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5 February 1980

Memorandum For: MEMBERS

Subject: Draft of AIA/NA's Comments on EPA's Advance Notice of Proposed Rulemaking (ANPRM); forwarding of

REF: A. AIA/NA Memorandum of November 21, 1979, Subj.: Information Regarding Response to CPSC's and EPA's Advance Notices of Proposed Rulemakings (ANPRMs) as Published in the Federal Register on October 17, 1979

B. AIA/NA Memorandum of December 7, 1979, Subj.: Same as above

By the above references, members were previously provided with the following work products as prepared by the Association's Special Counsel for Federal Regulatory Affairs (law firm of Kirkland & Ellis):

1. Suggested guidelines for use by AIA/NA members in preparation of any response that may be submitted to CPSC and/or EPA (K&E letter to Executive Director of November 21, 1979).

2. K & E memorandum of December 7, 1979 analyzing (1) the confidentiality protection provisions available at EPA and CPSC to AIA/NA and its members when they submit information to the agencies, either voluntarily or in response to legal compulsion; and (2) the scope of each agency's authority to gather information through legal compulsion.

3. Preliminary outlines for an Association response to CPSC and EPA's ANPRMs.

As previously mentioned in reference B, both CPSC and EPA extended the comment period on their ANPRMs from December 17, 1979 to February 18, 1980. Special Counsel has now prepared a detailed draft for consideration as an Association response to EPA's ANPRM which is enclosed. Your attention is invited to K & E's cover letter of February 4 which provides a brief of the material developed as well as to the draft itself. Comments or suggestions by members will be welcomed.

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February 4, 1980

Mr. B. J. Pigg
Executive Director
Asbestos Information Association/
North America
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Dear Bob:

Attached is a draft of AIA/NA's comments on EPA's ANPRM for your members' review.

The draft expands on the basic themes in our earlier December 1979 outline. That is, we stress the following arguments and evidence:

(1) EPA has assumed far too much in even reaching the tentative conclusion in its ANPRM that asbestos poses an unreasonable risk to health and the environment.

(2) Before EPA can propose any regulation under the Toxic Substances Control Act (TSCA), it must first find that a chemical poses an unreasonable risk, and such a determination can be made only after careful assessment of a wide range of risk and benefit evidence.

(3) With respect to asbestos, determination of unreasonable risk can be made only after detailed scrutiny of a number of factors, including variations in health effects among asbestos fibers and fiber sizes, the environmental fate of asbestos, the significant reductions that have already occurred in release of respirable fibers in asbestos use, the medical evidence indicating absence of any risk at low exposures, the adverse economic and health consequences of asbestos substitutes, and the adverse effects of TSCA regulation on small business and technological innovation.

(4) Even if EPA could demonstrate unreasonable risk in asbestos use, it is permitted to promulgate only the least burdensome regulations, and the three proposed options, each in effect a ban on asbestos use, are by no means such regulations.

(5) EPA must therefore thoroughly explore a wide variety of voluntary and regulatory alternatives to asbestos bans, each of which promises to be less burdensome and more efficacious in promoting safer asbestos use.

The draft thus urges EPA, before issuing any proposed rules under TSCA, to assess carefully the evidence, as we believe such an assessment will convince EPA that asbestos use does not pose unreasonable risks, or, at a minimum, that the three presently proposed bans are not the proper means of regulating asbestos.

The current draft of comments to CPSC makes much the same arguments and cites much the same evidence as the EPA comments. It focuses, however, on the different statutory framework (CPSA) under which that agency must act.

We hope to add a number of additional references and factual examples prior to the Executive Committee meeting next week. Prior to that time, we invite any suggestions or comments that you or your members may have.

Sincerely,

Ed

Edward W. Warren

EWW/gka

Attachment

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DRAFT 2/4/80

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

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February 18, 1980

TABLE OF CONTENTS

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 54 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; and (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 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 concentration or after short exposure periods." 44 Fed. Reg. 60062.

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), 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.

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" which would be necessary to "protect adequately" against any risk, even if it were possible to conclude that one or more present 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, 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 current uses of 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 would more effectively and less burdensomely promote safer asbestos use.

Accordingly, AIA/NA suggests the case for TSCA § 6 bans on use of asbestos in the American economy has not yet been made, and, after full examination of all relevant factors, cannot be made.

I. NO "REASONABLE BASIS" EXISTS 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 exposure levels 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.

An objective and forthright assessment of the risk and benefit evidence regarding asbestos precludes any such finding here.

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 ill-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. There is no risk so great that TSCA raises an irrebutable presumption that countervailing benefits do not outweigh it. 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;[1/] however, 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 is 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:

> [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 for purposes of section 6 than for a determination for purposes of section 4 or 5(g).

