ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 763

[OPTS-62036G; FRL-3476-2]

Asbestos; Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is issuing this final rule under section 6 of the Toxics Substances Control Act (TSCA) to prohibit, at staggered intervals, the future manufacture, importation, processing, and distribution in commerce of asbestos in almost all products, as identified in the rule. EPA is issuing this rule to reduce the unreasonable risks presented to human health by exposure to asbestos during activities involving these products. The rule requires that asbestos-containing products that are subject to the bans be labeled to promote compliance with and enforcement of the rule. The rule provides that exemptions from the rule's bans on manufacture, importation, processing, and distribution in commerce may be granted by EPA in very limited circumstances.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on July 26, 1989. The effective date of this rule is August 25, 1989, except for the information collection requirements of 40 CFR 763.173, 763.178, and 763.179. These information collection requirements have not been approved by the Office of Management and Budget (OMB) and are not effective until OMB has approved them. EPA will issue a notice in the future establishing an effective date for the information collection requirements.


SUPPLEMENTARY INFORMATION: The preamble accompanying this final rule is divided into the following Units:

I. Authority
II. TSCA Actions to Date
III. Provisions of the Rule
   A. General Provisions
   B. Manufacture, Importation, and Processing Bans
   C. Bans on Distribution in Commerce
   D. Labeling

E. Exemption Application Procedures
F. Military Exemptions
G. Recordkeeping

IV. Summary of Analysis Supporting this Final Rule
V. Regulatory Assessment
   A. Health Effects and Magnitude of Exposure to Asbestos
   B. Environmental Effects
   C. Asbestos Substitutes
   D. Economic Effects of the Rule
   E. Other Options Considered
   F. Summary of Individual Product Categories

VI. Other EPA Statutes
VII. Analysis under Section 9(a) of TSCA
   A. Other Authorities Affecting Asbestos
   B. EPA's Determination Under Section 9(a) of TSCA
VIII. Enforcement
IX. Confidentiality
X. Rulemaking Record
XI. References
XII. Regulatory Assessment Requirements
   A. Executive Order 12291
   B. Regulatory Flexibility Act
   C. Paperwork Reduction Act

This rule prohibits the manufacture, import, processing, and distribution in commerce of certain asbestos-containing products. The rule also requires that asbestos-containing products that are subject to this rule be labeled to facilitate compliance with and enforcement of the rule.

Public reporting burden for this collection of information is estimated to average less than 2 hours annually per firm over the 3-year period reviewed for the analysis of regulatory burden. This burden estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This estimate of annual burden is a relatively low figure because of the small number of firms affected by the regulatory actions taken during the period reviewed for the analysis of regulatory burden. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503; Attention: Desk Officer for EPA.

I. Authority

Section 6(a) of TSCA authorizes EPA to impose certain regulatory requirements on activities involving a chemical substance or mixture if EPA finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, presents or will present an unreasonable risk of injury to human health or the environment. Section 6(a)(1) authorizes EPA to prohibit or limit the manufacture, processing, or distribution in commerce of substances or mixtures if EPA finds that these activities pose an unreasonable risk. Section 6(a)(2) authorizes EPA to prohibit or limit such activities for a particular use of such substances or mixtures. Section 6(a)(3) authorizes EPA to require labels for such substances or mixtures. Sections 6 and 8(a) authorize EPA to require the maintenance of records related to enforcement of EPA actions under section 6. These sections of TSCA provide EPA the authority to issue this rule.

II. TSCA Actions to Date

EPA issued an Advance Notice of Proposed Rulemaking in the Federal Register of October 17, 1979 (44 FR 60051), announcing its intent to explore the use of section 6 of TSCA to reduce the risk to human health posed by exposure to asbestos. EPA then issued a reporting rule under section 8(a) of TSCA in the Federal Register of July 30, 1982 (47 FR 33207-40 CFR 763.60), to collect information on industrial and commercial uses of asbestos. Information collected under that rule, as well as analyses developed by EPA and other organizations, were evaluated and used to support a proposed rule, published in the Federal Register of January 29, 1986 (51 FR 3738).

In the proposed rule EPA found that exposure to asbestos poses an unreasonable risk to human health and discussed regulatory options for prohibiting or restricting the mining and importation of bulk asbestos and the manufacturing, importation, and processing of asbestos-containing products as means of reducing the risk. The following options were discussed in the proposed rule:

1. Two options involving bans of some products soon after promulgation of the final rule and a phase out of others over 10 years by means of a permit system for asbestos use.
2. A 2-stage ban, with the first ban, on asbestos construction products and clothing, to begin soon after promulgation of the final rule and the second ban, on friction products, to begin in 5 years, and after promulgation of the final rule, the collection of additional data on other products.
3. A 3-stage ban on all asbestos products to begin soon after the
proclamation of the final rule, and 5 years and 10 years after promulgation.

Requiring labeling of asbestos-containing products was also discussed. EPA received over 200 comments in response to the proposed rule.

Prior to issuing the proposal, EPA received and granted two TSCA section 21 petitions (45 U.S.C. 2620). Under section 21 of TSCA, a person may petition EPA to initiate a proceeding for the issuance of a rule under various sections of TSCA. One petition requested the prohibition of the future use of asbestos in asbestos-cement pipe; this petition was granted in the Federal Register of October 18, 1979 (44 FR 60153). The other petition requested the prohibition of the future use of asbestos in motor vehicle brakes; this petition was granted in the Federal Register of December 18, 1984 (49 FR 49311). In granting these petitions, EPA stated that it would, as part of the rulemaking proceeding and the final rule, consider including prohibitions of the future use of asbestos in asbestos-cement pipe and in motor vehicle brakes. Both uses are prohibited by this final rule.

Pursuant to section 6(c)(2) of TSCA, EPA also provided interested parties opportunities to participate in a legislative hearing on the proposed rule in July 1986, and in extensive cross-examination of EPA personnel and contractors on factual issues related to the rule in October 1986.

