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ASBESTOS INFORMATION ASSOCIATION
NORTH AMERICA
1745 Jefferson Davis Highway, Crystal Square 4, Suite 509
Arlington, Virginia 22202 • (703) 979-1150

PLAINTIFF'S EXHIBIT
DOW-852

Sub file

February 17, 1980

ST0073609

Mrs. Joni T. Repasch
Record Clerk
Office of Toxic Substances (TS-793)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

D003938

Re: Commercial and Industrial Use of Asbestos Fibers: ANPRM, OTS-61-005

Dear Mrs. Repasch:

Please find enclosed the comments of the Asbestos Information Association/North America on EPA's ANPRM on Commercial and Industrial Use of Asbestos Fibers, 44 Fed. Reg. 60061 (Oct. 17, 1979), as amended 44 Fed. Reg. 73127 (Dec. 17, 1979).

AIA/NA submits these comments in the hope that EPA will be dissuaded from embarking on a time-consuming regulatory proceeding based on an unfounded supposition that present uses of asbestos pose an unreasonable risk, and the preconceived regulatory control solution that asbestos use must be banned when lesser, and potentially more effective, options have not been considered.

In these comments, AIA/NA outlines the provisions of TSCA that EPA must follow, and therefore, the issues that must be explored before EPA can proceed with proposed rules. We then outline the significant factual evidence indicating the Agency will not be able to meet the required statutory showing of an "unreasonable risk to health or the environment." Finally, we detail alternatives to TSCA section 6 bans that appear both more effective and less burdensome than the outright bans suggested by EPA.

AIA/NA shares EPA's concerns that commercial and industrial use of asbestos be as safe as is scientifically and economically feasible. However, it does not share EPA's assumption that

commercial and industrial use of asbestos per se presents an unreasonable risk to health and the environment. Accordingly, AIA/NA urges EPA to assess carefully the numerous factual issues relevant to any TSCA section 6 regulatory proceeding prior to issuing any proposed regulations. We are persuaded that, having been properly assessed, the factual evidence will convince EPA that no TSCA section 6 rulemaking is warranted.

In light of these conclusions, AIA/NA hopes that it will be possible to continue its cooperation and dialogue with the Agency on asbestos and the asbestos industry. In particular, we believe that a meeting between AIA/NA and EPA representatives would be useful for the purpose of discussing the AIA/NA and Association of Asbestos Cement Pipe Producers' Recommended Standard for Occupational Asbestos Exposure in Construction and Other Non-Fixed Work Operations which we attach to our comments.

This document demonstrates industry's concern for developing safer methods of use of asbestos. It also demonstrates that scientifically sound, economically justifiable and operationally pragmatic actions are possible to provide greater safety in use of asbestos-containing products without the unwarranted action of banning use of asbestos.

In addition, a meeting would perhaps prove useful in further considering EPA's need for information and the conflicts created by AIA/NA members' need to maintain the confidentiality of such information. As our comments indicate, the concern that information will not be held entirely confidential is a serious impediment to provision of certain information to the Agency.

Sincerely yours,

B. J. Pigg
Executive Director

cc: Messrs. John DeKany (w/encls)
Richard Guimond (w/encls)

Enclosures

BJP/ws

UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY

COMMERCIAL AND INDUSTRIAL USE OF ASBESTOS FIBERS: ADVANCE NOTICE OF PROPOSED RULEMAKING	40 C.F.R. 763 OTS 61005; FRL 1332-4A

COMMENTS OF THE ASBESTOS INFORMATION ASSOCIATION/NORTH AMERICA

Edward W. Warren
Timothy S. Hardy
David K. Perdue

Kirkland & Ellis
1776 K Street, N.W.
Washington, D.C. 20006

February 18, 1980

COMMENTS OF THE ASBESTOS
INFORMATION ASSOCIATION/NORTH AMERICA ON
THE COMMERCIAL AND INDUSTRIAL USE OF ASBESTOS FIBERS

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UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY

COMMERCIAL AND INDUSTRIAL USE OF ASBESTOS FIBERS: ADVANCE NOTICE OF PROPOSED RULEMAKING	40 C.F.R. 763 OTS 61005; FRL 1332-4A

COMMENTS OF THE ASBESTOS INFORMATION ASSOCIATION/NORTH AMERICA

INTRODUCTION

The Asbestos Information Association/North America (AIA/NA) welcomes this opportunity, on behalf of its more than 50 member companies -- miners, processors and manufacturers of asbestos and asbestos-containing products -- to comment on EPA's Advanced Notice of Proposed Rulemaking (ANPRM) on Commercial and Industrial Use of Asbestos Fibers, 44 Fed. Reg. 60061 (Oct. 17, 1979), as amended, 44 Fed. Reg. 73127 (Dec. 17, 1979).

AIA/NA submits that the proposals advanced in the ANPRM would represent unwarranted and unauthorized use of EPA's authority under the Toxic Substances Control Act (TSCA). The ANPRM fails to take into account adequately: (i) the extent to which use of asbestos in the United States today has already been limited; (ii) the extent to which presently-marketed asbestos-containing products use asbestos in forms that minimize release of respirable fibers; (iii) the reductions of workplace exposure to asbestos that have

occurred in recent years; (iv) the extensive regulation of asbestos under statutes administered by EPA and other agencies; (v) the consequent cumulative reduction in asbestos fiber release brought about by these developments; and (vi) the fact that scientific evidence bearing on the risks posed by asbestos derives from occupational exposures far higher than are experienced in the workplace today, let alone by the general population.

Although EPA's ANPRM purports to be seeking information to evaluate asbestos, it appears throughout that the Agency has already determined that asbestos presents an unreasonable risk of injury to health and the environment and should therefore be banned from the U.S. economy. The ANPRM begins with a Joint Statement on Coordination of Regulatory Activities, 44 Fed. Reg. 60056, wherein EPA and CPSC state a common objective for their endeavors, namely "to significantly reduce unreasonable human health risk from exposure to asbestos through complementary actions". This objective sets a theme for the ANPRM and reflects an apparent disregard of the fact that no regulatory actions, complementary or otherwise, are warranted unless "unreasonable risks" from exposure to asbestos are shown to exist.

The same theme continues in the summary of EPA's ANPRM. Without citation, EPA concludes that "many population segments remain exposed to, and inadequately protected from both direct and diffuse sources of asbestos." 44 Fed. Reg. 60061.

This terse conclusion is evidently based on the further conclusion: "Studies of exposed populations have shown that asbestosis . . . and various types of cancer are associated with asbestos exposure, even at low concentrations or after short exposure periods." 44 Fed. Reg. 60062. However, nowhere does EPA hint what it considers to be "low" or "short" exposure. Nor do the sources cited support any such proposition. Indeed, not one of the studies discussed in the referenced pages of the Bogoviski book, The Biological Effects of Asbestos (1972),[1/] or the HEW publication, Asbestos: An Information Resource (1978), concludes that regulation of general population level exposures is required based on the available scientific evidence.

1/ Moreover, none concludes that any reduction in current permissible occupational exposure levels is necessary. Thus, McDonald (in Bogoviski, p. 158) states:

> The data seems sufficient to justify the conclusion that if the risk of clinically significant disease is to be kept below 1% for a working life of 50 years, workers in [the mining and milling] industry should not be exposed to dust concentrations of more than 2 mppcf.

And, Sluis-Cremer and du Troit (in Bogoviski, p. 164) conclude:

> A maximal allowable dust concentration standard has been assessed from various data. It is believed to lie between 2 and 15 actual long [greater than 5 microns] fibres per ml, depending on the degree and mode of progression of exposure, particular working conditions and the composition of the dust.

The ANPRM is, therefore, based on incorrect factual premises and all too hastily suggests the conclusion that asbestos "may present an unreasonable human health risk." 44 Fed. Reg. 60062. EPA, in effect, suggests that any emission of asbestos fibers from any source into either air or water must be eliminated -- with exceptions only for undefined "essential" uses. But TSCA does not contemplate, nor does it sanction, such a result. For, to accept the approach implied by the ANPRM would be to relieve EPA of its burden of demonstrating the existence of an unreasonable risk -- the very showing upon which any regulation under TSCA § 6 must be predicated.