Legislative History, supra, at 422.

1/ 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 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.

Although TSCA does not explicitly define what risks are "unreasonable," the legislative history shows that such a determination involves 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 as follows:

> (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 can be made, and thus no remedies suggested or imposed, until such a detailed assemssment is completed.

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

The mandate of TSCA that a wide variety of risks and benefits be thoroughly assessed before any determination is made about "unreasonable risk" requires that thorough review of many factual issues concerning asbestos occur prior to any § 6 regulation. Specifically, that means that EPA must consider the following types of evidence before concluding that asbestos poses an unreasonable risk:

> (1) The relative disease-causing potential of different fiber sizes and types of asbestos.

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.[2/] 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, 60-64 (1979).

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 risks. 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 the effects.

(2) The amount of asbestos released to the environment naturally through wind and water erosion of asbestos-containing rock formations.

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

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2/ 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 ($Na_2O.Fe_2O_3.3FeO.8SiO_2.H_2O$).

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, the risk must therefore be recognized to be incremental to any natural risk that may exist and accordingly weighed against the incremental benefits of use.

(3) The amount of asbestos released to the ambient environment at each step and by each method of its mining, milling and processing and use.

Because it is generally accepted that only respirable fibers pose any risk to human health, careful consideration must be given to the extent to which such fibers are released into the environment because of 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, and disposal of asbestos to determine to what extent, if any, respirable fibers are released for each of the product lines for which asbestos is used at each step. Obviously, variations exist at each step for each product line in the extent which respirable fibers are released. 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) The 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 respirable fibers. 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) The number of persons that come in contact with asbestos-containing products and the number of disease-causing fibers to which they are exposed.

Given the dose/response correlations demonstrated by the medical evidence on asbestos, careful consideration must be given to the actual numbers of person 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 such 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 a risk. See, e.g., E.C. Hammond et al., "Asbestos Exposure, Cigarette Smoking and Death Rates," Annals N.Y. Acad. 330: 473-490 (1979). Each of these factors must be considered to determine the relevance of exposure to risk.

(6) The actual effect on human health of inhaling asbestos and the dosage at which health effects appear.

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 the health effects of asbestos exposure at concentrations many orders of magnitude less than those experienced by the general population. Even if one accepts the proposition that there is no level of asbestos exposure that is absolutely 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 terms both of peak and average exposures 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 at _____. 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) The actual effect on human health of ingesting asbestos and the dosage at which health effects appear.

In assessing the health effects of asbestos, clear distinctions must be drawn between the effects of inhalation and ingestion. Markedly different findings have been characteristic of the scientific work to date on the two routes of administration. Human ingestion epidemiology studies have been predominantly negative, and results of the occupational inhalation studies have been inconsistent in their findings of whether or not a correlation existed between asbestos inhalation and gastro-intestinal cancer or peritoneal mesothelioma. Accordingly, separate consideration of the health effects of ingestion and inhalation is necessary.3/

(8) The benefits to society of use of asbestos.

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

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

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.

(9) The economic efficiency cost of removing asbestos or replacing asbestos in any of the products in which it is now used.

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.

With asbestos, as with any chemical, ripple effects throughout the market for all products containing asbestos and their competitiors 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) The health effects of substitutes for asbestos.

As the ANPRM recognizes, 44 Fed. Reg. at 60063, 60065, many of the substitutes that have been suggested for asbestos themselves may pose risks to health and the environment. Congress did not intend that more risky 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.

Some such substitutes (such as polyvinyl chloride for 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 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 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 substistutes as to asbestos itself.

(11) The effect of the proposed regulations on the national economy, including sales, investment, profits, the viability of firms and employment in the asbestos industry.

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) The effect of the proposed regulations 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. As TSCA singles such firms out for special consideration, they must be assessed as part of any unreasonable risk determination.

(13) The effect of any 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 the unreasonable risk determination. The currently proposed three options, each tending toward complete bans on asbestos use, will discourage such innovation by removing any 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. The disincentive to find safer ways of employing asbestos is an important segment of the unreasonable risk calculation that weighs heavily against EPA's three current options.

* * *

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 that "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. There Is No Reasonable Basis for TSCA § 6 Regulation of Asbestos.

Applying the substantive standards of TSCA § 6 to asbestos, there is no reasonable basis on which the Administrator may conclude that commercial and industrial use of asbestos per se poses 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.[4/]

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

1. Official Reviews of the Scientific and Health Evidence on Asbestos Have Uniformly Found Little or No 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 three highly respected governmental organizations, and their conclusions are unanimous that there is no basis for considering asbestos manufacture and use dangerous to the general public. 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.[5/] The report finds:

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

5/ 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.

