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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products

Submission of the Government of Canada

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Submission of the Government of Canada EXECUTIVE SUMMARY

This written submission represents the considered views of the Government of Canada regarding EPA's proposed asbestos phaseout and ban, after reviewing the evidence presented in the seven volume "Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products", March, 1988, and the previous record relating to this proposed rule. The Government of Canada continues to believe that EPA has not demonstrated the existence of substantial net benefits from the proposed rule. While the new evidence suggests benefits smaller than those previously presented by EPA, it is likely that the actual benefits will be still less than the present estimates and the costs will be far greater. There is a disturbing possibility that the proposed rule may increase rather than decrease overall risks for the American public.

The Government of Canada believes that asbestos risks can be controlled and are controlled by current laws and regulations in the United States. OSHA's recent exposure limits allow only small risks for occupational exposures to asbestos. The EPA's own estimates of environmental exposures are at such extremely low levels that health risks are insignificant if not actually zero. The Government of Canada urges the EPA to adopt realistic goals in its rule-making, and to pursue the reduction of substantial risks, rather than insubstantial ones. The international community has accepted the philosophy of controlled use, an approach which the Government of Canada urges the EPA to consider in place of the proposed comprehensive ban.

In estimating environmental risks, EPA uses worst-case assumptions that overestimate both exposures and risks. EPA also uses methods for analyzing airborne asbestos levels that have been explicitly rejected in other recent EPA regulations of asbestos.

Where, as here, the exposures to airborne asbestos fibres are low, the per capital risk rates are extremely small, if not zero. If the proposed rule should give rise to increased risks, as it may if non-asbestos brake linings increase motor vehicle accidents, or if substitute materials cause health risks, these may easily cancel out the small reduction in asbestos risks. The EPA's evidence has not established that the proposed rule will necessarily reduce fatality risks at all, once offsetting risks are considered.

The revised support documents reveal that the basic scientific underpinnings of the proposed rule do not reflect the thrust of the scientific literature especially with respect to the potency of different fibre types and dimensions. These documents reveal confusion and inconsistency with respect to the risks presented by different types of asbestos and by various fibrous asbestos substitutes. The principles that EPA has used for evaluating asbestos substitutes are inexplicably not used for evaluating different asbestos types.

The Government of Canada urges the EPA to recognize the limited benefits of the proposed rule, and its substantial costs and possible added risks by withdrawing the rule entirely. Alternatively, the Government of Canada urges the EPA to replace this rule with one that is far more limited, for which the EPA can clearly demonstrate significant risk reductions without offsetting risk increases. If the proposed rule

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is not withdrawn, the Government of Canada requests that the EPA schedule formal hearings in which EPA's experts can be cross-examined on the evidence supporting their exposure, potency, and risk estimates.

I. Introduction

The Government of Canada welcomes the publication of the revised Regulatory Impact Analysis (RIA), which represent a substantial revision of the basis for the proposed rule. However there are weaknesses in the basic scientific underpinning of the rule regarding the potency of different types of asbestos, and of fibres of different dimensions. There is confusion and inconsistency with respect to the risks presented by different types of asbestos and by various fibrous substitutes. Errors in the estimates of both exposure and potency greatly overstate the risk reductions associated with some asbestos product lines.

The revised RIA does not respond to a number of arguments raised by the Government of Canada in its Written Reply Comments of January, 1987. Those arguments are not repeated here. However, the more narrow focus of the present submission should not be taken as an indication that the previous concerns have been satisfied. On the contrary, this submission should be regarded as supplemental to that of January, 1987.

II. The New Studies Change the Data Supporting the Rule

In the 1986 documentation, almost half of the alleged benefits of the proposed rule (468 cases) arose from banning vinyl-asbestos floor tile (VAT). The new support documents attribute no benefits to the ban on VAT, since production in the United States has apparently ceased. In 1986, banning asbestos-cement pipe was alleged to avoid 82 cases; this has now been reduced to 6 cases in the 1987 RIA. The estimated benefits have been greatly reduced for some categories of products subject to the

proposed ban and phaseout. Surely when the quantitative basis for the rule changes so greatly, the proposed rule itself should be amended or withdrawn as the Government of Canada urged in January, 1987 when the deficiencies in the original support documents became apparent.