Having all too swiftly assumed that asbestos will be found to pose unreasonable risks, the ANPRM proceeds to propose drastic remedies without even a passing suggestion that less burdensome controls have been or will be considered. The specific regulatory alternatives advanced by EPA go far beyond the "least burdensome requirements" that would be necessary to "protect adequately" against any risk, even if it were possible to conclude that one or more current uses of asbestos presents an "unreasonable risk to health or the environment." For, although the Agency nominally advances three regulatory options, each effectively calls for banning asbestos use in the American economy.

Little or no attention has apparently been given to the statutorily mandated requirement that EPA first consider and

rule out less burdensome options before determining to impose such sweeping remedies. To be sure, other statutes and authorities, including rules already applicable to asbestos, are mentioned but nowhere does EPA detail why such presently applicable statutes and rules are inadequate to deal with the asbestos "problem." Thus, neither the ANPRM, nor EPA's stated regulatory plans, canvass the many possible steps, both voluntary and government-mandated, already undertaken or planned for the future -- each of which will, by promoting safer asbestos use, reduce even further whatever risks may be posed by asbestos.

Accordingly, AIA/NA submits these comments in the hope that EPA will be dissuaded from embarking on an ill-considered and time-consuming regulatory proceeding based on the supposition, without proof, that present uses of asbestos pose an unreasonable risk, and the preconceived solution that asbestos use must be banned when lesser, and potentially more effective, options have not, and will not, be considered.

In these comments, AIA/NA outlines the provisions of TSCA that EPA must follow, and, therefore, the issues that must be explored before EPA can proceed with proposed rules. We then outline the significant factual evidence indicating the Agency will not be able to meet the required statutory showing of an "unreasonable risk to health or the environment." Finally, we detail the many alternatives to TSCA § 6 bans that appear both more effective and less burdensome than the outright bans suggested by EPA.

I. NO "REASONABLE BASIS" HAS BEEN DEMONSTRATED TO CONCLUDE THAT ASBESTOS PRESENTS AN "UNREASONABLE RISK OF INJURY TO HEALTH OR THE ENVIRONMENT."

A finding of "unreasonable risk" is the threshold prerequisite to any regulation of a chemical under TSCA § 6. Such a finding is not obviated simply because TSCA was enacted to provide federal regulatory authority to protect health and the environment from dangerous chemicals, or because the medical evidence confirms that exposure to asbestos is dangerous at concentrations many orders of magnitude higher than experienced by the general population. Rather, TSCA places the burden of making such an "unreasonable risk" finding on EPA. Such a finding can be upheld only after consideration of a wide range of risk and benefit factors and only if the Administrator's determination is supported by substantial evidence.

A. Congress Mandated, and EPA Endorsed, the Necessity of Showing "Unreasonable Risk" Based on the Weighing of a Wide Variety of Risks and Benefits as a Prerequisite to Any Regulation under TSCA § 6.

The concept of unreasonable risk undergirds the regulatory framework of TSCA. Section 6(a), on which the ANPRM relies in proposing asbestos regulatory control options, states that before the Administrator may impose any of its delineated regulatory requirements, he must find

> that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or

> that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment.

TSCA does not permit EPA to regulate chemicals simply because they pose some risk; Congress "limited the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the [Congress] does not make." House Comm. on Interstate & Foreign Commerce, Legislative History of the Toxic Substances Control Act 423 (1976).

During the hearings preceding passage of TSCA, EPA recognized the lack of wisdom of a regulatory policy aimed at the elimination of all risks. In a letter to the Subcommittee on the Environment of the Senate Commerce Committee, Dr. William Upholt, EPA's Senior Science Advisor for Water and Hazardous Materials, stated:

> [M]ost scientists now agree that absolute safety is rarely achievable. Moreover, philosophically I am persuaded . . . that absolute safety is rarely even socially desirable . . . [T]he function of a regulatory agency should be to reduce risks to the extent feasible without reducing the quality of life of the general population . . . . [T]he public is capable of understanding that regulatory agencies are not eliminating all risk of cancer but that they are attempting to minimize such risks to the extent consistent with the quality of life we are demanding.

Toxic Substances Control Act, Hearings on S. 776 before the Subcomm. on the Environment of the Senate Comm. on Commerce, 94th Cong., 1st Sess. 320-21 (1975) (emphasis added).

Congress accepted this and similar advice from numerous other sources. Accordingly, TSCA contemplates, not the complete elimination of risk, but rather the reduction of risks to socially acceptable levels, taking full account of the degree of risk presented and the costs to society.

This risk-benefit balancing is required for every substance EPA might consider regulating. No risk is so great under TSCA that it cannot be outweighed by countervailing benefits.[2/] Congress was urged to adopt in TSCA a Delaney-type Clause that would have created such a presumption of unreasonable risk for substances found to be carcinogenic;[3/] but such an approach was soundly and expressly rejected. Accordingly, Congress' message is clear: the risk of inducing even a serious disease like cancer is acceptable if the risk is low, the benefits of the substance are great, or the cost of reducing the risk extravagant.

Moreover, the legislative history indicates that the showing required to demonstrate unreasonable risk under § 6 is greater than under other provisions of the Act due to the potential severity of the regulatory action that may be taken:

2/ Conversely, some risks will be so small by comparison to risks that society routinely accepts, that any benefit will serve to tip the balance against regulation. Thus a risk could be so de minimis that no balancing would be necessary to find it reasonable.

3/ See, e.g., statement of Andrew Biemiller, Toxic Substances Control Act, Hearings on S.776 before the Subcommittee on the Environment of the Senate Commerce Committee, 94th Cong., 1st Sess. 250 (1975).

> [A] requirement under section 6 . . . may remove a substance from the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society may be far reaching. As a result regulatory effect will be of greater significance in a determination of unreasonable risk for purposes of section 6 than for a determination for purposes of section 4 or 5(g). Conversely, with respect to secton 4 or 5(g), because the regulatory effect of action taken under either of those sections is less than that of action taken under section 6, the requirements for a determination of unreasonable risk for purposes of section 4 or 5(g) are less demanding.

Legislative History, supra, at 422.

A similar differentiation must be made among the remedies provided by § 6. Thus, a partial or complete ban on some or all uses of a substance will require a greater showing of risk than a testing or labeling requirement; for, while the latter only affects the manner of handling a substance, the former completely deprives society of the substance's benefits. Since all of the control options proposed in the ANPRM involve, in one way or another, a ban on use of asbestos, EPA has a heavy burden to show unreasonable risk to support any such regulations.

B. Numerous Factual Issues Concerning Asbestos Must Be Examined Prior to Any TSCA § 6 Regulation.

TSCA does not explicitly define what risks are "unreasonable." Congress, however, clearly expressed its intent in TSCA § 2(c) that the "Administrator shall consider the

environmental, economic and social impact of any action the Administrator takes or proposes to take under this Act." Consistent with this explicit intent, the legislative history shows that any unreasonable risk determination must involve balancing a substance's risk of harm against its benefits to society:

> In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.

House Report, Legislative History, supra, at 422.

Congress thus outlined in TSCA § 6 the factors relevant to reaching an unreasonable risk determination:

> (A) the effects of [the chemical] substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.
>
> (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
>
> (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and
>
> (D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

15 U.S.C. § 2605(c).

In short, a full range of risk and benefit evidence must be considered before any "unreasonable risk" determination is made under TSCA § 6. No such determination has been made, and thus no remedies can be suggested or imposed, until such a detailed assessment is completed.

The mandate of TSCA that a wide variety of risks and benefits be thoroughly assessed before any determination is made about "unreasonable risk" applies fully in the case of asbestos. Specifically, EPA must consider the following types of evidence before concluding that asbestos poses an unreasonable risk:

1. Health Significance of Fiber Size and Shape.

Unspecific use of the phrase "asbestos" in any assessment of the substance's health effects may lead to inaccurate assessment of risks. First, the term asbestos includes several types of fibers, each with its own chemical formula.[4/] Although the data are not conclusive, differing fiber types may differ in potency and even in the types of effects they cause. See, e.g., Asbestos: Final Report of the British Advisory Committee, Vol. I, pp. 60-64 (1979).

4/ They include chrysotile (3 $MgO.2SiO_2.2H_2O$), actinolite ($2CaO.4MgO.FeO.8SiO_2.H_2O$), tremolite ($2CaO.5MgO.8SiO_2.H_2O$), anthophyllite ($7MgO.8SiO_2.H_2O$), amosite ($5.5FeO.1.5MgO.8SiO_2.H_2O$) and crocidolite ($Na_2O.Fe_2O_3.3FeO.8SiO_2.H_2O$).