Since the end of cross-examination in October 1986, EPA has updated the data collections and regulatory analyses used to support the findings on which this rule is based. EPA believes that adequate data and analyses existed in the rulemaking record for the proposal to support the options discussed therein. The data collections and analyses were updated due to the passage of time since the publication of the proposal and in response to specific public comments that the data base supporting the proposed rule, gathered largely in 1982, was outdated.

EPA has gathered updated data relating to: (1) Asbestos consumption, (2) manufacturing, import, and processing volumes of asbestos-containing products, (3) trends in the development of non-asbestos substitutes, (4) costs of capital conversion to the production of non-asbestos products, (5) production, processing, use, and disposal practices for asbestos-containing products, and (6) occupational and non-occupational release and exposure from the manufacture, processing, installation, use, repair, removal, and disposal of asbestos-containing products. These data were derived from, among other sources, the 1987 EPA Asbestos Exposure survey, the 1987 EPA Asbestos Market survey, and 1987 Occupational Health and Safety Administration (OSHA) compliance data. EPA has also modified and updated its Asbestos Regulatory Cost Model (ARCM), Health Benefits Model, and asbestos exposure models which were used to evaluate the costs and benefits of various regulatory options. Additionally, EPA has furthered its analysis of the availability and possible hazards posed by asbestos substitutes.

These updated data and analyses were reflected in documents released for public comment in notices published in the Federal Register of April 1, 1988 (53 FR 10549), and May 4, 1988 (53 FR 15867); EPA received over 40 public comments in response to these notices. In addition, EPA allowed further cross-examination of EPA personnel and contractors on factual issues related to the updated analytical data base in September 1988. The materials released for public comment contain the technical basis for the actions taken in this final rule. EPA afforded the opportunity for public comment on the updated documents and for further cross-examination as an exercise of its discretion and as a means of ensuring that any remaining disputed issues of material fact in the updated data and analyses could be identified and resolved before promulgation of this final rule. EPA has reviewed the comments received and the testimony elicited and has updated the record accordingly.

Pursuant to its procedural rules at 40 CFR 750.4(b), EPA also announced to interested parties in the Federal Register of September 16, 1988 (53 FR 36227), the opportunity to provide EPA with reply comments relating to the rulemaking proceeding. EPA received reply comments from three commenters. The record which serves as the basis for the actions taken in this rule consists of over 45,000 pages of analyses, comments, testimony, correspondence, and other materials. The record for this rule also incorporates by reference the extensive record developed by OSHA in its rulemaking to lower its Permissible Exposure Level (PEL) for asbestos, published in the Federal Register of June 20, 1986 (51 FR 22612). EPA has fully considered these materials in developing this final rule. In addition, all significant testimony or public comments made on the proposed rule, in conjunction with the legislative hearing, cross-examination hearing, or reply comments, or in response to the materials announced in the April and May 1988 Federal Register notices, cited above, were considered in the development of the final rule. EPA's responses to all significant comments are found either in this preamble or in a separate Response to Comments document that is available in the Public Docket (Ref. 40).

Based on the numerous detailed analyses performed by EPA in support of this rule and after careful consideration of the extensive public comments received, EPA has concluded that the continued commercial manufacture, import, processing, and distribution in commerce of the products identified in this rule poses an unreasonable risk of injury to human health under section 6 of TSCA.

III. Provisions of the Rule

A. General Provisions

Consistent with an option described in the proposal, this rule imposes a 3-stage ban on the manufacture, importation, processing, and distribution in commerce of various asbestos-containing products. The rule also contains a requirement that products subject to a manufacture, importation, and processing ban, but not yet subject to a ban on distribution in commerce, be labeled in the manner described at § 763.171. In addition, the rule includes procedures for requesting an exemption from the rule's provisions.

The effective dates of the various bans are as follows (with exceptions as noted in Unit III.B of this preamble for some asbestos friction products):

Manufacture, Import, and Processing Ban:

Stage 1—August 25, 1990
Stage 2—August 25, 1992
Stage 3—August 25, 1994

Distribution in Commerce Ban:

Stage 1—August 25, 1990
Stage 2—August 25, 1992
Stage 3—August 25, 1994

B. Manufacture, Importation, and Processing Bans

As of the dates indicated below, the manufacture, importation, and processing of all asbestos-containing products within the categories listed must cease as follows for each stage:

Stage 1: Manufacture, Importation, and Processing of the Following Products Must Cease by August 25, 1990:
- Flooring Felt
- Roofing Felt
- Pipeline Wrap
- Asbestos/Glass (A/C) Flat Sheet
- A/C Corrugated Sheet
- Vinyl/Asbestos Floor Tile
- Asbestos Clothing
Pursuant to section 12(a)(2), EPA finds that the manufacture or processing for export of the asbestos-containing products that are subject to this rule will present an unreasonable risk of injury to human health. Therefore, the manufacture and processing of the asbestos-containing products for export is not exempted from this rule under section 12(a)(1), and is subject to this rule's bans on manufacture, processing, and distribution in commerce. Much of the life cycle and a significant portion of risk posed by export products occurs in the United States. The most significant source of exposure that could be quantified by EPA for this rule is primary and secondary manufacturing. During primary manufacture, asbestos fibers are introduced into the production process. During secondary manufacture, an asbestos fiber-containing component is used. EPA has concluded that these activities cause significant occupational and non-occupational exposures to workers and their families, populations surrounding plant sites, and the general population. In light of the high individual risk caused by exposure to asbestos, EPA has concluded that exposures due to manufacturing or processing of these asbestos-containing products for export pose an unreasonable risk of injury to human health in the United States.

EPA has not found that asbestos-containing products imported into the United States for the sole purpose of shipment to another country pose an unreasonable risk. Therefore, such activities are not subject to this rule's bans. However, for the reasons described above, imported products that are repackaged or otherwise processed in the United States before shipment to another country are subject to the rule's bans.