III. The Occupational Risks Can be Controlled

Most of the risks that are alleged in the new support documents are occupational risks. OSHA has regulated worker exposures to asbestos fibres, recently reducing the allowed exposure to 0.2 f/cc, one-tenth its previous level, and one one-hundredth the exposure experienced during the 1960's. The EPA has greatly overestimated the exposures that will be experienced under the current regulation (ICF, 1988, p. 150) by the use of pessimestic or worst-case assumptions, assuming positive exposures where zero exposures were measured, and assuming that good work practices are not followed (Bragg, 1988.) Surely if the EPA believes that some exposures under the OSHA regulation exceed acceptable levels, the solution should be to amend the workplace exposure regulations or to promote good work practices to provide satisfactory safety levels. In the case of brake mechanics, whose risks account for the vast majority of the risks alleged in the revised RIA, good work practices and reasonable exposure estimates would yield far lower risks than the EPA has projected. EPA has not demonstrated in its revised RIA that the OSHA regulations are inadequate to protect worker health. Most other countries have adopted control limits rather than imposing a comprehensive ban on the use of asbestos, recognizing that control limits provide adequate protection, and that risks must be considered in

relation to all other risks. EPA has not demonstrated that the remaining risks warrant a regulation as drastic as the proposed ban.

IV. The Environmental Risks Are Extremely Small

The new support documents show very low exposure levels for the general public. At these low exposures, risks are not proven; there may in fact be no health risks. Moreover, if there are risks, the per capita risk rates may be so small that they should be regarded as insignificant. EPA has not demonstrated that the environmental risks are sufficiently great that they warrant the drastic and unusual action of banning the use of a substance.

When the per capita environmental risk rates are so low, the proposal of a product ban implies that EPA's goal is to completely eliminate asbestos risks in the environment, a goal that EPA has explicitly enunciated. However, asbestos is a naturally occurring mineral present in the earth's crust in much of the world. With widespread natural asbestos emissions, it is impossible to achieve an asbestos-free environment. If, as the EPA assumes, even very low asbestos exposure levels create risks, it follows that an environment free of asbestos risks cannot be obtained.

The attempt to eliminate asbestos risks seems more quixotic, given the existence of non-asbestos risks that cannot be eliminated by any practicable means. The very asbestos substitutes whose use will be promoted by the proposed rule may present the risk of cancer. The Government of Canada urges the EPA to adopt realistic goals in its rule-making, and to pursue the reduction of substantial risk rates, rather

than insubstantial ones.

V. The Net Effect of This Rule May be to Increase Risks

When exposures are as low as those estimated for the environmental exposures in the support documents, the health risks are speculative at best; they may in fact be zero. In the case of brake repair workers, the exposures, even as estimated by EPA, are very low compared to historical occupational asbestos exposures, so that risk rates for these workers are very low. Even if the asbestos risks are not zero, the risk rate for each exposed individual is very small. This means that if there is an offsetting risk increase associated with the asbestos ban, it may cancel out any risk reduction from reduced asbestos uses. EPA has not evaluated these offsetting risks.

In the case of exposures due to brake linings, the Government of Canada believes that the EPA has greatly overstated the risks because of EPA's failure to recognize differences in the potency of different types of asbestos fibres. Recognition of the low health risks from exposure to asbestos in brake linings (ORCA, 1984, Ch. 7) would reduce by at least 80 percent the EPA's estimates of the benefits of this rule. This would yield benefits of less than 40 cases in place of the approximately 200 cases that EPA projects. Furthermore, there are risks to the general public and to brake repair workers if the substitute products contribute to health risks, a possibility that has not been ruled by the EPA's own evaluation of the substitute products. Even small health risks from substitute products may overwhelm the small reductions in asbestos risks projected for the proposed rule. Finally, there are risks of injury or

fatality due to accidents if brake performance degrades. (Anderson, 1988.) Even a small increase in brake-related motor vehicle accidents would impose great risks on the American people, overwhelming the small reduction in asbestos risks projected for the proposed rule. The EPA cannot be certain that brake-related health and safety risks will not increase as a result of banning asbestos in brake linings.

In the case of vinyl-asbestos floor tile, the Government of Canada, like many other observers, does not accept that normal surface wear of such tile will yield significant levels of airborne asbestos fibres. Even if it does, very few of these fibres are longer than five micrometers. The true risks from this exposure, if there are any, are at an exceptionally low level. No reasonable basis has been demonstrated for including this product in the proposed rule.

The assessment of asbestos substitutes does not conclude that all have been proven safe; such a conclusion can rarely be drawn. In fact, some substitutes have been shown to be biologically active. When the projected risk rates from asbestos exposure are extremely low, the introduction of a substitute that also has a demonstrated risk cannot be assumed to yield a risk reduction, especially when the exposures to substitutes are neither regulated nor controlled. To promulgate a rule as drastic as a complete product ban in the face of such uncertainty is not a reasonable means to improve public health.

The rule should be withdrawn or amended to limit it to those products for which the risks avoided are substantial, and demonstrably greater than those associated with available substitutes.