TSCA § 6 directs the assessment of risk of "a chemical substance," which is defined in TSCA § 3 as "any organic or inorganic substance of a particular molecular identity." Each of these minerals is a distinct "chemical substance" for which TSCA § 6 requires a particularized risk assessment.

Moreover, asbestos fibers range widely in size and dimension. The concentration of fibers of various sizes and dimensions varies from product to product and in varying environments. Thus, it has been demonstrated that only fibers of certain ranges (generally between .5 and 2.5 um in diameter and 10 and 80 um in length) pose any health risk. See, e.g., Commission of the European Communities, Public Health Risks of Exposure to Asbestos 63-69 (1977). Consequently, any health assessment for asbestos must carefully examine the type and size of asbestos in order to attempt to determine accurately their varying effects. See, e.g., "Workshop: Significance of Aspect Ratio in Regulation of Asbestos Fiber Exposure," Annals N.Y. Acad. Sci. 330: 601 (1979).

2. Natural Emission of Fibers.

Determination of whether man's industrial and commercial use of asbestos poses an unreasonable risk cannot be a made without consideration of the natural background level of asbestos in the ambient environment. In proposing to regulate use of asbestos, EPA is necessarily considering whether such use creates risks over and above whatever risks may naturally exist in the environment. As part of any determination of whether such use poses an unreasonable risk, exposure levels must therefore be recognized to be incremental to any natural exposure and accordingly incremental risk, if any, must be weighed against the incremental benefits of use. See National Academy of Sciences, Asbestos 24 (1971).

3. Mining, Milling, Processing, and Use Fiber Release.

Because it is generally accepted that only when fibers are set free do they pose any risk to human health, see Commission of the European Communities, supra, at 7, careful consideration must be given to the extent to which such fibers are released into the environment by man's industrial and commercial use of the substance. Such consideration must carefully examine each step in the asbestos process, from mining, processing, manufacturing, installation, use in situ, through disposal to determine to what extent, if any, fibers are released during each step for each product line using asbestos. Obviously, variations in the amount of fibers in general, and of respirable fibers in particular, released exist for each step for each product line. EPA must closely examine these variations before drawing any blanket conclusion about the nature of the risk posed by asbestos industrial or commercial use.

4. Environmental Fate of Asbestos.

Implicit in EPA's ANPRM is the theory that as man uses asbestos there is a cumulative increase in its concentration in the ambient environment with consequent cumulatively increasing human exposure. EPA terms that theory "asbestos build-up in the biosphere." 44 Fed. Reg. at 60062. Although possible, little, if any, evidence exists to demonstrate the validity of this theory. Whether or not ambient environmental

levels of asbestos are indeed increasing is a question to be examined, not a conclusion to be drawn. Close examination is required of the eventual resting point of once-released fibers, with particular attention paid only to those fibers that are respirable and are of any significance to health. Further significant questions exist, even if such is the case, about which of the many uses of asbestos at what stage of their use contributes to any such build-up.

5. Number of Persons Exposed and Amount of Exposure.

Given the dose/response correlations demonstrated by the medical evidence on asbestos, see, e.g., British Advisory Report, supra, Vol. II, pp. 34-40, careful consideration must be given to the actual number of persons exposed to varying levels of asbestos. As it cannot be assumed a priori that any exposure is per se unreasonable, careful calculation of such exposure levels is necessary.

Obviously exposures vary from person to person depending on a number of variables including occupation and geographic location. In addition, other variables, most prominently whether or not individuals smoke, have significant impact on the extent to which asbestos exposure poses any risk. See, e.g., E.C. Hammond et al., "Asbestos Exposure, Cigarette Smoking and Death Rates," Annals N.Y. Acad. Sci. 330: 473-490 (1979). Each of these factors must be considered to determine the relevance of exposure to risk.

6. Health Effects of Inhalation.

Although extensive epidemiological evidence exists on the health effects to workers who have inhaled high levels of asbestos in the past, such evidence tells us little about health effects to the general population exposed to concentrations of asbestos several orders of magnitude lower. Even if one accepts the proposition that there is no level of asbestos exposure that is safe, EPA must show far more in order to demonstrate an unreasonable risk under TSCA § 6.

EPA's risk analysis must carefully consider the exposure levels experienced by the cohorts examined in order to make a valid assessment of the dose/response correlation for asbestos. The medical evidence has demonstrated that significance may be placed on both peak and average exposures in determining adverse effects. See, e.g., NAS 1971 Report, supra, 16-19; P. Enterline, "Pitfalls in Epidemiological Research, An Examination of the Asbestos Literature," J. Occup. Med. 18: 150-156 (1976). In many such epidemiologic studies, exposure levels for the cohort are no more than highly imprecise estimates, such that the uncertainty inherent in such estimates must be taken into account in calculating any assessments of risks at lower levels.

7. Health Effects of Ingestion.

In assessing the health effects of asbestos, clear distinctions must be drawn between the effects of inhalation and ingestion. Markedly different findings have characterized

the scientific work to date on the two routes of administration. Human ingestion epidemiology studies in the non-occupational setting of populations exposed to asbestos fiber in drinking water and animal feeding studies have failed to show any impact on the morbidity or mortality of gastro-intestinal disease; and results of the epidemiology studies of occupational groups exposed to airborne asbestos have been inconsistent in their findings of whether or not a correlation exists between asbestos inhalation and gastro-intestinal cancer or peritoneal mesothelioma. Accordingly, separate consideration of the health effects of ingestion and inhalation is necessary.5/

8. Benefits of Asbestos Use.

Asbestos' use in more than 3,000 types of products in the American economy is a testament to its versatility and unique characteristics as an incombustible, flexible, electrically resistant, stable inorganic compound available at a reasonable cost. An unreasonable risk finding can be made only after fully assessing such benefits. Those benefits may be derived in a number of ways: reduced cost, increased effectiveness, consumer preferences, established availability. Each of these possible benefits for each end-use of asbestos is thus relevant to a determination of unreasonable risk.

5/ See AIA/NA's comments on EPA's water quality criteria document and risk assessment for a full discussion of the ingestion evidence. Attachment A.

9. Economic Efficiency of Asbestos Use.

TSCA mandates that in considering the benefits of chemical use, EPA also assess and determine the availability of substitutes for the chemical. In making such a determination, EPA must assess not only the relative cost and effectiveness of such substitutes, but also the extent of market dislocations that would occur should asbestos no longer compete with such substitutes (where they exist). EPA must consider the consequent economic impact of the loss of such competition, as well as the impact of any mandated reduction in asbestos use on the cost and availability of asbestos for other uses. The TSCA Conference Committee was concerned that limitations on the production of a chemical substance, "if not carefully drawn, could produce monopoly profits." It therefore advised consultation with the Attorney General and the Federal Trade Commission "to avoid any anticompetitive consequences." Conference Report, Legislative History, supra, at 688.

With asbestos, as with any chemical, ripple effects throughout the market for all asbestos-containing products (and potential substitutes) would result from any limitations on some uses. For example, different uses of asbestos require different types and grades of mined asbestos; regulatorily mandated reduction of use of any particular type or grade would impact the economics of mining and marketing other grades. Economic analysis of the substitutability of

asbestos in its many uses will require detailed and complex investigation of all asbestos markets and their inter-relationships.

10. Health Effects of Substitutes.

As the ANPRM recognizes, 44 Fed. Reg. at 60063, 60065, many of the substitutes that have been suggested for asbestos or asbestos-containing products themselves may pose risks to health and the environment. Congress did not intend that riskier substances replace chemicals posing less risk, for it directed that in assessing risk the Administrator "take into account the availability of substitutes for the substance or mixture which do not require regulation." House Report, Legislative History, supra, at 422 (emphasis added).

Some such substitutes (such as polyvinyl chloride pipe) have already been investigated to some extent; others (such as metallic fibers), because they are relatively new, have not been extensively investigated. Regardless, the health consequences of alternative substances are crucial to determination of unreasonable risk. Accordingly, any regulation that would tend to increase use of these other substances would itself affect the risk side of the unreasonable risk determination.

In addition, many uses of asbestos promote health and safety by, for example, reducing the dangers of combustion, or providing assurance of adequate braking. To the extent substitutes are less able to serve such functions, the

health and safety risk of changing to substitutes must be added to the risk assessment. It is important, therefore, that any unreasonable risk calculation give as careful attention to the adverse health consequences of substitutes as to asbestos itself.