The proposal would have exempted the import of small quantities of otherwise banned asbestos-containing products for personal use from the rule's bans. EPA received comments indicating that many new automobiles are imported by individuals. However, EPA is uncertain about the extent of any risk reduction that would be achieved by a ban on these activities. Therefore, the final rule's ban on importation excludes the act of bringing small quantities of articles into the United States for normal personal or business activities (not including distribution of asbestos-containing products in commerce) involving the use of a banned product either alone or as a component or part of a larger object. Similarly, the definition of import excludes activities such as the movement of automobiles with asbestos-containing products as integral parts of the auto, back and forth across the United States border during the normal course of personal or business activities. The final rule bans the import of products that are purchased or otherwise acquired outside of the United States for the sole purpose of resale.

For example, after the effective date of the ban on OEM brake pads, a 1994 or later model year automobile containing banned asbestos-containing parts cannot be purchased in Canada or another country and be transported by a person to the United States for resale. However, the rule does not ban the import by a person of such a vehicle for personal use in the United States. For purposes of enforcing this provision, EPA will consider a vehicle to be imported for personal use if the person importing the vehicle imports no more than one vehicle containing banned products every 5 years. If a person imports a vehicle repeatedly, EPA will presume that the activity is subject to the rule's bans. Other activities that are excluded from the definition of import include driving across the U.S. border in a 1994 or later model year automobile containing banned products during the course of transacting business or for recreational purposes, or purchasing a used (i.e., pre-1994 model year) vehicle containing asbestos brakes in another country and transporting it into the United States.

C. Bans on Distribution in Commerce

Available evidence shows that the release of asbestos fibers occurs not only in the manufacture and processing of asbestos products, but also in their use and maintenance. EPA proposed to ban activities involving asbestos products because of this life cycle risk. The proposed ban also implicitly would have prohibited the eventual distribution of these products in commerce because persons would not be permitted to manufacture, import, or process asbestos products.

Consistent with the intent of the proposal, this final rule explicitly prohibits the distribution in commerce of asbestos products within the specified timeframe after manufacture, importation, and processing bans for the products become effective. The time periods for distribution in commerce were established to afford affected parties sufficient time to sell existing stocks and therefore limit the likely economic impact of the ban. This was done after balancing the likely risks presented by continued use of asbestos products with the economic impact of an outright ban on this activity.

As stated above, this rule bans the distribution in commerce of asbestos products...
products after manufacture, importation, and processing bans for the products become effective. The ban on distribution in commerce for products subject to the Stage 1 manufacture, importation, and processing ban will become effective on August 25, 1992. For Stage 2 products, the ban on distribution in commerce will become effective on August 25, 1994. For Stage 3 products, the ban on distribution in commerce will become effective on August 25, 1997. Remaining "stock-on-hand" of an affected product must be disposed of within 8 months of the effective date of the ban on distribution in commerce. Remaining stocks include all units of the product in the possession or control of the person subject to the distribution in commerce ban. Disposal must be by means that are in compliance with applicable local, State, and Federal restrictions.

The rule's distribution in commerce ban does not cover all actions taken with respect to asbestos-containing products. For purposes of the rule, the term "distribution in commerce" does not cover end use activities, for example, sale, resale, holding, or delivery, with respect to asbestos products by persons who use the product after it is manufactured, imported, or processed. For example, the term "distribution in commerce" does not include the resale of homes or motor vehicles that contain asbestos-containing parts or products or the installation of asbestos-containing brake pads in a person's automobile after the distribution in commerce of such brake pads is banned. (However, it is a violation of this rule for a person to engage in selling brake pads to anyone.) This provision also does not cover the disposal of asbestos-containing products.

EPA recognizes that some asbestos-containing products which are excluded from the ban may be very similar in form to asbestos-containing products that are banned. For example, this rule's bans do not cover the manufacture, importation, processing, and distribution in commerce of high-grade electrical paper, a product which may be similar in some cases to millboard or other asbestos paper products. Persons might try to manufacture or distribute the excluded products for uses that are banned. Such activities would violate this rule's bans because this conversion of use will be interpreted by EPA to be processing or distribution in commerce of the banned products. The definitions of processing and distribution in commerce are broad and will be interpreted by EPA to cover activities which involve the conversion of excluded asbestos-containing products in this manner.

D. Labeling

Products that are subject to a current or future ban on manufacturing, processing, import, or distribution in commerce must be labeled as follows:

Notice—This product contains ASBESTOS. The U.S. Environmental Protection Agency has banned the distribution in U.S. commerce of this product under section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) as of [insert the effective date of ban on distribution in commerce]. Distribution of this product in commerce after this date and unintentionally removing or tampering with this label are violations of Federal law.

The purpose of this labeling requirement is to facilitate efforts by manufacturers, importers, processors, and distributors to comply with this rule's bans and EPA's efforts to enforce the rule. Labels must be applied by manufacturers, importers, and processors to specified products produced after the dates listed below, and to all stock-on-hand of these products in their possession or control at that time. The effective dates of the labeling requirement are as follows:

<table>
<thead>
<tr>
<th>Products</th>
<th>Date by which products must be labeled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products banned in Stage 1</td>
<td>Aug. 27, 1990</td>
</tr>
<tr>
<td>Products banned in Stage 2, plus aftermarket disc and drum brake products</td>
<td>Aug. 25, 1992</td>
</tr>
<tr>
<td>All other products banned in Stage 3</td>
<td>Aug. 25, 1995</td>
</tr>
</tbody>
</table>

Therefore, a manufacturer, importer, or processor of a product banned in Stage 2 must label all stock-on-hand of the product as of August 25, 1992, as well as any further stock of that product manufactured, imported, or processed after that date. Products must be labeled at the times indicated to ensure that a substantial portion of the stock in the chain of distribution after the effective date of the manufacture, importation, or processing bans are labeled to facilitate enforcement and compliance efforts. Asbestos-containing brake pads, drum brake linings, and brake blocks must be labeled earlier than other products because of the relatively long potential shelf life of brake products and to facilitate compliance with the two-part ban of asbestos friction products.