VI. EPA Has Not Responded to Criticisms of the Scientific Basis for the Proposed Rule

The EPA risk model has not changed substantially since 1984. Since that time, continuing development in the scientific literature on the health effects of asbestos cast serious doubt on that model.

EPA's RIA recognizes that several commissions and study groups have accepted that health risks differ among the types of asbestos. The EPA rejects this conclusion on the grounds that risks differ within a single type of asbestos; chrysotile yields low risks in friction products manufacturing and high risks in textile manufacturing. (EPA, 1988, Vol. I, pp. 26, 27.) This paradox is resolved, however, with the recognition that risk depends not only on fibre type, but also on the industrial process giving rise to the exposure, and that textile processes differ from friction products processes in ways that are significant for worker health risks, an argument that was articulated by the Ontario Royal Commission on Asbestos (ORCA, 1984). The EPA's risk assessment document recognizes and does not refute this argument, but proceeds to ignore it in averaging disparate risks from diverse exposures. The RIA does not refute this argument, and fails to respond to a substantial body of more recent literature supporting and accepting the argument that risks vary greatly by fibre type and industrial process. For example, a recent issue of the British Journal of Industrial Medicine carries the statement: "The existing evidence is so convincing that continued failure to differentiate between fibre types by governmental regulatory agencies such as the United States Occupational Safety and Health Administration is difficult to justify. ". (Hughes, et al., 1987, p. 172.) Further

recent evidence is offered by Wagner et al. (1986), Churg (1985), and Wagner (1987). On this issue, the EPA appears to be isolated from the mainstream of scientific opinion.

The difference in potency among fibre types is related to at least two factors. First, chrysotile breaks down in the lungs far more rapidly than do the amphiboles, as evidenced by a continuing stream of literature to which EPA has not responded. (See, e.g. Churg, 1985; 1986.) Second. longer fibres present far greater hazards than do short fibres. The EPA recognizes that fibres longer than 8 micrometers are more hazardous. (EPA, 1988, p. 27.) However, the EPA refuses to reflect this in its regulatory deliberations because there is no proof of a clear threshold between carcinogenic and non-carcinogenic dimensions. The fallacy in EPA's reasoning is that there may be very large differences in the potency of long and short fibres, with a continuum of potency for lengths in between. That there is no sharp break in potency does not dispose of the argument that short fibres are far less hazardous. If EPA accepts that as fibre length falls below 8 micrometers the health risks fall greatly, then even if the shape of the length-potenty relationship is not known precisely, EPA's regulations should focus on the longer fibres as the primary source of the health risks it is trying to avoid. The EPA has not refuted the role of fibre dimension in explaining otherwise puzzling differences in the potency of different types of asbestos. Further recent support for low risks of short fibres is provided by Platek et al. (1985), Lemaire et al. (1985), Davis et al. (1986), Moalli et al. (1987), Adamson and Bowden (1987a, 1987b) and Bowden and Adamson (1987). The EPA has not responded to the numerous studies and

conferences since 1984 that confirm the fibre dimension argument, including the concluding remarks by Sir Richard Doll at the 1987 WHO Symposium on Mineral Fibres in the Non-Occupational Environment in Lyon:

"... we should base our estimate of potential risk on both the chemical consititution of the fibres and their size, counting only those fibres that are respirable and more than 5 μ long."

Third, there is the continuing debate whether the very low exposures to asbestos that form the basis for much of the benefits alleged by EPA for its proposed rule present any health risks at all. It has been argued that the body's clearance mechanisms may render harmless low exposures to asbestos. Since 1984, several studies have failed to detect risks from low exposure levels, particularly for chrysotile asbestos. (Ohlson and Hogstedt, 1985; Gardner at al., 1986; McDonald, 1985; and Churg, 1986.) By failing to accept that risks may differ by fibre type, and that chrysotile is cleared from the lungs far more rapidly than are other types of asbestos, the EPA has foreclosed its consideration of this hypothesis.

EPA's refusal to consider fibre type and dimension in evaluating asbestos risks is inconsistent with its assessment of the risks of asbestos substitutes. In evaluating the risks presented by asbestos substitutes, EPA states that their potency is influenced by respirability, durability, fibre length and fibre size. Yet EPA refuses to accept that precisely these factors give rise to different potency for the different types of asbestos, and that different fibre sizes generated by different industrial processes give rise to different potency among those processes. The Government of Canada urges EPA to extend its

consideration of fibre durability, length and size to the evaluation of the potency of different types of asbestos.

