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The Embassy of Canada presents its compliments to the Department of State and has the honour to refer to recent announcements by the Environmental Protection Agency (EPA) that it intends to issue a final rule on its regulatory proposal to ban and phase out asbestos and asbestos products.

In January 1986, the EPA published a Notice of Proposed Rulemaking in the Federal Register (51 FR 3738) which set in motion the regulatory process for the proposed rule under section 6 of the Toxic Substances Control Act. This proposed rule would have the effect of banning immediately the manufacture, import and processing of certain asbestos products, and would phase out the remaining products over a 10 year-period. The formulation of the proposal did not seem to take account of all the scientific evidence which was then available. The controversy it generated led to 200 written comments being received by the EPA.

A synopsis of the scientific evidence starts with the findings of the 1982 World Symposium on Asbestos, co-sponsored by the Government of Canada, the Government of Québec and the

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Commission of the European Communities. Statements, scientific evidence and viewpoints were presented by internationally recognized medical experts and scientists, by labour and industry, and by government representatives during this first multi-disciplinary symposium on asbestos. The collective conclusion of these experts from some 50 countries was that the banning of asbestos was unnecessary; regulation and enforcement were necessary from its mining to its end-use products; more research was needed; substitutes raised as many unresolved questions; and no scientific or medical evidence indicated any risk for the general public using asbestos-based products. Much additional information about asbestos has been learned since 1982, but it all serves to reinforce these first views and conclusions.

In 1984, the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario (ORCA) issued its final report in three volumes and 900 pages. This exhaustive four-year review, still considered the most thorough as well as the most authoritative study on asbestos, recommended the controlled-use regulatory approach for chrysotile asbestos. This approach means that through the enforcement of appropriate

regulations to rigorously control exposure, the risks associated with exposure to chrysotile asbestos in mining, milling, product manufacture, transportation and handling can be reduced to acceptable levels. Clearly, where such exposures and consequently risks cannot be properly controlled, the specific use should either be discontinued or prohibited. An example of an inappropriate use is sprayed insulation.

In 1985, the United Kingdom Health and Safety
Commission published a report by Sir Richard Doll and Professor
Julian Peto which independently reached the same conclusions as
ORCA: asbestos is not an environmental problem; asbestos
insulation in buildings does not present a health hazard to
occupants; risks from chrysotile asbestos in the workplace are
generally low, though efforts should be made to reduce exposure
levels to as low as technologically feasible.

It was this scientific evidence, inter alia, which provided the objective basis for the International Labour Organization's Convention No. 162 on Safety in the Use of Asbestos. In 1986, this Convention received unanimous support from 124 countries, including the United States. The Convention, for the benefit of workers worldwide and as a guide to asbestos regulation for all countries, comes into force as an international instrument on June 16, 1989.

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Also in 1986, the World Health Organization, under its Programme on Chemical Safety, issued a report summarizing the views of its Task Group on Environmental Health Criteria for Asbestos and Other Natural Mineral Fibres Report. On the basis of qualitative assessment, this group of international scientists, including an expert from the U.S. EPA, concluded as follows:

- (a) At present, past exposure to asbestos in industry or in the general population has not been sufficiently well defined to make an accurate assessment of the risks from future levels of exposure, which are likely to be low. A simple risk assessment is therefore not possible for asbestos.
- (b) Among occupational groups, exposure to asbestos poses a health hazard that may result in asbestosis, lung cancer, and mesothelioma. The incidence of these diseases is related to fibre type, fibre dose, and industrial processing.

 Adequate control measures should significantly reduce these risks.

- (c) In para-occupational groups including persons with household contact, those living in the vicinity of asbestos-producing and -using plants, and others, the risks of mesothelioma and lung cancer are generally much lower than for occupational groups. The risk of asbestosis is very low. These risks are being further reduced as a result of improved control practices.
- (d) In the general population, the risks of mesothelioma and lung cancer, attributable to asbestos, cannot be quantified reliably and are probably undetectably low. Cigarette smoking is the major etiological factor in the production of lung cancer in the general population. The risk of asbestosis is virtually zero.
- (e) On the basis of available data, it is not possible to assess the risks associated with exposure to the majority of other natural mineral fibres in the occupational or general environment. The only exception is erionite, for which a high incidence of mesothelioma in a local population has been associated with exposure.

Because the original 1986 EPA documentation was obscure, deficient and contradictory, many, including the Government of Canada, urged the EPA to schedule formal cross-examination hearings in order to consider all of the scientific evidence currently available. These hearings occurred in October 1986.

Many times during the cross-examination hearings EPA witnesses admitted errors pertaining to crucial elements of the risk assessment. Further, they conceded that the work done to date was so flawed that the EPA case was almost totally being redone. Indeed, the record shows that new studies were commissioned by the EPA on almost every aspect of its case.

In its written reply comment of January 1987, the Government of Canada documented its concerns. (While the Embassy is not repeating all the technical arguments raised, their comments are appended for your information). Significant deficiencies in EPA's case were noted, specifically: the evidence did not indicate substantial, positive net benefits; there was an absence of differentiation of fibre type and fibre potency; the risks associated with asbestos were overstated; the proposed rule

seemed to be unnecessary, in part, because the high risk uses of asbestos had already been eliminated; and lastly, the proposed rule must flow from such need for the rule as was demonstrated by the supporting case. The fact that the Agency commissioned new studies lends support to the EPA's <u>de facto</u> acceptance of this principle.