For purposes of this labeling requirement, "stock-on-hand" means all units of the product in the possession or control of the manufacturer, importer, or processor. This includes products stored by a separate commercial entity, but still within the direction or control of the manufacturer, importer, or processor.

Manufacturers, Importers, and processors must insert in the label they apply to their products the effective date of the ban on distribution in commerce for that product. Labels must be displayed prominently on product packaging, as described below. Labels must be either printed on product packaging or in the form of either a sticker or tag made of plastic, paper, metal, or another durable material and securely adhered or attached to product packaging. Labels must be securely attached so that they cannot be removed without being defaced or destroyed. They must be written in English in block letters and numerals. Text in other languages is permitted in addition to the English language text. The color of the text must contract with the background of the label. Labels must be applied in a visible location on the exterior of the immediate packaging in which a product is distributed in commerce. However, if the product packaging has no visible surface larger than 5 square inches, the person subject to the labeling requirement must either securely attach a tag containing the required language to the product packaging or must label the next outer container in which the smaller wrapped products are packed for storage, transport, or distribution.

Labels must be applied directly onto products which are stored, shipped, or distributed in commerce without packaging or wrapping. However, if a product is otherwise properly labeled and is removed from the properly labeled packaging only when distributed to the end user, the product does not need to also be labeled directly.

Compliance with the labeling requirements of this rule does not fulfill labeling requirements established under the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261).

E. Exemption Application Procedures

EPA believes that exemptions from the rule's bans on future manufacture, importation, processing, and distribution in commerce will fall into two different categories, those involving existing asbestos-containing products or existing uses of asbestos in products and those involving new uses of asbestos in products or new asbestos products. This rule provides two approaches to obtaining an exemption from these bans.

EPA has already determined that activities involving most asbestos-containing products present unreasonable risks of injury to human health. Therefore, procedures in the final rule for evaluating exemption
applications involving manufacture, importation, processing, and distribution in commerce of asbestos-containing products in categories identified in this rule or uses of asbestos in those products place the burden upon the applicant to show that he or she has made demonstrable good faith efforts to develop substitutes for its product and that granting the exemption will not result in an unreasonable risk of injury to human health.

EPA is uncertain about the facts and circumstances that will attend any potential exemption involving new asbestos-containing products or new uses of asbestos. In view of this uncertainty about these products or uses, EPA believes that it is appropriate to employ a different process for reviewing exemptions for new asbestos-containing products or uses. Thus, requests for exemption for new products or uses will be treated as a petition to amend this rule pursuant to section 21 of TSCA. Such petitions should comply with the procedures of section 21 and contain, at a minimum, the type of information set forth in this final rule for exemption applications.

The remainder of this Unit discusses general exemption procedures for applications involving products identified in the rule. Exemptions for military uses are discussed in Unit III.F of this preamble.

1. Information requirements. This provision allows that EPA will exempt products from the rule's bans if an applicant can show that the activity described in the application will not result in an unreasonable risk of injury to human health and that the applicant has made demonstrable good faith efforts to develop substitutes that do not pose an unreasonable risk. EPA will balance the various information received in an exemption application in determining whether the applicant has met the criteria for granting an exemption. Applicants for exemptions must submit to EPA data or discussions addressing each of the following issues regarding their product:

a. Data demonstrating the exposure level over the life cycle of the product that is the subject of the application.

b. Data concerning:

i. The extent to which non-asbestos substitutes for the product that is the subject of the application fall significantly short in performance under necessary product standards or requirements, including laws or ordinances mandating product safety standards.

ii. The costs of non-asbestos substitutes relative to the costs of the asbestos-containing product and, in the case in which the product is a component of another product, the effect on the cost of the end use product of using the substitute component.

iii. The extent to which the product or uses serve a high-valued use.

iv. Evidence of demonstrable good faith attempts by the applicant to develop and use a non-asbestos substance or product which may be substituted for the asbestos-containing product or the asbestos in the product or use that is the subject of the application.

v. An explanation of why the continued manufacture, importation, processing, distribution in commerce, and use, as applicable, of the product will not present an unreasonable risk of injury to human health.

Exemption applications which do not contain these items of information and the other information required under § 763.173(d) will be considered incomplete and will be returned to the applicant without further action by EPA. Exemption applications that are returned as incomplete can be resubmitted with the additional required information. The resubmitted application will carry the resubmittal date as the date of receipt.

2. Procedures for submitting exemption applications. Exemption applications cannot be submitted for products subject to the following bans before the dates indicated, as follows:

- **Manufacture, Importation, and Processing**
  - Stage 1—August 25, 1989
  - Stage 2—February 28, 1992
  - Stage 3—February 27, 1995

- **Distribution in Commerce**
  - Stage 1—February 26, 1990
  - Stage 2—February 28, 1993
  - Stage 3—February 26, 1996

EPA believes that, because of the rapid development of asbestos substitutes, decisions on exemption applications made before these dates would be premature. However, EPA will consider, if appropriate, arguments made for an exemption from a ban on distribution in commerce for a product at the time and applicant submits an application for an exemption from a manufacture, importation, or processing ban.


3. EPA review and decision. EPA's review periods for exemption applications for existing products will vary, depending on the timeliness of their submission and the adequacy of the data that is submitted. If a complete exemption application is submitted more than 1 year before the effective date of the applicable ban (or 9 months before the effective date of the ban in the case of Stage 1 manufacture, importation, and processing bans), EPA will complete its review of the application and issue its decision prior to the effective date of the ban. If EPA fails to meet this deadline, the applicant will be granted an automatic extension of up to 1 year, or until EPA decides whether to approve the application, during which the applicant can continue the activity that is the subject of the application. EPA will render its decision during the extension period.