> 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. at 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, at 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).

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, at 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. at 60.

In short, the unanimous opinion of these respected authorities, all of whom have investigated the issue in depth, is that exposure to asbestos from the ambient environment poses no public health risk. For EPA to contradict the

findings of these authorities would take far more persuasive evidence than the ANPRM indicates is available.

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 (POGF). 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.

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

2. Although EPA's TSCA "Risk Assessment" Remains to Be Completed, Its Already Announced Risk Assessment for Ingested Asbestos Demonstrates that Conclusions of Unreasonable Risk Can Be Made Only through Arbitrary Use of Data and Questionable Methodology.

The unanimous opinions of previous official reviews of the scientific and health evidence on asbestos by themselves cast severe doubts on EPA's tentative conclusions 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 employed by the official review groups discussed above.

Although EPA has yet to finish or release for comment its assessment 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 collection 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 public health risk. Both human and animal ingestion evidence is predominantly negative. Although that negative evidence cannot absolutely rule out the possibility that carcinogenic risks may exist from asbestos ingestion at high levels, it clearly does not demonstrate the presence of risk at lower levels.

EPA's water criteria document ignores such ingestion evidence and uses inhalation epidemiology results to calculate a risk assessment. It is far from certain that the high level inhalation exposure in these occupational studies is relevant to determination of low level ingestion risks. 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 risk of gastro-intestinal cancer or peritoneal mesothelioma in occupational settings.6/ 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 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

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6/ See, e.g., Peto, et al., "A Mortality Study among Workers in an English Asbestos Factory," Brit. J. Ind. Med. 34: 169-73 (1977); Meurmann, 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 Manufacturers," Am. Rev. Resp. Disease 120: 345-354 (1979).

studies having more carefully estimated worker exposure data.7/

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 such risk. Similarly, EPA assumed exposure levels for the cohorts on which its assesment was based that are lower than historical records indicate was likely to be the case.

Because this preliminary EPA work on asbestos may indicate the type of reasoning 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. 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 and suggest that an objective assessment would convince EPA not to proceed with a § 6 TSCA proceeding.

7/ See Attachment I, pps._____, 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; Br. J. Ind. Med., 30:162-166 (1973); McDonald, et al., "Dust Exposure and Mortality in Chrysotile Mining, 1910-1975," (1977).

3. Human Exposure to Asbestos Fibers Is Already Quite 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 obscure definable exposures that could be measured in the workplace and in actual use of asbestos products. Numerous questions about this novel approach for determining the risk from a chemical substance limit the ability of AIA/NA to comment at this time on EPA's intentions.

As a naturally occurring mineral, asbestos has been present in the biosphere for millions of years. Although it is thereoretically 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 the substantial evidence of absence of any 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 exposure to asbestos human is subject to many uncertainties. Historical data is sparse, and what data do exist is based on measurement techniques that have been refined over the years. Translation of historical results to current measurement scales is difficult and quite imprecise. Moreover, even current measurement techniques are limited in their detection abilities and subject to significant uncertainties.

Despite these uncertainties, the existing data show differences of many orders of magnitude between the historical 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 demonstrate 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 250 million

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

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

***/ Asbestos 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 that minimize fiber release; manufacture of some products has been terminated; and numerous steps have been taken to reduce workplace emissions and exposure. 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 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 individual fibers would be released under any conditions. Asbestos-cement products, which comprise the single largest category of asbestos use, bind the fibers into the cement so that they are not released under normal use.

Asbestos is no longer marketed to be sprayed-on for insulation and fireproofing purposes. Nor is asbestos today marketed in spackling compounds, joint tapes, molded thermal insulation, insulating cements, modeling clay, artificial

emberizing materials in fireplaces, injectable drug filters, or general-use garments. Most recently, manufacturers of hair dryers have voluntarily ceased use of asbestos in those products.

Exposure to asbestos in the workplace is currently at levels dramatically lower than in the the past. Long before OSHA began establishing occupational 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 what EPA considers to be the "many population segments" who are "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 small subgroups. At a minimum, even if such small subgroups exist, there is no basis to conclude that use of asbestos is <u>per se</u> an unreasonable risk to the entire population.

4. <u>Asbestos Is of Great Benefit to Society.</u>

Arrayed against minimal risks from current asbestos use are the manifold societal benefits of asbestos. 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 its 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. Some 3,000 different products use asbestos in some amount, a fact that attests to its value. To mention but a few applications, it serves as a strengthening ingredient in cement and plastics, provides heat insulation and sound absorption in many applications, 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 to asbestos. 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, several organic fibers nearly equivalent to asbestos in strength and acid resistance break down in the high temperature 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 should not 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 continue to hold 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 ANY 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 manufactured 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 overburden 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 constitutes flagrant disregard of 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 in effect presumes the existence of an unreasonable risk and therefore impermissibly reverses the burden of proof. A chemical substance is presumptively safe until the Administrator establishes that it poses an unreasonable risk. He cannot shift the burden of justification to the manufacturers.