11. Effects of Regulation on the National Economy.

TSCA specifically mandates that any unreasonable risk determination be made in light of the consequences of regulation on the national economy. Most prominently affected by any such regulation would be firms producing asbestos and asbestos-containing products. Thus, careful consideration is necessary regarding effects of the regulations on the ability of such companies to continue in operation, invest in new research and development and capital formation, and employ workers.

Moreover, given the current significance of energy supplies to the national economy, close attention is necessary to the energy requirements for production of asbestos-containing and substitute products.

12. Effects of Regulation on Small Business.

TSCA mandates particular attention to the effect of any § 6 regulations on "small business." Although companies producing asbestos and asbestos-containing products run the gamut from major national corporations to small, closely held businesses, a substantial number of the companies who produce

asbestos-containing products are quite small. Such companies would in many cases be unable to conduct the research and development or make the capital investments that might be required to remove asbestos from their product lines.

The legislative history reveals Congress' particular solicitude for the plight of small businesses. During the house debate, Rep. McCollister, a member of the House Committee on Interstate and Foreign Commerce, expressed the sentiments of many members:

> I am very concerned about the impact of this legislation on small business. I hope that we have drafted a bill that will protect the interests of small business as well as the interest of the public. Whether we have done that or not will, I think, probably be determined by the attitude of the EPA in administering the law.

Legislative History at 538. As TSCA singles small firms out for special consideration, they must be assessed as part of any unreasonable risk determination.

13. Effects of Regulation on Technological Innovation.

Depending on the type and scope of regulations implemented by EPA, great differences would occur in their impact on technological innovation, another factor that TSCA singles out for special consideration in any § 6 unreasonable risk determination, consistent with the TSCA § 2(b)(3) policy that "authority over chemical substances and mixtures should be exercised in such a manner not to impede unduly or create unnecessary economic barriers to technological innovations."

The currently proposed three options, each tending toward complete bans on asbestos use, will discourage such innovation by removing incentives for development of improved methods of processing or manufacturing asbestos, or improving the contents of asbestos-containing products, in ways that would reduce release of respirable fibers.

* * *

In sum, complex questions must be explored as part of an unreasonable risk determination under TSCA. The statute requires that EPA exhaustively canvass both the risk and benefits of asbestos, with careful attention to the correlative risks and benefits of substitute chemicals. EPA has recognized: "Government regulatory agencies must proceed on the basis of the best available data in making their determination of unreasonable risk to health and the environment." Chlorofluorocarbon Final Action Support Document 18 (March 17, 1978). Given asbestos' many qualities that have led it to be employed for a multitude of uses, such an assessment will raise many factual issues that will require careful scrutiny.

C. No Reasonable Basis Has Been Demonstrated for TSCA § 6 Regulation of Asbestos.

Applying the substantive standards of TSCA § 6 to asbestos, the ANPRM discloses no reasonable basis for the Administrator to conclude that commercial and industrial use of asbestos need per se pose an unreasonable risk of injury to health or the environment. Given the lack of evidence in

the ANPRM, it is necessary to outline some of the substantial evidence demonstrating the absence of any unreasonable risk in continued commercial and industrial use of asbestos.[6/]

1. Official Reviews of the Scientific and Health Evidence on Asbestos Have Uniformly Found an Absence of Evidence Indicating Risk from Low-Level Exposure.

AIA/NA will not attempt in these comments to analyze in depth the available medical evidence on asbestos. That task has already been performed by at least four highly respected governmental organizations, and their conclusions are unanimous that there is an absence of evidence indicating risk to the general public from low-level exposure. None of these reports considered the substantial benefits provided by asbestos. Even without considering the commensurate benefits, however, they reached conclusions at odds with the tentative findings suggested in the ANPRM.

In 1971, the National Academy of Sciences prepared a report collecting the available information on asbestos as an air pollutant.[7/] The report finds:

6/ For a very different product under very different circumstances, EPA only once to date has found an unreasonable risk under TSCA § 6(a) -- in the continued use of fully halogenated chlorofluoroalkanes as aerosol propellants. 43 Fed. Reg. 11318 (1978).

7/ National Academy of Sciences, Asbestos, The Need for and Feasibility of Air Pollution Controls (1971). The report was prepared by the Panel on Asbestos of the Committee on Biologic Effects of Atmospheric Pollutants at the request of the National Air Pollution Control Administration.

> Industrial experience indicates that pulmonary fibrosis sufficient to interfere with respiratory or cardiovascular function can be prevented by reducing asbestos dust concentrations to levels that are still far above any likely to be encountered in community air.

NAS 1971 Report 4 (emphasis added). In its Conclusion and Recommendations, the NAS adds:

> The most important question in the case of persons with nonoccupational exposures to asbestos is whether there is an increased risk of malignancies. Industrial experience indicated that there is no likelihood of significant asbestosis in nonoccupational exposures. The major potential for risk appears to lie in those with indirect occupational contacts, household contacts, or residence in the immediate neighborhood of an asbestos source; and even there, the actual risk is poorly defined. The appearance of a gradient of effect in such groups, however, suggests that there are levels of inhaled asbestos without detectable risk. It is not known what range of respirable airborne asbestos fibers will ultimately be found to have no measurable effects on health. At present, there is no evidence that the small numbers of fibers found in most members of the general population affect health or longevity.

Id. 31 (emphasis added).

The National Academy of Sciences Safe Drinking Water Committee similarly concluded in its 1977 Summary Report: Drinking Water and Health:

> [E]vidence of the toxicity of ingested particles of asbestos minerals is not conclusive. (at 2)

And:

> The available data with respect to asbestos orally ingested through drinking water do not suggest an immediate hazard to public health.

Full Report, Drinking Water and Health 191 (1977).

The International Agency for Research on Cancer, after surveying and evaluating all the available published literature on asbestos, also concluded:

> At the present time, there is no evidence that exposure of the general population to past levels of asbestos dust in the ambient air or in beverages, drinking-water, food or pharmaceutical preparations increased the risk of cancer.

IARC, Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, Vol. 2, p. 36 (1973). The IARC did not retreat from this basic conclusion in a subsequent review published in 1977. IARC, Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, Vol. 14 (1977).

In 1977, after a thorough review of the available data, a working group of experts reported to the Commission of the European Communities that:

> [T]here is no established evidence that true ambient exposure through air, water, drugs, beverages, food, as prevalent in Western European countries at this moment carries . . . a definite [health] risk; however there exist too many uncertainties to deny such a risk, though if the risk was substantial, it is likely it would have been detected by now.

Commission of the European Communities, Public Health Risks of Exposure to Asbestos 122-23 (1977).

Finally, the Advisory Committee on Asbestos of the United Kingdom Health and Safety Commission has just recently completed an exhaustive three year study of the health risks from asbestos. In its final report, the Advisory Committee states:

> [T]here is no quantitative evidence of a risk to the general public from exposure to asbestos dust.

Health & Safety Comm., Asbestos, Final Report of the Advisory Committee, Vol. 1, p. 89 (1979) (see also page 59).

The British Report further concludes:

> There is . . . no evidence of the existence of risk in animals associated with the ingestion of asbestos. Industrial experience suggests that any risks in man may be limited to persons exposed to high doses. Id. 60.

In short, the uniform opinion of these respected authorities, each of which has investigated the issue in depth, is that there is an absence of evidence indicating exposure to asbestos from the ambient environment poses a public health risk. For EPA to contradict the findings of these authorities would take far more persuasive evidence than the ANPRM suggests may be available.

Significantly, the National Academy of Sciences has recently initiated a new study of the health effects of asbestos. National Academy of Sciences, Panel on the Geochemistry of Fibrous Materials Related to Health Risks. The study will undertake to assess the cancer risk from fibrous

minerals, focusing primarily on commercial asbestos. The proposal explaining the need for such a study states:

> [T]he present U.S. government limits for asbestos content of air may be sub-optimun with respect to both relevant health and economic considerations . . . . Some of the more stringent regulations proposed may impose prohibitive limitations on mining and other related industries, in some instances without appreciable benefits to environmental factors affecting health risks. Factors that may have a critical bearing on health effects and how they are related to the economic considerations are not well enough understood. In particular, the morphology, chemical content, and crystal structure of mineral fibers have not been adequately considered in establishing the health hazards associated with mining, processing, and uses of various fibrous materials. (at 7)

In light of the past uniform conclusions of no detectable public health risk, EPA should, at a minimum, delay any action on asbestos pending the conclusion of the new NAS assessment.

