulators, given that other safe, less costly options are attainable.

As the most current scientific data remains uninvestigated by the EPA, the Government of Canada again urges the EPA to reconsider its proposed ban and phase-out of asbestos. Canada is confident that such an investigative review by the EPA, coupled with a consistent rational approach which considers all costs and benefits, providing these are substantial net benefits, will result in the development and issuance of a U.S. asbestos-related regulation which reflects the regulatory wisdom of the world's most developed nation.

APPENDIX

This appendix summarizes some asbestos product information from the cross-examination hearings in the matter of the EPA's asbestos ban and phase-down rulemaking. The following questions and answers concerning key asbestos products result in grave concerns to the Government of Canada.

1. On regulatory products which are no longer in production and/or for which there is no information on exposure, for the purpose of EPA estimating benefits from reduction of exposures, is of concern (for questions and answers in the transcripts, September 20, see pp. 1457-1467).
 - vinyl asbestos floor tile - no production; no importation
 - commercial paper - no production
 - rollboard - no production
 - roofing felt - no production, perhaps importation
 - flooring felt - no production
 - AC corrugated sheet - no production
 - protective clothing - no production
 - battery separators - no information on exposure
 - arc chutes - no information on exposure
 - acetylene cylinders - no information on exposure
 - diaphragms - no production
 - AC pipe - no manufacturing (???)
 - AC shingles - no manufacturing
 - disc brake pads (heavy vehicles) - no information
 - automatic transmission components - no information
2. Comments by EPA staff and consultants concerning asbestos - cement pipe, such as the following:
 - "I have not been asked about controlling exposures during installation of pipe." (Transcript, September 19, p. 1423).
 - "I have not been asked to evaluate controls of stack emissions from ac pipe plants." (Transcript, September 19, p. 1424).
 - "(Exposures from) primary manufacture of AC pipe, no information." (Transcript, September 20, p. 1479).
 - "Cost per cancer avoided in respect to AC pipe is \$113 million." (Transcript, September 22, p. 2020).

3. Comments concerning asbestos - cement shingles such as:

- ° "(AC shingle) has a very long life... perhaps 50 years. When it wears away, what happens to the asbestos fibres? Well common sense, at least my common sense, suggest they are released." (Transcript, September 20, pp. 1588-1589). Common-sense however, is not a substitute for good science!
- ° "Cost per cancer avoided in respect to roof coatings is \$156 million." (Transcript, September 22, p. 2024).

4. Comments concerning asbestos containing brakes:

- ° NIOSH really became the source of (EPA's) brake shop data." (Transcript, Edelstein, September 20, p. 1595). Of note is the fact that other EPA staff have dismissed the NIOSH findings (Transcript, September 20, pp. 1534-1540).
- ° "The problem with Dr. Bragg's data is I do not know of Dr. Bragg's background." (Transcript, Wong, September 20, p. 1614).
- ° "I am not in a position to evaluate Dr. Bragg's comments... and to make the determination of whether the information should be used to revise other estimates..." (Transcript, Augustyniak, September 20, p. 1494).