EPA recognizes that the biological activity of a number of substitutes has been demonstrated. If the different types of asbestos are to be banned, despite their differing potency, consistency would require EPA to ban the substitutes as well, since they have been demonstrated to present some risk. If EPA will not ban the substitutes, then it should be prepared not to ban those types and uses of asbestos for which risks have been demonstrated to be low, such as friction products made with chrysotile, or for which no risk has been demonstrated, such as VAT. EPA's failure to recognize the implications of evidence that is now generally accepted by the international scientific community not only leads it to inconsistent regulatory actions, it leaves it isolated in the world scientific community.

The EPA estimates of environmental asbestos exposure are based on the indirect preparation of filter samples, and computation of the mass of airborne asbestos. This methodology is complex and subject to error, and does not yield direct estimates of the number of respirable fibres longer than five micrometers. These deficiencies led to the rejection of this methodology for implementing EPA's recent regulation regarding asbestos in schools, AHERA. The Government of Canada believes that EPA's methodology leads it to substantially overestimate environmental exposures and risks.

The new support documents do not allege benefits from banning VAT because this product is no longer made in the United States. However it is still assumed that ordinary office workers will experience substantial

exposures and risks from walking on VAT. 1 There has been no response to the argument that the primary source for this proposition dealt with severely worn tile, and cautioned that further research was necessary before one could safely conclude that floor tiles were the source of the airborne fibre. There has been no response to the argument that such exposure, if it does occur, is almost exclusively to fibres shorter than five micrometers in length and therefore does not give rise to significant health risks.

VII. Product Bans for Low Risks Are Inconsistent

Even accepting the EPA risk assessments, which the Government of Canada does not, the per capita risks are very small, according to the revised documents. If such low risk levels warrant an ultimate ban on a product, then surely other substances that present similar risk levels must also be banned. Yet the list of substances that cause risks as great as those attacked by the proposed rule include many that could not easily be abandoned, such as benzene, a component in gasoline, and natural toxins in common foods, such as aflatoxin in peanut butter.

EPA appears to be pursuing a policy of eliminating all risks, with respect to asbestos exposure. But it is obvious that all risks from other substances cannot be eliminated. EPA has admitted this by accepting risk levels from radon gas that are one thousand times as great as the asbestos risks addressed in this rule. The EPA stands virtually alone among the major industrialized nations in its apparent pursuit of zero risk from asbestos, given the other natural and man-made risks that

¹ Versar (1987, p. 4-1) assumes 25 or 50 ng/m^3 .

exist at far greater intensity.

VIII. If a Rule Is Needed, A Less Burdensome Rule Is Feasible

The 1986 proposed rule and most scenarios in the revised support documents ultimately ban virtually all asbestos use. But the net benefits of a ban where per capita risks are very low is debatable. If there is to be a rule, it should focus on the situations where per capita risks may be relatively large. These include exposures to crocidolite, amosite, and any type of asbestos in textile manufacturing. With such a prohibition added to the existing prohibition on friable insulation products in buildings, all the situations where there is a significant chance that there are real net benefits will have been dealt with. The remaining products in the proposed rule should not be regulated because EPA has not shown, not having quantitatively analyzed brake safety and the health effects of substitutes, that the benefits of reduced exposure exceed the increased risks that may accompany the loss of asbestos.

IX. The International Community Has Adopted Controlled Use

The proposed rule is out of step with the positions taken by other major nations and international organizations. The philosophy of controlled use has been adopted in many jurisdictions. The International Labour Organization's 1986 Convention on Safety in the Use of Asbestos will come into force as an international instrument in June, 1989. This Convention bans only crocidolite and the spraying of asbestos, calling for controlled use in all other situations. The Government of Canada urges the EPA to consider such regulatory approaches.

X. The Proposed Rule Should Be Withdrawn or Amended

Canada argued in January, 1987 that the rule should be withdrawn, pending the production of new evidence. The new evidence presented to date reinforces Canada's belief that the rule is not supported by the evidence and should be withdrawn.

Canada argued in January, 1987 that the EPA should consider the regulatory positions of other countries and organizations in deciding its own position. EPA has not appeared to take into account the international position.

Canada argued in January, 1987 that the small risk reductions that may be achieved by this rule could be offset by risk increases from substitutes and by degraded product performance. The primary benefits according to the new evidence arise from the ban on asbestos in friction products, for which the offset argument is particularly important. EPA has not estimated these offsetting risks, nor laid to rest this concern.

The Government of Canada urges the EPA to recognize the limited benefits of the proposed rule, and its substantial costs and possible added risks by withdrawing the rule entirely. Alternatively, the Government of Canada urges the EPA to replace this rule with one that is far more limited, for which the EPA can clearly demonstrate significant risk reductions without offsetting risk increases. If the proposed rule is not withdrawn, the Government of Canada requests that the EPA schedule formal hearings in which EPA's experts can be cross-examined on the evidence supporting their exposure, potency, and risk estimates.

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