For example, if a ban becomes effective on September 1, 1994, an exemption application for a product subject to that ban cannot be submitted to EPA before March 1, 1993. To ensure a decision by EPA on an application before the ban's effective date, the applicant must submit the application to EPA before September 1, 1993.

If an exemption application is submitted less than 1 year before the effective date of the applicable ban or after the ban, EPA will issue a decision as soon as is feasible. The submitter of this "late" application must cease the banned activity as of the effective date of the ban unless EPA grants the exemption.

For example, if a manufacture or importation ban becomes effective on September 1, 1994, and an application for a product subject to the ban is received by EPA on April 1, 1994, EPA will render its decision on the application as soon as is feasible. If EPA has not rendered a decision granting the exemption by September 1, 1994, the applicant must cease manufacture or importation of the product.

If EPA denies an exemption application before the effective date of a ban, the applicant must cease the activity as of the effective date of the ban, or within 30 days after receipt of the denial if it is issued less than 30 days before the effective date of the ban. If a denial is rendered during an extension period, the applicant must cease the banned activity within 30 days after the issuance of the denial.

For example, if the effective date of a ban is November 1, 1994, and EPA renders a denial on June 1, 1994, the activity must cease by November 1, 1994. If the effective date of the ban is July 1, 1994, and EPA renders a denial on June 15, 1994, the activity must cease by July 15, 1994. Further, if an extension period runs until December 1, 1994, and
EPA issues a denial on June 1, 1994, the activity must cease by July 1, 1994.

The time frames discussed in the preceding paragraphs for EPA’s review of exemption applications do not apply to applications pertaining to new uses of asbestos. Applications for new uses will be subject to the deadlines for EPA review and decision specified in section 21 of TSCA.

Upon receipt of a complete exemption application, EPA will issue a notice in the Federal Register announcing receipt of the application and inviting comments. EPA will consider any comments received in determining whether to grant or deny the application. EPA may request further information from the applicant to assist in determining whether the exemption application meets the rule’s criteria.

When denying an application, EPA will send the applicant a copy of the denial via registered mail. This written denial is a final Agency action for purposes of judicial review. If EPA proposes to grant an application, EPA will issue a notice in the Federal Register requesting comments on its proposal or the submission of supplementary information. EPA will consider any comments received when preparing its final decision. A final grant of an exemption application will be issued by Federal Register notice and, likewise, is a final Agency action for purposes of judicial review.

Exemption renewal applications cannot be submitted earlier than 15 months before the end of the exemption period, unless so allowed in the notice granting the original exemption. Notices received between 15 months and 1 year before the end of the exemption period will be granted or denied before the end of the exemption period. Renewal applications received thereafter will be granted or denied by EPA as soon as is feasible. The activity that is the subject of the renewal application may not continue beyond the original exemption period unless EPA grants the renewal.

4. Factors considered in evaluating exemption applications. EPA has concluded that the future manufacture, importation, processing, and distribution in commerce of most asbestos-containing products results in an unreasonable risk of injury to human health. The rule seeks the elimination of these risks by banning the future use of asbestos in many products in U.S. commerce. Therefore, exemptions will be granted by EPA only in those instances where a clear showing is made by an applicant that the activity described in the exemption application meets the criteria set out in this preamble and rule. The criteria require the applicant to demonstrate that the activity described in the application will not result in an unreasonable risk of injury to human health and that the applicant has made demonstrable good faith efforts to develop substitutes that do not pose an unreasonable risk. EPA believes that these criteria are consistent with the findings in this rule, yet provide applicants an opportunity to demonstrate that they are entitled to an exemption in certain non-routine circumstances.

EPA’s evaluation of exemption applications will involve a balancing of a number of factors which go into determining whether the exemption criteria have been met. These factors include the availability of suitable substitutes and the feasibility of substituting for asbestos in the product, asbestos exposure risks posed by the continued use of the asbestos product, whether the asbestos use is a high-valued use, and the efforts of the applicant to develop substitutes. EPA will grant an exemption only after carefully balancing all the factors presented in an application. The paragraphs that follow provide guidelines which EPA will follow in applying the above-stated exemption criteria in making decisions on exemption applications.

Generally, EPA does not intend to grant exemptions to applicants who are merely seeking to avoid their share of the costs imposed by the actions taken in this rule. Also, EPA does not intend to grant exemptions that would indefinitely extend the use of asbestos in products. EPA has concluded that exposure to asbestos during the life cycles of the products that are subject to this rule poses an unreasonable risk of injury to human health. Therefore, EPA does not intend to grant exemption applications that are based solely on the rationale that relatively low levels of exposure exist, because exposure levels may be only one of several factors balanced in determining whether the use described in an exemption application would pose an unreasonable risk. EPA has also found that suitable non-asbestos substitutes exist for most uses of asbestos.

Therefore, if a non-asbestos substitute exists for a product and is in use by one or more of the producers in the market for the product, EPA does not intend to grant an exemption to one producer based on the cost or difficulty of modifying its production process or of setting up a supply system for obtaining the substitute. EPA has, in establishing the effective dates for the bans, afforded sufficient time to allow producers and distributors to develop and implement transition plans. Therefore, EPA does not intend to grant an exemption because an applicant has yet to purchase the necessary equipment to set up systems of supply for substitutes, or to make other transition plans.

Also, EPA does not intend to grant or renew an exemption if the applicant has failed to make a tangible, documented effort to identify, develop, and use suitable non-asbestos substitutes for the product which is the subject of the exemption application.

In addition, EPA does not intend to grant an exemption merely because using a substitute is somewhat more costly in the production of a product than using asbestos. However, EPA may grant an exemption for an existing asbestos product if, in addition to other factors, a non-asbestos substitute for the product has not been developed or adapted, despite the best efforts of the requestor, or if available substitutes are unreasonably expensive to purchasers.