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REFERENCES

- ACGIH. American Conference of Governmental Industrial Hygienists. Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH for 1980. Cincinnati: ACGIH. 1980.
- Acheson, E. D. and M. J. Gardner. Asbestos: The control Limit for Asbestos. London: H. M. Stationery Office. 1983.
- Berry, Geoffrey, and Muriel L. Newhouse. "Mortality of Workers Manufacturing Friction Materials Using Asbestos." Brit. J. of Ind. Med. 40:1. February, 1983. Pp. 1-7.
- BOHS. British Occupational Hygiene Society, Committee on Hygiene Standards. "Hygiene Standards for Chrysotile Asbestos Dust." Annals of Occ. Hyg. 11. 1968. Pp. 47-48.
- Bragg, Gordon M. "Exposures to Asbestos: An Analysis of the Technical Aspects of the Environmental Protection Agency Proposal to Ban and Phase Out Asbestos." Appendix B 3 to the opening written comments of the AIA/NA and the AI. June, 1986.
- CHAP. Chronic Hazard Advisory Panel on Asbestos. Report to the U.S. Consumer Product Safety Commission. Washington: U.S. Consumer Product Safety Commission. 1983.
- Churg, Andrew. "Lung Asbestos Content in Long-Term Residents of a Chrysotile Mining Town." Am. Rev. Resp. Dis. 134:1. July, 1986. Pp. 125-127.
- Commings, B. T. "The Significance of Asbestos and Other Mineral Fibres in Environmental Ambient Air". Maidenhead: Commings Associates, 1985.
- Constant, Paul C. Jr., Fred J. Bergman, Gaylord R. Atkinson, et al. Airborne Asbestos Levels in Schools, EPA 560/5-83-003. Washington D.C.: U.S. Environmental Protection Agency, Office of Toxic Substances. 1983.
- Crump, Kenny S. "Asbestos Potency Assessment for EPA Hearing." Appendix B 1 to the opening written comments of the AIA/NA and the AI. June, 1986.
- Davis, J. M. G., J. Addison, R. E. Bolton, K. Donaldson, A. D. Jones, and T. Smith. "The Pathogenicity of Long Versus Short Fibre Samples of Amosite Asbestos Administered to Rats by Inhalation and Intraperitoneal Injection." Brit. J. Exp. Path. 67. 1986. Pp. 415-430.
- Dement, John M., Robert L. Harris, Jr., Michael J. Symons, and Carl M. Shy. "Estimates of Dose-Response for Respiratory Cancer Among Chrysotile Asbestos Textile Workers." Annals Occ. Hyg. 26. 1982. Pp. 869-887.
- Deweese, Donald N. Controlling Asbestos in Buildings: An Economic Investigation. Washington: Resources for the Future. 1986.
- Doll, Richard, and Julian Peto. Asbestos-Effects on Health of Exposure to Asbestos. London: H.M.S.O. 1985.
- EM&R. Energy Mines and Resources Canada. Asbestos. Ottawa: Supply and Services Canada. 1986.
- Enterline, P. "Mortality Update for a Cohort of Workers Exposed to MMMF, 1941-1982". Paper presented at the WHO International Symposium on Man-Made Mineral Fibers in the Working Environment. Copenhagen, Oct. 28-29, 1986.
- EPA. U. S. Environmental Protection Agency. Support Document Asbestos--

- Containing Materials in Schools: Health Effects and Magnitude of Exposure. Washington: U.S. EPA. Doc. No. EPA-560/12-80-003. 1980.
- _____. Airborne Asbestos Health Assessment Update. Research Triangle Park: U.S. EPA. Doc. No. EPA-600/8-84-003F. December, 1985.
- _____. "Asbestos; Proposed Mining and Import Restrictions and Proposed Manufacturing Importation and Processing Prohibitions". Proposed Rule. 51 Federal Register 3738-3759. January 29, 1986a.
- _____. "Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products - Summary." Washington: EPA, Office of Toxic Substances. 1986b.
- _____, U.S. Department of Health and Human Services. A Citizen's Guide to Radon. Washington: U.S. EPA. Doc. No. OPA-86-004. Aug., 1986c.
- HWC. Health and Welfare Canada. Report of the Committee of Experts Advising the Department of National Health and Welfare Concerning the Scientific Basis for Occupational Standards for Asbestos. Ottawa: Environmental Health Directorate. 1984.
- Hughes, Janet M. and Hans Weill. "Asbestos Exposure-Quantitative Assessment of Risk." Am. Rev. Resp Dis. 133:1. Jan, 1986. Pp. 5-13.
- International Labour Office. Safety in the Use of Asbestos. Geneva: International Labour Organisation. 1984.
- International Labour Organization. International Labour Conference. Convention 162. Convention Concerning Safety in the Use of Asbestos. Adopted at its seventy-second session. Geneva: ILO. 1986.
- McDonald, J. Corbett. "Health Implications of Environmental Exposure to Asbestos." Environ. Health Perspectives. 62. p. 319. 1985.
- _____, F. Douglas K. Liddell, Graham W. Gibbs, Gail E. Eyssen, and Alison D. McDonald. "Dust Exposure and Mortality in Chrysotile Mining, 1910-75." Brit. J. Ind. Med. 37. 1980. Pp. 11-24.
- Newhouse, Muriel and Geoffrey Berry. "Patterns of Mortality in Asbestos Factory Workers in London." Annals N. Y. Academy Sci. 330. December, 1979. Pp. 53-60.
- NRC: National Research Council. Nonoccupational Health Risks of Asbestiform Fibers. Washington: National Academy Press. 1984.
- ORCA. Ontario Royal Commission on Asbestos. Report of the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario. Toronto: Queen's Printer, 1984.
- OSHA. U.S. Department of Labor. Occupational Safety and Health Administration. Quantitative Risk Assessment for Asbestos Related Cancers. (Mimeo) Washington, D.C.: OSHA. October, 1983.
- Platek, S. Frank, David H. Groth, Charles E. Ulrich, Lloyd E. Stettler, Myra S. Finnell, and Margrit Stoll. "Chronic Inhalation of Short Asbestos Fibers." Fund. Appl. Toxicology. 5. 1985. Pp. 327-340.
- RIA. See EPA, 1986b.
- Robinson, Cynthia F., Richard A. Lemen, and Joseph K. Wagoner. "Mortality Patterns, 1940-1975 Among Workers Employed in an Asbestos Textile, Friction and Packing Products Manufacturing Facility." in Richard A. Lemen and John M. Dement, eds. Dusts and Diseases. Park Forest South, Ill.: Pathatox. 1979. Pp. 131-143.