2. EPA's Risk Assessment for Ingested Asbestos Demonstrates the Error of Assessing Risk through Arbitrary Use of Data and Questionable Methodology.

The uniform opinion of previous official reviews of the scientific and health evidence on asbestos, by themselves, cast severe doubts on EPA's tentative conclusion that asbestos manufacture and use poses an unreasonable risk. Indeed, one may question why EPA is even proposing the severe remedies outlined in the ANPRM. For, if EPA is to find an unreasonable risk , it must do so by means far different than were employed by the official review groups discussed above.

Although EPA has yet to finish or release for comment its assessment under TSCA of the risks of asbestos exposure, it has published an ingested asbestos risk assessment as part of the criteria development process mandated under the Clean Water Act, 44 Fed. Reg. 56632-35 (Oct. 1, 1979). AIA/NA has reviewed and commented extensively on that risk assessment. Based on such comments, AIA/NA fears that arbitrary data selection and improper methodology used in the water quality criteria may carry over to the risk assessment EPA is preparing in connection with the TSCA ANPRM.

As AIA/NA's water quality comments note, the available scientific knowledge on the risk of asbestos ingestion is not suggestive of any unreasonable public health risk. Both the human and animal ingestion evidence predominantly suggest an absence of carcinogenic risk. This evidence does not demonstrate the presence of detectable risk at lower levels, even if it cannot completely rule out the possibility that carcinogenic risks may exist from asbestos ingestion at high levels not experienced in ambient drinking water.

EPA's water criteria document ignores such ingestion evidence and uses inhalation epidemiology results to calculate a risk assessment. It is an open question, however, whether the high level inhalation exposure in these occupational studies is relevant to determination of low level ingestion exposure from drinking water. But, even if the relevance of such calculations were scientifically supported, the risk assessment EPA calculates from such evidence is wholly inadequate.

EPA's assessment totally ignores the studies which have found no detectable risk of gastro-intestinal cancer or peritoneal mesothelioma from asbestos inhalation in occupational settings.[8/] Rather, the EPA risk assessment arbitrarily selects three of the twenty or more existing occupational inhalation studies without presenting any rationale for using only these three studies. Based on this thin slice of the available epidemiologic data, EPA calculates its asbestos in water risk assessment. As AIA/NA's comments demonstrate, risks differing substantially from those calculated by EPA would be determined -- even accepting the methodology used -- had EPA instead based its risk assessment on other, more appropriate epidemiology studies having more carefully estimated worker exposure data.[9/]

8/ See, e.g., Peto, et al., "A Mortality Study among Workers in an English Asbestos Factory," Brit. J. Ind. Med. 34: 169-73 (1977); Meurman, et al., "Mortality and Morbidity among the Working Population of Anthophyllite Asbestos Miners in Finland," Brit. J. Ind. Med. 31: 105-112 (1974); Weill, et al., "Influence of Dose and Fiber Type on Respiratory Malignancy Risk in Asbestos Cement Manufacturing," Am. Rev. Resp. Disease 120: 345-354 (1979); Rubino et al., "Mortality of Chrysotile Asbestos Workers at the Balangero Mine, Northern Italy," Br. J. of Ind. Med. 36: 187-194 (1979); Hobbs, et al., "Monitoring of Cancer Risk in Previous Crocidolite Miners in Western Australia," and Jones, et al., "The Tracing of Personnel Who Were Exposed to Asbestos Dust in a Wartime Gas Mask Factory," papers submitted to the IARC Conference on Biological Effects of Mineral Fibers (Sept. 25-27, 1979, Lyon, France).

9/ See Attachment A, pp. 39-47, with risk assessments based on Weill (1979) supra; Enterline, et al., "Respiratory Cancer in Relation to Occupational Exposures among Retired Asbestos Workers," J. Occup. Med., 14:1897-1901 (1972); McDonald, et al., "Dust Exposure and Mortality in Chrysotile Mining, 1910-1975," Br. J. Ind. Med. (to be published).

Further, in calculating its risk assessment, EPA made numerous assumptions of dubious validity that served only to inflate the calculated risk. For instance, EPA calculated risks based on the number of total fibers present in ambient water despite evidence suggesting strongly that only fibers of certain sizes and dimensions pose any risk. Similarly, EPA assumed exposure levels for the cohorts on which its assessment was based that are significantly lower than historical records indicate was likely to be the case.

Because this preliminary EPA work on asbestos may indicate the reasoning and approach that the Agency intends to employ in a TSCA § 6 proceeding, we attach a copy of our entire comments on the water criteria documents to these ANPRM comments (Attachment A). We trust that EPA will not commit the same errors of science and objectivity in its risk assessment for TSCA purposes that it has committed in the water quality criteria document. Indeed an objective assessment, along the lines suggested by our comments, would convince EPA, we believe, not to proceed with a § 6 TSCA proceeding.

3. Human Exposure to Asbestos Fibers Is Already Extensively Limited.

The ANPRM states that large numbers of persons are exposed to asbestos because of the prevalence of asbestos-containing products. The many products utilizing asbestos

are testimony to its usefulness, but exposure to asbestos-containing products is not equivalent to a risk of exposure to fibers.

EPA's ANPRM indicates that the Agency believes there may be some health risk created because asbestos is a "ubiquitous pollutant" which, once mined, remains for years in the biosphere, 44 Fed. Reg. at 60061, 60062. The Agency thus proposes a "life cycle" approach to risk assessment that will "weigh overall risks" presented by asbestos from mining and milling to final disposal. Id. This approach ignores the fact that exposures will vary at each stage of the "life cycle," and the factors relevant to a determination of unreasonable risk will change at each step and for each product. A "life cycle" method of risk assessment suggests an unwarranted disregard of these distinctions.

As a naturally occurring mineral, asbestos has been present in the biosphere for millions of years. Although it is theoretically possible that the amount of respirable fibers in the general environment to which man is exposed could increase over time through mining, manufacturing and use of asbestos-containing products, substantial doubt exists as to whether such increases are in fact occurring, or, even if occurring, whether the increases are other than de minimis.

The eventual fate of asbestos in the general environment is affected by a complex set of variables including fiber

size and shape, the location of the emission sources, rates of air and water flow, electrostatic forces, and fiber agglomeration, subdivision and decomposition. Especially in light of substantial evidence indicating the absence of any detectable risk -- let alone any unreasonable risk -- from levels of asbestos in the general environment, it must be questioned whether this life cycle approach to risk assessment will have any meaning or significance to the statutory requirement that EPA assess "unreasonable risk."

Nonetheless, one fact is clear and that is that human exposure to asbestos at levels demonstrated in the medical evidence to have adverse health effects is predominantly a historical phenomenon. Determination of past and present levels of human exposure to asbestos is subject to many uncertainties. Historical data are sparse, and what data do exist are based on measurement techniques that have been refined over the years. Translation of historical results to current measurement scales is difficult and quite imprecise. Even current measurement techniques are limited in their detection abilities and subject to significant uncertainties.

Despite these uncertainties at low levels, the existing data show differences of several orders of magnitude between the historically high occupational exposures and the exposure levels experienced by the general population today. Although each of the figures in the table below is subject to uncertainty, the table serves to highlight these enormous differences:

ASBESTOS AIRBORNE CONCENTRATIONS IN VARIOUS ENVIRONMENTS

	Concentration (Nanograms/m^3)		
	Average	Range	
U.S. Urban Areas:*/			
Twenty Cities	18	.02-200	
Manhattan	30	8-65	
Pittsburgh, PA	4	2-8	
Frankfort, KY	.09	.02-.15	
British Urban Areas***/		1-100	
British Rural Areas***/		.1-1	
Areas near Vermont mine-mill:**/			
Within 1 km	30,000	2,000-106,000	
1.5 km away	96	12-180	
The current OSHA workplace 2 fiber/cc standard***/	100,000		
Pre-regulation workplaces****/	750,000-1,500,000		Up to 25 million

*/ U.S. DHEW, "Asbestos: An Information Resource" Pub. No. 79-1681, at E-1 (citing five published studies) (May 1978).