F Military Exemptions

EPA and the Department of Defense will develop a Memorandum of Understanding establishing mechanisms for dealing with asbestos-containing products used for military purposes. Along with the criteria for consideration of general exemptions described in the preceding Unit, consideration will be given to the military nature of such uses and the mission of the Department of Defense. EPA and the Department of Defense will jointly develop procedures for exemptions from the rule for asbestos-containing products used for military purposes.

G. Recordkeeping

To ensure compliance with this rule, and to assist enforcement efforts, EPA is requiring under the authority of sections 6 and 8 of TSCA that all manufacturers, importers, and processors of certain asbestos-containing products keep records. Section 8(a) provides broad authority for EPA to require manufacturers, importers, and processors to keep records. Section 8(a) exempts small businesses from reporting in certain cases. However, EPA may require manufacturers, importers, and processors of a substance subject to a rule under section 6 of TSCA to maintain records. Since asbestos is
already subject to rules under section 6 and is also subject to this one, the small business exemption of section 8(a) would not apply. EPA believes that these recordkeeping requirements represent very little burden and are necessary for the enforcement of this rule.

EPA also has authority under section 6 to require recordkeeping and reporting related to the other regulatory requirements imposed by EPA under section 6. In this case, section 6 provides the authority to apply the recordkeeping and reporting requirements to distributors of asbestos-containing products who are not also manufacturers, importers, or processors of these products subject to section 8(a). EPA has used this section 6 recordkeeping and reporting authority previously in its polychlorinated biphenyl and asbestos rules promulgated under TSCA section 6 in 40 CFR Parts 761 and 763.

1. Inventory

As of the effective date of a ban on manufacture, importation, or processing, all manufacturers, importers, and processors of products subject to the ban must take an inventory of their stock-on-hand of the banned products. This inventory must consist of a count of the number of product units in stock, in terms of the unit measure or form in which the product is used or sold, and the location of current stock. “Stock-on-hand” covers all product owned or controlled by the manufacturer, importer, or processor. This includes stock in a storage location owned by the person, as well as stock in storage locations owned by others if the stock remains within the direction or control of the person. Results of this inventory must be retained by the manufacturer, importer, or processor for 3 years after the effective date of the ban. The purpose of this inventory is to serve as a baseline for EPA’s enforcement of the rule’s bans on manufacture, importation, processing, and distribution in commerce. Inventory results will be compared by EPA inspectors with the business records maintained under § 761.77(b)(1) to determine compliance with this rule.

2. Records

Manufacturers, importers, and processors must maintain a copy of all labels used in compliance with § 763.171 for 3 years after the effective date of the ban on distribution in commerce to which the label applies. For example, if the label is required for a product banned from distribution in commerce as of October 1, 1992, the records regarding the label must be maintained until October 1, 1995.

Manufacturers, importers, processors, and those persons subject to bans on distribution in commerce must maintain normal business and sales records—recording the dates and quantities purchased of all products subject to bans. These records must be maintained for transmittals from the effective date of the manufacture, importation, or processing ban for a product until the effective date of the ban on distribution in commerce for the product. These records must be maintained for 3 years after the effective date of the ban on distribution in commerce for a product.

For example, if a manufacturer produces an asbestos-containing product that is subject to a manufacture ban that takes effect on September 1, 1992, the manufacturer must by that date, make an inventory of the stock-on-hand of the banned product as of that date. A record of the inventory must be maintained until September 1, 1996. The manufacturer must also keep records of all sales or transfers of the product between September 1, 1993, and the effective date of the ban on distribution in commerce (for purposes of this example, September 1, 1994). These records must be maintained by the manufacturer until at least September 1, 1997.

IV Summary of Analysis Supporting This Final Rule

EPA’s basis for this rule, as described in the proposal, remains largely unchanged. EPA’s unreasonable risk findings under section 6 of TSCA are based on extensive data gathering, modeling, analysis, and review of public comments. EPA’s findings are summarized briefly in this preamble. This preamble also addresses significant public comments raised during the course of this rulemaking. EPA has addressed other comments in a separate Response to Comments document, which is incorporated by reference in this preamble and is included in the public docket. The following documents are also contained in the public docket and serve as the primary, although not exclusive, basis for the actions taken in this rule.

1. Regulatory Impact Analysis, EPA, 1988. This document analyzes the costs and benefits of various options for regulating the risks of exposure to asbestos, and includes an analysis of available substitutes for asbestos-containing products, a regulatory flexibility analysis, and materials on the models and computational procedures used, survey results, health effects and studies, costs of converting capital equipment from asbestos-using processes, the producer surplus loss determination, economic impacts data and analyses, and sensitivity analyses.

2. Three documents evaluating the magnitude of potential routes of human exposure to asbestos: (a) Asbestos Exposure Assessment, EPA, 1988. This document analyzes the occupational exposure to asbestos and asbestos releases from manufacturing plants and commercial operations in the U.S. (b) Asbestos Modeling Study, EPA, 1988. This document analyzes the ambient exposure levels resulting from the release of asbestos to the atmosphere from industrial and commercial sources. (c) Non-occupational Asbestos Exposure Report, EPA, 1988. This document analyzes the level of consumer and ambient exposures to asbestos.

3. Three reports evaluating the extensive data base on human health hazards posed by asbestos: (a) Airborne Asbestos Health Assessment Update, EPA, 1986. This document was prepared by EPA’s Office of Research and Development and was reviewed, critiqued, and updated in response to peer review comments from the Environmental Health Committee of the EPA Science Advisory Board (SAB). The SAB advises the EPA Administrator on scientific matters. (b) Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Asbestos, CPSC, 1983. This document was written by a panel of seven scientists selected by CPSC from a list of nominees by the National Academy of Sciences after a nationwide solicitation. (c) Asbestiform Fibers: Non-occupational Health Risks, National Academy of Sciences, Committee on Non-occupational Health Risks of Asbestiform Fibers, 1984. This document was written by an expert panel of 13 members.