B. EPA's Proposed Regulatory Options Are Clearly 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 possible 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 records of production;

(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.

As 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 necessary 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, voluntary efforts of the industry itself in the past and planned, and marketplace economics that are promoting safer asbestos use.

1. Given the Extensive Regulation of Asbestos under Statutes other than TSCA, Regulation under This Statute Is Not Justified.

TSCA contains explicit provisions deferring to the regulatory authority provided by 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.8/

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

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8/ This injunction is repeated in TSCA § 9(b), 15 U.S.C. § 2608(b) as to action under any section of TSCA, not just § 6(a). Moreover, TSCA § 9(b) specifically directs that "[the] Administrator shall coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator."

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).

EPA already regulates emissions of asbestos 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.R.F. § 61.22. 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 1983 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, 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 preemptorily 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.

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 risk of 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 achieving such a reduction. Obviously, should any reduction be mandated by OSHA, there will be workplaces where actions will have to be taken by employers that will reduce the

release of respirable fibers. Such actions will both reduce worker exposure and release to the general environment.

OSHA regulatory efforts thus serve as an example of Federal regulatory initiatives already on the books and in the works that will require safer use of asbestos in the future. 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 if they wish to continue marketing them.

As a result, great market incentives already exist for the asbestos indutry 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) have jointly presented to OSHA a Recommended Standard for 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 provide adequate health protection for workers without imposing impracticable and unnecessary regulation. It imposes the usual fixed-site requirements, presumptively applicable to construction and other non-fixed workplaces, but provides for partial and complete exemptions 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 most 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. It represents industry's commitment to reduce risk in a reasonable, responsible manner and demonstrates the lack of any basis for the expansive remedies being advanced by EPA in its ANPRM. Should OSHA adopt such a Standard, substantial further progress would be achieved in promoting safer asbestos use.

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.9/

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

Even if EPA is able to conclude that asbestos poses an unreasonable risk because of gaps in the regulatory framework for asbestos present and future, and even if those gaps are 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 a stringent step as a total ban on asbestos.

The statute's list of possible alternatives suggests the range of less burdensome regulations that must be ruled

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9/ Such OSHA-directed activities, are however, are not the only activities 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 advise concerning its proper handling. For instance, one major producer has terminated all sales of asbestos to distributors and now sells asbestos only directly to asbestos-containing product manufacturers.

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

out prior to concluding that only a ban will adequately protect against unreasonable risk. EPA can ban particular uses of a substance or limit the amount of asbestos for such use; it can mandate labelling which includes instructions on proper use for any particular product; it can regulate the manner or method of use of any particular product (much as AIA/NA's proposed Model Standard would); it can regulate disposal of the product. Any of these requirements can be limited in geographic application. TSCA § 6(c).

The intention of Congress was not that EPA jump quickly to the conclusion that a substance should be banned, but rather that any regulations be closely tailored to the particular facts of particular uses of a chemical substance. The clear intention was for EPA to create incentives for safer use of chemicals, not to ban them.

* * *

AIA/NA urges EPA, should it intend to proceed with its intentions 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. Some such possibilities are suggested above in connection with other Federal regulatory initiatives and marketplace and voluntary industry activities. Rather than concentrating on some narrow definition of "essential" uses that will be permitted after a ban, EPA should focus on practical steps that will encourage safer asbestos use.

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 logically, scientifically, and economically justifiable. We suggest that rather than expending its considerable administrative energies building a case against any use 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 EPA, and other government agencies, 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 18, 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 17, 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. Although AIA/NA remains willing to provide information that will be helpful to the Agency in formulating reasonable policy, the continued breadth of the information requests limits the industry's ability to be truly responsive.

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 very reluctant to disclose such information under any circumstances in which confidentiality is not completely assured.

In light of both the voluminous character of EPA's ANPRM request and the serious issues surrounding maintenance of confidentiality of such information, therefore, it is clear to AIA/NA and its members that further discussions with EPA are necessary prior to industry ability to respond to some of the ANPRM information requests.

CONCLUSION

AIA/NA shares EPA's concerns that commercial and industrial use of asbestos be as safe as is logically, scientifically and economically feasible. It does not, and cannot

based on the best available evidence, however, share EPA's assumption that commercial and industrial use of asbestos 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,

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