**/ USEPA, "Background Information on National Emission Standards for Hazardous Pollutants," EPA-450/2-74-009a (1974).

***/ Asbestosis Research Council, in British Advisory Council Report on Asbestos Appendix, at 14-15 (1979).

****/ Based on estimates of 15-30 fibers/cc and studies showing peak exposures up to 500 fibers/cc.

A number of factors explain the wide variations in human exposure. As medical evidence has illuminated the risks of high level asbestos exposure, methods have been developed to produce asbestos-containing products in which the fiber was locked-in or encapsulated to minimize fiber release; manufacture of some products has been terminated; and numerous steps have been taken to reduce workplace emissions and exposure. According to U.S. Bureau of Mines statistics, apparent consumption of asbestos in the United States has declined in each of the past six years. Asbestos, Mineral Commodity Profiles 17 (1979). As a result, persons both within the immediate vicinity of asbestos and asbestos-containing products and in the general population have experienced a reduction in exposure.

Virtually all presently produced asbestos products contain asbestos in a form that precludes or renders highly unlikely the release of significant number of respirable fibers under normal conditions of use. For example, in the construction industry, which consumes more than three-fourths of the asbestos produced in the United States, products such as roofing felts, gaskets, and flooring bind asbestos in a matrix from which it is virtually impossible that a consequential amount of fibers would be released under normal or industry-recommended use conditions. Asbestos-cement products, which comprise the single largest category of asbestos use, bind the fibers into the cement so that a de minimis number are released under normal or industry-recommended end use.

See Attachment B, AIA/NA and AACPP Recommended Standard for Occupational Asbestos Exposure in Construction and Other Non-Fixed Work Operations, pp. 5b-8b.

Exposure to asbestos in the workplace is currently at levels dramatically lower than in the the past. Long before OSHA began establishing exposure standards in 1971, asbestos manufacturers and processors began reducing the exposure levels of their employees. Further advances in reducing exposure have been achieved in the last decade. As a result, worker exposure to asbestos today is markedly less than in the epidemiologic studies attributing risks to high level asbestos exposure.

In light of these significant reductions in the possibilities for exposures that might pose human risk, it is difficult to discern why EPA considers "many population segments" to be "inadequately protected." The ANPRM gives little hint of any such populations, and AIA/NA believes that EPA, upon closely examining the evidence, will find few, if any, such groups. At a minimum, even if small subgroups exist, there is no basis to conclude that use of asbestos is per se an unreasonable risk to the entire population.

4. Asbestos Is of Great Benefit to Society.

Arrayed against minimal risks from current asbestos use are its manifold societal benefits. The physical properties of asbestos that make it commercially valuable include its heat stability, thermal and electrical resistance, flexibility, high

tensile strength, ability to subdivide into smaller fibers, and stability in acids or alkalis. Its name reflects one of its principle characteristics -- "asbestos" is derived from the Greek word for "incombustible."

These attributes make asbestos attractive for a wide variety of applications. To mention but a few, it serves as a strengthening ingredient in cement and plastics, provides heat insulation and sound absorption, and is an essential ingredient in brake linings, clutch facings and other friction products.

In response to the increasing cost of asbestos and the concern over possible health risks, industry has been working diligently to develop substitutes. For some uses, that effort has been successful; but for many applications there is no present alternative. For example, there are substitutes for asbestos in some disc brake pads, but for drum brakes, no other material has yet been found that provides the moderate but stable friction, resistance to fade, low wear rates and absence of scoring and squeal that asbestos brake pads exhibit.

Some materials can adequately duplicate the properties of asbestos under user conditions, but are effectively "unavailable" for that use because they cannot be adapted to the commercial manufacturing process. For example, fibrous glass, which is a possible substitute for asbestos in several applications, is much more abrasive and thus wears out processing

equipment much faster; and several other organic fibers nearly equivalent to asbestos in strength and chemical resistance break down in the high temperature and alkalinity production processes for fiber reinforced pipe.

Where substitutes are available, they most often cost more, sometimes substantially more, than asbestos. For example, specially treated nylon fiber could serve the place of asbestos cloth in firefighting and foundry protective clothing, but the cost is nearly prohibitive.

Moreover, asbestos products now compete with alternatives in many markets and the effect on price competition of removing asbestos products cannot be ignored. If asbestos is the only competitor in a market, removal would tend to create a monopoly with concomitant higher prices.

* * *

As any EPA determination of "unreasonable risk" can be made only after such benefits of asbestos commercial and industrial use are weighed carefully against its risks, and in light of the magnitude of the benefits and the highly speculative nature of the risks, AIA/NA takes strong exception even to the tentative conclusions in the ANPRM that asbestos poses such a risk.

No TSCA regulation can be promulgated until an unreasonable risk finding is first made and supported by substantial evidence. AIA/NA urges EPA to assess carefully the risks and benefits and to offer the evidence and assessment for

outside review prior to proceeding with a formal notice of rulemaking along the lines suggested in the ANPRM. As the brief outline of the evidence here suggests, it is highly unlikely, after such an assessment, that EPA will find the support TSCA requires for the views advanced in the ANPRM.

II. EPA'S PROPOSED REGULATORY OPTIONS FOR ASBESTOS WOULD BE UNDULY BURDENSOME AND EXTEND WELL BEYOND ANY RESTRICTION "NECESSARY TO PROTECT ADEQUATELY" AGAINST RISK TO HEALTH OR THE ENVIRONMENT.

EPA has stated it is considering three regulatory options for asbestos:

(1) Declining limits on the annual tonnage of asbestos processed or imported into the United States;

(2) Bans on particular asbestos-containing products; and

(3) A ban on all uses of asbestos at some date in the future with the burden placed on industry to establish particular uses as "essential" and therefore exempt from the ban.

Even assuming that it could be shown that asbestos poses an unreasonable risk, implementation of any of EPA's proposed regulatory options would be a drastic over-reaction at odds with the requirement of TSCA that regulation be proportionate to the risk shown and not overly burdensome to the affected parties.

Nowhere in the ANPRM does EPA evidence any serious consideration of the existing or planned regulatory actions

against asbestos under other statutes, voluntary efforts by industry to reduce the release of respirable fibers in asbestos use, or the myriad of regulatory approaches that, rather than outlawing asbestos, would create incentives for its safer use. Such consideration is required by TSCA before § 6 bans can be ordered.

As we discuss below, AIA/NA believes that an analysis of these activities would convince EPA that it should not promulgate proposals of the types suggested in the ANPRM and force expensive, time-consuming administrative proceedings that would only demonstrate the absence of any basis for such regulation.

A. EPA's Proposed Regulatory Options Are Expansive and Exceed Any Justifiable Regulation.

TSCA § 6(a) permits the Administrator, upon a finding that a substance presents an unreasonable risk, to impose one or more of seven specified regulatory restraints on the substance, but only "to the extent necessary to protect adequately against such risk, using the least burdensome requirements."

The actions proposed by EPA with respect to asbestos all involve, in one way or another, banning the use of asbestos. This is the most drastic and far-reaching of all the TSCA § 6 options. At a minimum, the requirement that the Administrator impose regulations only "to the extent necessary to protect adequately against such risk" means

that EPA must consider and explain its reasons for rejecting each of the less severe alternatives provided in the statute. To jump immediately to the conclusion that only a partial or complete ban on a substance will "adequately" protect against a risk flagrantly disregards the statutory limitation on EPA's powers.

Furthermore, it is questionable whether EPA could legally impose its third option -- a complete ban on production and use after some future date with exemptions for "essential" uses. TSCA § 6 charges EPA with the task of developing a "reasonable basis" for a finding of unreasonable risk. To require manufacturers to establish the essentiality of asbestos in their products presumes the existence of an unreasonable risk and therefore impermissibly reverses the burden of proof. In short, a chemical substance is presumptively safe until the Administrator establishes that it poses an unreasonable risk; he cannot dispense with this required finding simply by shifting the burden of justification to the manufacturers.[10/]

10/ This illegal shifting of the burden of proof is clearly illustrated in the document "Commercial and Industrial use of Asbestos (Potential Control Options)" released by EPA on January 8, 1980. The agency proposes to require a manufacturer to show that a product meets at least one criterion from each of three categories in order to obtain an exemption. This is not the balancing of risks and benefits that TSCA contemplates, an obligation that EPA cannot avoid before imposing any § 6 regulation.

B. EPA's Proposed Regulatory Options Are Not the "Least Burdensome Requirements."

The other half of the limiting clause of TSCA § 6(a) -- that EPA use only "the least burdensome requirements" -- has also been disregarded in the ANPRM. EPA has proposed the most burdensome requirements without any explanation of why less drastic alternatives would not suffice. All three options are based on the false premise that the presence of asbestos in the environment per se presents an unreasonable risk. There is simply no basis in fact for this assumption.