Other materials used in the development of this rule are cited in the text of this preamble and listed in Unit XI of this preamble.

V Regulatory Assessment

Section 6 of TSCA authorizes EPA to promulgate a rule prohibiting or limiting the amount of a chemical substance that may be manufactured, processed, or distributed in commerce in the U.S. if
EPA finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of these activities, presents or will present an unreasonable risk of injury to human health or the environment.

Section 6(c)(1) of TSCA requires EPA to consider the following factors when determining whether a chemical substance presents an unreasonable risk:

1. The effects of such substance on human health and the magnitude of the exposure of human beings to such substance.
2. The effects of such substance on the environment and the magnitude of the exposure of the environment to such substance or mixture.
3. The benefits of such substance for various uses and the availability of substitutes for such uses.
4. The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health.

To determine whether a risk from activities involving asbestos-containing products presents an unreasonable risk, EPA must balance the probability that harm will occur from the activities against the effects of the proposed regulatory action on the availability to society of the benefits of asbestos. EPA has considered these factors in conjunction with the extensive record gathered in the development of this rule.

EPA has concluded that the continued manufacture, importation, processing, and distribution in commerce of most asbestos-containing products poses an unreasonable risk to human health. This conclusion is based on information summarized in the following paragraphs and discussed in the units that follow.

EPA has concluded that exposure to asbestos during the life cycles of many asbestos-containing products poses an unreasonable risk of injury to human health. EPA has also concluded that section 6 of TSCA is the ideal statutory authority to regulate the risks posed by asbestos exposure. This rule’s pollution prevention actions under TSCA are both the preferable and the least burdensome means of controlling the exposure risks posed throughout the life cycle of asbestos-containing products. Findings supporting this conclusion include the following:

1. Exposure to asbestos causes many painful, premature deaths due to mesothelioma and lung, gastrointestinal, and other cancers, as well as asbestosis and other diseases. Risks attributable to asbestos exposure and addressed by this rule are serious and are calculated for this rule using direct evidence from numerous human epidemiological studies. Studies show that asbestos is a highly potent carcinogen and that severe health effects occur after even short-term, high-level or long-term, low-level exposures to asbestos. Asbestos exposure is compatible with a linear, no-threshold dose-response model for lung cancer. In addition, there is no undisputed evidence of quantitative differences in potency based on fiber size or type.

2. The effects of such substance on human health or the environment. To determine whether a risk from activities involving asbestos-containing products presents an unreasonable risk, EPA has used dose-response constants for lung cancer and mesothelioma that were the geometric means of the "best estimates" from a number of epidemiological studies. If EPA had instead used an upper bound estimate, as is normally done by the scientific community and in EPA regulatory risk assessment, the predicted lung cancer and mesothelioma deaths could increase by a factor of 10 and mesothelioma deaths could increase by a factor of 20 (Ref. 1).

3. People are frequently unknowingly exposed to asbestos and are rarely in a position to protect themselves. Asbestos is generally invisible, odorless, very durable, and highly aerodynamic. It can travel long distances and exist in environments for extended periods. Therefore, exposure can take place long after the release of asbestos and at a distant location from the source of release.

4. Additions to the current stock of asbestos-containing products would contribute to the environmental loading of asbestos. This poses the potential for an increased risk to the general population of asbestos-related disease and an increased risk to future generations because of asbestos' long memory.

5. Asbestos fibers are released to the air at many stages of the commercial life of the products that are subject to this rule. Activities that might lead to the release of asbestos include mining of the substance, processing asbestos fibers into products, and transport, installation, use, maintenance, repair, removal, and disposal of asbestos-containing products. EPA has found that the occupational and non-occupational exposure existing over the entire life cycle of each of the banned asbestos-containing products poses a high level of individual risk. EPA has determined that thousands of persons involved in the manufacture, processing, transport, installation, use, repair, removal, and disposal of the asbestos-containing products affected by this rule are exposed to a serious lifetime asbestos exposure risk, despite OSHA’s relatively low workplace PEL. In addition, according to the EPA Asbestos Modeling Study, millions of members of the general U.S. population are exposed to elevated levels of lifetime risk due to asbestos released throughout the life cycle of asbestos-containing products. EPA believes that the exposure quantified for the analyses supporting this rule represent an understatement of actual exposure.

6. Release of asbestos fibers from many products during life cycle activities can be substantial. OSHA stated in its PEL of 0.2 f/cc that remaining exposures pose a serious risk because of limitations on available exposure control technologies. Even with OSHA’s controls, thousands of workers involved in the manufacture and processing of asbestos-containing products are exposed to a lifetime risk of 1 in 1,000 of developing cancer. Many other exposures addressed by this rule are not affected by engineering controls required by OSHA’s PEL or by other government regulation. Because asbestos is a highly potent carcinogen, the uncontrolled high peak episodic exposures that are faced by large populations pose a significant risk.

7. Because of the life cycle or “cradle-to-grave” nature of the risk posed by asbestos, attempts by OSHA, the Consumer Product Safety Commission (CPSC), and other EPA offices to regulate the continued commercial use of asbestos still leave many persons unprotected from the hazards of asbestos exposure. Technological limitations inhibit the effectiveness of existing or possible exposure control actions under non-TSCA authorities. Many routes of asbestos exposure posed by the products subject to this rule are outside the jurisdictions of regulatory authorities other than TSCA. EPA has determined that the residual exposure to asbestos that exists despite the actions taken under other authorities poses a serious health risk throughout the life cycle of many asbestos-containing products. This residual exposure can only be adequately controlled by the exposure prevention actions taken in this rule.