- Saracci, R. "Mortality and Cancer Incidence in Production Workers in the European MMMF Study: Extension of the Follow-up Until 1982." Paper presented at the WHO International Symposium on Man-Made Mineral Fibers in the Working Environment. Copenhagen, Oct. 28-29, 1986.
- Sebastien, Patrick, J. Bignon, and M. Martin. "Indoor Airborne Asbestos Pollution: From the Ceiling and the Floor." Science 216. June 25, 1982, pp. 1410-1413.
- Shannon, Henry S. "Mortality Experience of Glass Fibre Workers: Extended Follow-up." Paper presented at the WHO International Symposium on Man-Made Mineral Fibers in the Working Environment. Copenhagen, Oct. 28-29, 1986.
- Transcript. Transcripts of formal hearings: In the Matter of Cross Examination on EPA's Proposed Rule Under Section 6 of TSCA Proposing Ban and/or Phase Out of Asbestos. Control No. OPTS-62036. Washington, D.C.: Acme Reporting Co. Oct. 6 to 21, 1986.
- UKAC. U. K. Advisory Committee on Asbestos. Asbestos: Final Report of the Advisory Committee. London: H. M. Stationery Office. 1979.
- WHO. World Health Organization. Environmental Health Criteria 53: Asbestos and Other Natural Mineral Fibres. Draft. Geneva: WHO. 1985.
- _____. International Symposium. Man-Made Mineral Fibers in the Working Environment. Copenhagen, Oct. 28-29, 1986.

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GOVERNMENT OF CANADA

APPENDIX

Table A-1

Risk of Death by Cause, USA 1983
(Mortality rate per 100,000 population/year)

Accidental Deaths^a

Motor vehicle	19.1
Falls	5.0
Fires, burns	2.0
Drowning	2.8
Firearms	0.8
Choking	1.4
Poison gas	0.6

Intentional Deaths^c

Suicide	12.3
Homicide	10.7

Disease^c

Heart disease	325.8
All cancers	188.8
Pneumonia	22.3
Diabetes mellitus	15.1
Emphysema	5.7
Chronic bronchitis	1.5
Asthma	1.4
Tuberculosis	0.8
Influenza	0.6

Asbestos Disease from Building Exposure

ORCA model (0.001 f/cc: 10 yrs)	0.022
Doll and Peto (0.0005 f/cc: 20 yrs)	0.014

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- a. National Safety Council (World Almanac, 1985, p. 700).
 - b. Between 1980 and 1982, passengers in autos and taxis averaged 1.2 fatalities per 10⁸ passenger-miles. National Safety Council.
 - c. National Center for Health Statistics, U.S. Department of Health and Human Services.

Table A-2

Risk of Contracting Various Cancers, USA 1973-81
Age 60-64 Males
(Rate per 100,000 population/year)

<u>Location</u> ^a	<u>Rate</u>
Lung and bronchus	304
Pancreas	37.2
Larynx	35.2
Stomach	38.6
Colon	108.8
Urinary and bladder	75.5
Kidney and renal pelvis	32
Prostate	189.2

Asbestos Disease from Building Exposure^b

(0.001 f/cc for 10 years from age 22) 0.06

Notes:

- a. U.S. Department of Health and Human Services, USPHS, "Cancer Incidence and Mortality in the U.S. 1973-81", November 1984.
- b. Simulated using $K_l = 0.0101$, $K_m = 13.3 \times 10^{-9}$, assuming 40% smokers.