The seven regulatory options under TSCA § 6(a) are:

(1) Banning or limiting the production and distribution of the substance;

(2) Banning or limiting production or concentrations employed for particular uses;

(3) Requiring labelling with instructional materials;

(4) Requiring testing and maintenance of production records;

(5) Regulating the manner or methods employed for particular uses;

(6) Regulating methods of disposal.

(7) Requiring that manufacturers or processors give notice of an unreasonable risk to distributors and the public, and replace or repurchase the chemical substance.

Because the banning options are listed first emphatically does not mean they are to be preferred. As stated by Congressman McCollister during the House debate on TSCA:

> EPA is directed to issue the least burdensone requirement possible . . . . EPA could not ban a substance for a particular use if a labeling requirement would provide adequate protection.

Legislative History, supra, at 521.

EPA has failed to date to review systematically the myriad of requirements that could be used to reduce any risks of asbestos that might conceivably be found to be "unreasonable." An outline of the possibilities is therefore necessary in order to assess EPA's preconceived assumption that only some type of ban on asbestos use will suffice. Pertinent to this review are both regulatory actions already taken against asbestos, or planned for the future, by EPA and other agencies; past and presently contemplated voluntary efforts of the industry itself; and market forces that are promoting safer asbestos use.

1. Given the Extensive Regulation of Asbestos under Other Statutes, Regulation under TSCA Is Not Justified.

TSCA contains explicit provisions deferring to the regulatory authority under other statutes before TSCA may be invoked. Considering the extent to which asbestos is already regulated, further regulation would be cumulative and therefore contrary to the terms of TSCA.

TSCA § 6(c) states:

> If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in

> part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act.

By this provision, Congress intended that EPA first utilize its statutory authority other than TSCA to control risks. The statute requires that

> the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.

TSCA § 6(c). The Conference Report states explicitly that, " a reviewing court is expected to require that the Administrator have examined the other authorities and present the results of that examination when making the finding that it is in the public interest to use this Act." Legislative History, supra, at 698.

In short, Congress intended TSCA to serve as a statute of last resort, and intended EPA to act upon and regulate against only those risks which some other Federal statutes cannot sufficiently address. The Senate Committee on Commerce explained:

> If an unreasonable risk may be prevented or reduced sufficiently by other Federal laws, the Administrator must request the

> agency administering the law to issue an order declaring whether or not such a risk is presented. If the agency agrees that such a risk is presented, it must determine if the risk can be prevented or reduced to a sufficient extent by action taken under the law administered by it. If the other Federal agency issues the order declaring that there is no other law, the Administrator may not take action under this authority to prevent the unreasonable risk.

S. Rep. No. 94-698, 94th Cong., 2d Sess. 8 (1976) (emphasis added).

EPA already regulates asbestos emissions to the environment pursuant to two other statutes. Under the Clean Air Act Amendments of 1970, 42 U.S.C. § 7412, asbestos has been designated a hazardous air pollutant and a "no visible emission" standard has been set for mills and manufacturing operations. 40 C.F.R. § 61.22(a). In addition, spraying of asbestos in buildings for insulation or fireproofing is prohibited, and strict work practice rules apply to demolition or renovation operations involving removal of friable asbestos material. Id. And, under the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. § 1311, effluent limitations and new source performance standards are in effect for asbestos manufacturing point sources. 40 C.F.R. Part 427. Zero discharge has been set as the 1984 limitation. Id.

EPA thus has other statutory authorities to regulate asbestos in both air and water. TSCA requires that it assess the extent to which any unreasonable risk could be

reduced by, the costs of complying with, and the effectiveness of, regulation under these statutes prior to making any determination to impose TSCA regulatory options.

TSCA § 9(a) further provides that whenever the Administrator decides there is a reasonable basis to conclude that a chemical substance presents an unreasonable risk, "and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator," he must report his findings to the agency that administers the other act. If the other agency initiates action to protect against the risk, "the Administrator may not take any action under [TSCA] section 6 or 7 with respect to such risk." Id.

This language forcefully conveys Congress's intent that environmental hazards already subject to regulation by other agencies should not be peremptorily regulated under TSCA. Close attention is therefore warranted to the regulatory actions, past and future, at other agencies intended to lead to safer use of asbestos and safer asbestos-containing products.

OSHA, for one, regulates most workplace exposure, and the Mine Enforcement and Safety Administration has set exposure limits for workers in mines, the only area outside OSHA's jurisdiction that presents any opportunities for high levels of asbestos dust. OSHA proposed in 1975 that its workplace exposure limitation be reduced from 2 fibers/cc to

.5 fibers/cc. It is no secret that OSHA is now considering whether to conduct regulatory proceedings with the aim of imposing such a reduction. Obviously, should any reduction be mandated by OSHA, there will be workplaces where employers would be required to reduce the release of respirable fibers. Such actions would reduce both worker exposure and release to the general environment.

OSHA regulatory efforts thus serve as an example of Federal regulatory initiatives already in effect or proposed that will require safer use of asbestos in the future.[12/] Such Federal regulatory efforts are only part of the myriad of alternatives to banning asbestos use that promise reduction of risk from asbestos, whether it be deemed unreasonable or not.

2. The Asbestos Industry and the Marketplace Have Reacted to Calls for Safer Asbestos-Containing Products

Given the breadth and depth of publicity about asbestos' alleged hazards to human health, it is not surprising that the marketplace has reacted. Rare is the buyer of products containing asbestos not now aware of such publicity. As a result, buyers of such products have placed great economic pressures on sellers to increase the safety of their products.

12/ Another example is the Department of Transportation's regulations concerning the proper packaging, handling, and labeling of asbestos for shipment in interstate commerce under the Hazardous Material Transportation Act, 49 U.S.C. §§ 1803-1804. See 49 C.F.R. §§ 172.101, 173.1090, 174.840, 175.640, 176.906, 177.844.

Consequently, great market incentives already exist for the asbestos industry to replace asbestos in products where that is economically viable, to reformulate products so as to reduce asbestos release potential, or to seek better methods of recommended use for such products.

Industry is strongly supportive of pragmatic regulations to reduce workplace asbestos exposure. Just this month, AIA/NA and the Association of Asbestos-Cement Pipe Producers (AACPP) jointly presented to OSHA a Recommended Standard for Occupational Asbestos Exposure in Construction and Other Non-Fixed Work Operations. This Model Asbestos Standard establishes a series of economic and regulatory incentives for the development of work practices and product formulations that will enhance worker health protection in a highly cost-effective manner.

Specifically, the proposed model standard would, for construction and other non-fixed workplaces, provide for partial and complete exemptions from the usual fixed-site requirements based on a product classification scheme that:

(i) Defines a "Category A Product" as any product that, based on qualified scientific tests, will not, under any reasonably foreseeable use, release airborne asbestos fibers in excess of permissible exposure limits;

(ii) Defines a "Category B Product" as any product that, when validated work practices or

other protective measures are used, will not release airborne fibers in excess of permissible exposure limits; and

(iii) In the case of workplaces involving "Category C Products" -- i.e., products that are neither Category A Products nor Category B Products but the processing or use of which may release asbestos fibers in excess of the permissible exposure limits -- applies existing standards.

The purpose of this product classification scheme is to encourage the development of safer products and work practices that eliminate the need for impractical regulatory requirements and to create stronger incentives for primary manufacturers to develop validated work practices so that their construction industry customers will not be required to meet the burdensome fixed-site requirements of the current standard. An additional incentive is provided for innovative product formulations (Category A Products) that pose little or no foreseeable threat of dangerous asbestos exposure.

Because of the significance of efforts such as this Model Asbestos Standard to EPA's overall assessment of "unreasonable risk" in any TSCA proceeding, we attach to these ANPRM comments a copy of the AIA/NA and AACPP document describing the Standard (Attachment B). This model standard both signifies industry's commitment to reduce risk in a reasonable, responsible manner and simultaneously calls into question the need for EPA's extreme ban alternatives when far

less extreme measures are likely to produce far safer asbestos products.

EPA's ANPRM options evidently assume that only through stringent government edict will the economy reduce asbestos risks. In fact, the marketplace itself is already achieving much the same result.13/

3. TSCA Mandates that EPA Consider All Less Burdensome Alternative Remedies.

Even if EPA were able to conclude that asbestos poses an unreasonable risk because of gaps in the regulatory framework, and even if those gaps were not being closed by the asbestos industry's voluntary efforts and the marketplace forces calling for safer use of asbestos, TSCA mandates that the Agency rule out all less burdensome TSCA regulatory options before requiring such extreme action as a total ban on asbestos.