On April 1, 1988, the EPA placed four major documents, which were to be used to support its rulemaking for the ban and phase-out of certain asbestos based products, into the public record. The four new support documents were: the Asbestos Exposure Assessment; the Asbestos Modelling Study; the Non-Occupational Asbestos Exposure Report; and, the Regulatory Impact Analysis. The deadline for receipt of comments on these reports was May 31, 1988.

On May 4, 1988, the EPA placed four additional documents concerning substitutes for asbestos on the public record. These reports were: the Health Hazard Assessment of Non-Asbestos Fibre; the Review of Recent Epidemiological Investigations on Populations Exposed to Selected Non-Asbestos Fibres; the Durable Fibre Exposure Assessment; and the Durable

Fibre Industry Profile and Market Outlook. The deadline for the comment period was June 14, 1988. Because of the volume of evidence placed by the EPA on the public record, the Government of Canada, along with others, asked for and received an extension of the comment period to June 30, 1988.

The Government of Canada again submitted written reply comments to the EPA on its new support documents on June 29, 1988 (a copy is appended so that all of the Canadian technical points may be available to the Department of State). Canada's concerns remained that the use of asbestos should be controlled and not banned, and that the EPA documents did not demonstrate the existence of substantial net benefits from its proposed ban/phase-out rule. While the new evidence suggested benefits which were smaller than those presented by the EPA in 1986, it remained likely that the actual benefits would be even smaller and that the actual costs would be greater than those stated. Further, it was noted that implementation of the proposed rule could increase rather than decrease overall public risk because the risks associated with using substitutes remained unaddressed by the EPA.

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The 1988 EPA support documents revealed that the basic scientific underpinnings of the proposed rule still did not reflect the current international scientific literature and consensus, particularly in the areas of fibre type, potency and dimension. The documents also revealed inconsistencies with respect to the risks presented by different types of fibrous substitutes. The Government of Canada stated again its concern that the lack of information on the potential hazards of using substitutes should not be taken as certification of their safety, and consequently that the paucity of information about the effects of substitute materials should not be the basis for promoting their use, while banning asbestos.

The Government of Canada stated again that the proposed EPA rule must flow from such need for the rule as was demonstrated by the supporting evidence. As the potency, exposure and risk assessment data and conclusions remained material disputed issues of fact, the Government of Canada, amongst other parties, again sought cross-examination hearings. The EPA granted such hearings, which were held from September 19 to 22, 1988.

During the cross-examination hearings, the witnesses provided by the EPA again made comments which are of concern to many countries, including Canada, given the potential negative worldwide impact of an unduly restrictive and scientifically unsubstantiated EPA rule. Asbestos is an extremely versatile mineral which produces useful, cost-effective materials essential for providing potable water, sanitation, and affordable shelter in developing countries. Canada has received information from many of these countries indicating that they too have petitioned the EPA advocating the controlled-use option.

The Government of Canada again submitted written reply comments to the EPA (copy attached). Canada remains concerned because the numerous scientific comments made from the outset in 1987, and again in June 1988, remain unaddressed. Canada also remains concerned because it is the basic, scientific differentiation concerning fibre types, potency and risk which are pivotal with respect to regulation, cost-benefit analysis and risk analysis. When all these factors have been duly addressed individually by such august international bodies as the World Health Organization, the United Kingdom Health and Safety

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Commission, the International Labour Organization, and the European Communities, each has selected the controlled-use option rather than a ban. Further, these very same fundamental factors have led these international agencies to investigate the man-made mineral fibres which today raise questions similar to those posed by asbestos 50 years ago. The lessons we have all learned from the uncontrolled use of asbestos should encourage prudence prior to the widespread use of other fibrous materials. Because of the known hazards, asbestos is probably the most studied industrial material in use today. The hazards of other fibrous materials, however, are not yet fully known.

As the most current scientific data remain uninvestigated by the EPA, the Government of Canada would wish to be assured that all options for the regulation of asbestos, including that of controlled use, are examined before a final rule has been issued.

The Government of Canada also hopes that, prior to the final rule, the Government of the United States will consider the international impact of an EPA rule on the harmonization of

health and safety regulations, especially when the EPA appears to be at variance with international opinion and other U.S. agencies (e.g., the Occupational Safety and Health Administration).

A rule not justified on scientific or medical grounds would have implications for the principle of international product standard harmonization: a principle which is supported by the governments of Canada and the United States. Governments rightly should do everything necessary to protect the interests of their citizens. The Government of Canada believes that the possibility of a consensus between major trading partners should be further explored before radically different regulatory initiatives are launched, especially when one initiative is based on objective scientific evidence and the other on deficient and incomplete data.

The Canadian authorities have extensive expertise with regard to asbestos and are willing to provide whatever technical information is requested to further cooperation between the United States of America and Canada in this matter.

.../13

The Embassy of Canada avails itself of this opportunity to renew to the Department of State the assurances of its highest consideration.

WASHINGTON, D.C.
January 10, 1989