13/ OSHA-directed activities are, however, not the only actions undertaken by asbestos producers and producers of asbestos-containing products to reduce risk:

-- Asbestos producers have taken steps to scrutinize more closely the companies to whom they market asbestos in order to be able to give advice concerning its proper handling.

-- Producers of asbestos-containing products have labeled many of their products, especially those destined for the construction industry, in order to caution installers and users of proper precautions to prevent release of fibers.

-- Asbestos producers and producers of asbestos-containing products have been active in distributing educational materials to users of asbestos-containing products recommending work practices that will prevent release of fibers.

The statute's list of possible alternatives suggests the range of less burdensome regulations that must be considered and rejected before any of EPA's three ban options may be imposed. For example, a simple labeling requirement for asbestos-containing products could go a long way toward promoting their safer use. To the extent appropriate, such labels could warn against particular methods of handling or misuse. Such requirements would provide an incentive to producers to reformulate products to obviate the need for labels or similar restrictions.

Should EPA determine that particular processing or disposal methods entail an unreasonable risk of hazardous fiber release, the Agency has ample regulatory tools to deal adequately with such problems without barring asbestos use. These could include tighter emission standards under the Clean Air or Clean Water Acts, waste management regulations under the Resource Conservation and Recovery Act, 42 U.S.C. §§ 6921-6931, or TSCA § 6 regulations on concentrations of asbestos in products or manner or method of commercial use.

In short, Congress' intention that EPA ban substances only as a last resort means that EPA must, whenever possible, tailor its regulations to the particular facts of particular uses, for Congress' overriding purpose was to create incentives for safer use of chemicals, not to ban toxic chemicals outright.

* * *

AIA/NA urges that EPA, should it proceed with its intention of proposing TSCA § 6 regulations on asbestos, first closely examine the various major categories of asbestos use, and for each consider the wide range of possibilities for achieving safer use. Such "less burdensome" options include but are not limited to regulatory initiatives under other statutes, by EPA and other agencies, as well as creative use of the regulatory options enumerated in TSCA itself. Although AIA/NA believes the evidence on asbestos cannot and does not support any finding of unreasonable risk, it shares with EPA the goal of reducing risks from asbestos whenever such reduction is scientifically and economically justifiable. We suggest, therefore, that rather than expending considerable administrative energies building a case against all uses of asbestos that EPA divert its attention to promoting its safer use.

III. ANY DETAILED AIA/NA RESPONSE TO EPA'S INFORMATION REQUESTS WILL REQUIRE MORE TIME AND RESOLUTION OF CONFIDENTIALITY ISSUES.

Beyond advancing its tentative conclusions about asbestos and its three regulatory control options, EPA seeks through its ANPRM broad and detailed information on asbestos and the asbestos industry. The information requests, 44 Fed. Reg. at 60066-60068, in effect seek documentation of all scientific, health and economic facts about every aspect of the many product lines in which asbestos is used in this country.

AIA/NA has met with EPA staff and counsel on numerous occasions to assist the Agency in understanding the asbestos industry and to be responsive to its information needs. In addition, individual AIA/NA members have been contacted numerous times over the past decade by EPA, and other government agency contractors, to obtain similar data. As a result, the amount of information already possessed by the Government about asbestos and the asbestos industry is significant.

After the ANPRM was issued, AIA/NA representatives met with EPA once again to attempt to determine whether, in light of the substantial information the government already possessed on asbestos, it was possible to obtain a more specific understanding of what information EPA was now seeking. As AIA/NA representatives told EPA at that meeting on November 21, 1979, the breadth of the ANPRM request made it impossible for the Association or its members to respond in a meaningful manner without unduly burdensome information collection that would likely prove not to be beneficial to the Agency's true needs. The utter impossibility of even attempting to fulfill the information requests in the ANPRM by the initially announced December 17, 1979, comment deadline led AIA/NA (and others) to ask EPA to extend the deadline in order that further discussion might occur so that industry could ascertain excactly what information EPA desired and seek to determine if that information could be provided.

Although EPA extended the comment deadline to February 18, 1980, it has to date, with the exception of its provision of more detailed information requests concerning asbestos in automotive disc brakes, made its broad information request no more specific. AIA/NA remains willing to work with the Agency in formulating reasonable policy, and specifically to explore alternatives for promoting safe use of asbestos. The continued breadth of EPA's information requests, however, limits the industry's ability to be truly responsive. AIA/NA is hopeful that through further consultation the Agency's information needs can be focused and its regulatory efforts redirected in a more positive and flexible vein.

In the meeting of November 21, AIA/NA representatives also noted the serious problems concerning the confidentiality of much of the information requested by EPA in the ANPRM. EPA is prohibited by statute from disclosing confidential information in its possession regardless of whether such information was obtained voluntarily or through coercive means. There are, however, significant exceptions to such broad disclosure bans, and many uncertainties regarding the scope of available protection.

The basic provision of TSCA on the confidentiality of business information is § 14(a), 15 U.S.C. § 2613(a), which provides that "any information reported to, or otherwise obtained by" EPA that consists of "trade secrets and commercial or financial information obtained from a person and

privileged or confidential" shall not be disclosed "by any officer or employee of the United States."

There are several important exceptions to the broad disclosure ban of TSCA § 14(a), some of which significantly limit the extent of protection the statute provides for confidential information. These exceptions permit, and in some circumstances appear to require, the disclosure of information that a company may believe, and EPA may agree, is confidential:

(1) Studies of the health and environmental effects of a chemical substance, the underlying data supporting such studies, and "any data reported to, or otherwise obtained by [EPA] from a health and safety study which relates to a chemical substance" are not protected from disclosure, except to the extent that they describe manufacturing processes. TSCA § 14(b), 15 U.S.C. § 2613(b).

(2) TSCA states that EPA "shall" make available to Congress any information in its possession upon the written request of a duly authorized committee. § 14(e), 15 U.S.C. § 2613(e).

(3) TSCA states that EPA "shall" disclose confidential data to its contractors when "necessary for the satisfactory performance" of their work. § 14(a)(2), 15 U.S.C. § 2613(a)(2).

(4) TSCA states that EPA "shall" disclose confidential information if "necessary to protect health or the environment against an unreasonable risk of injury." § 14(a)(3),

15 U.S.C. § 2613(a)(3). Neither the statute nor EPA regulations define when disclosure under this exception is "necessary" or what constitutes an "unreasonable risk."

(5) Confidential information "may be disclosed in any proceeding under [TSCA], except that disclosure in such a proceeding shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding." § 14(a)(4), 15 U.S.C. § 2613(a)(4).

(6) TSCA states that confidential data "shall" be disclosed to any officer or employee of the United States:

> (A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or
>
> (B) for specific law enforcement purposes. § 14(a)(1), 15 U.S.C. § 2613(a)(1).

This exception is particularly important in light of EPA's stated intent to share information with CPSC, 44 Fed. Reg. at 60056, and CPSC's adoption of a policy in favor of disclosure, 16 C.F.R. § 1015.15(b).

These exceptions that contemplate disclosure even of information both industry and EPA consider confidential pose serious problems for AIA/NA and its members. Data on the economics of the asbestos industry and the substitutability of other substances in asbestos-containing products, especially, is very sensitive and of great competitive value. AIA/NA members are thus reluctant to disclose such information under circumstances in which confidentiality is not completely assured.

CONCLUSION

AIA/NA shares EPA's concerns that current commercial and industrial use of asbestos be as safe as is logically, scientifically and economically feasible. It does not, and cannot however, share EPA's assumption that commercial and industrial use of asbestos per se presents an unreasonable risk to health and the environment. AIA/NA thus urges EPA to assess with great care the numerous factual issues relevant to any TSCA § 6 regulatory proceeding prior to issuing proposed regulations. We are convinced, that once properly assessed, that factual evidence will convince EPA, as it has already convinced AIA/NA and its members, that no TSCA § 6 rulemaking is warranted.

Respectfully submitted,

Edward W. Warren

Edward W. Warren
Timothy S. Hardy
David K. Perdue

Kirkland & Ellis
1776 K Street, N.W.
Washington, D.C. 20006

Counsel for the
Asbestos Information
Association/North America

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