8. Despite the proven risks of asbestos exposure and the current or imminent existence of suitable substitutes for most uses of asbestos, asbestos continues to be used in large quantities in the U.S. in the manufacture or processing of a wide variety of commercial products. Total annual U.S.
consumption of asbestos dropped from a 1984 total of about 240,000 metric tons to less than 85,000 metric tons in 1987 according to the U.S. Department of Interior, Bureau of Mines data. This change suggests that the use of substitutes has increased markedly since the proposal. However, the 1987 consumption total indicates that significant exposure due to the commercial use of asbestos and the resultant risks would continue for the foreseeable future absent the actions taken in this rule.

Evidence supports the conclusion that substitutes already exist or will soon exist for each of the products that are subject to the rule’s bans. In scheduling products for the different stages of the bans, EPA has analyzed the probable availability of non-asbestos substitutes. In the rule, the various asbestos products are scheduled to be banned at times when it is likely that suitable non-asbestos substitutes will be available. However, the rule also includes an exemption provision to account for instances in which technology might not have advanced sufficiently by the time of a ban to produce substitutes for certain specialized or limited uses of asbestos.

8. EPA has calculated that the product bans in this rule will result in the avoidance of 202 quantifiable cancer cases, if benefits are not discounted, and 148 cases, if benefits are discounted at 3 percent. The figures decrease to 164 cases, if benefits are not discounted, and 120 cases, if benefits are discounted at 3 percent, if analogous exposures are not included in the analysis. In all likelihood, the rule will result in the avoidance of a large number of other cancer cases that cannot be quantified, as well as many cases of asbestos-related diseases. Estimates of benefits resulting from the action taken in this rule are limited to mesothelioma and lung and gastrointestinal cancer cases, avoided, and do not include cases of asbestososis and other diseases avoided and avoided costs from treating asbestos diseases, lost productivity, or other factors. EPA has estimated that the cost of this rule, for the 13-year period of the analyses performed, will be approximately $458.89 million, or $865.51 million if a 1 percent annual decline in the price of substitutes is not assumed. This cost will be spread over time and a large population so that the cost to any person is likely to be negligible. In addition, the rule’s exemption provision is a qualitative factor that supports the actions taken in this rule. EPA has concluded that the quantifiable and unquantifiable benefits of the rule’s staged-ban of the identified asbestos-containing products will outweigh the resultant economic consequences to consumers, producers, and users of the products.

9. EPA has determined that, within the findings required by section 6 of TSCA, only the staged-ban approach employed in this final rule will adequately control the asbestos exposure risk posed by the product categories affected by this rule. Other options either fail to address significant portions of the lifetime risk posed by products subject to the rule or are unreasonably burdensome. EPA has, therefore, concluded that the actions taken in this rule represent the least burdensome means of reducing the risk posed by exposure to asbestos during the life cycles of the products that are subject to the bans.

10. Based on the reasons summarized in this preamble, this rule bans most asbestos-containing products in the U.S. because they pose an unreasonable risk to human health. These banned products account for approximately 94 percent of U.S. asbestos consumption, based on 1985 consumption figures. The actions taken will result in a substantial reduction in the unreasonable risk caused by asbestos exposure in the U.S.

A few minor uses of asbestos and asbestos products are not included in the ban. These uses, which account for less than 6 percent of U.S. asbestos consumption based on 1985 data, do not pose an unreasonable risk, based on current knowledge. For some product categories, EPA was unable to find that the products pose an unreasonable risk because asbestos exposure is minimal over the product’s life cycle relative to the exposures posed by other products. In other instances, asbestos exposure is insufficient information about either asbestos exposure attributable to the products or the future availability of suitable substitutes to make a finding of unreasonable risk. Exposure information was considered insufficient in cases where monitoring data was largely unavailable for most major stages of a product’s life cycle and too little was known about exposures during these stages to estimate exposure by analogy to those posed by other products. When no information is available for a product indicating that cost-effective substitutes exist, the estimated cost of a product ban is very high. In all of these cases, the risk reduction potential that EPA could quantitatively or qualitatively estimate as a result of possible regulatory actions could not be justified in light of the resultant costs, under the criteria of section 6 of TSCA.

Human health effects of asbestos and EPA’s cancer risk extrapolation are discussed in Units V.A.1 and V.A.2 of this preamble. The extent of human exposure to asbestos and the resulting risks are discussed in Unit V.A.3 of this preamble. Asbestos substitutes are discussed in Units V.C. and V.F of this preamble. EPA’s evaluation of the viability of other regulatory options under TSCA is discussed in Unit V.E of this preamble. EPA’s evaluation of the viability of actions under authorities other than TSCA to control the risk posed by asbestos exposure is discussed in Units VI and VII of this preamble.

EPA’s estimates of the costs and benefits of this rule are discussed in Unit V.D. of this preamble. EPA’s evaluations of the risks posed by the different categories of asbestos-containing products are summarized in Unit V.F of this preamble.

Health Effects and Magnitude of Exposure To Asbestos

1. Health effects. The human health effects caused by exposure to asbestos are well-documented. This Unit reiterates the major health and the uncertainties that exist regarding this subject. More comprehensive analysis can be found in the Airborne Asbestos Health Assessment Update (Ref. 1), the Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Asbestos (Ref. 2), and Asbestiform Fibers: Non-occupational Health Risks (Ref. 3). Further responses to comments on this subject can be found in the Response to Comments document.

Asbestos is a chemical substance as that term is defined in section 3(2) of TSCA. It is well-recognized that asbestos is a human carcinogen and is one of the most hazardous substances to which humans are exposed in both occupational and non-occupational settings. As OSHA stated in its final rule, published in the Federal Register of June 20, 1986 (51 FR 22612), establishing a 0.2 fibers-per-cubic-centimeter (f/cc) PEL for asbestos, “OSHA is aware of no instance in which exposure to a toxic substance has more clearly demonstrated detrimental health effects on humans than has asbestos exposure.” There is widespread agreement that all types of asbestos fibers are associated with pulmonary fibrosis (asbestosis), lung cancer, and mesothelioma. Gastrointestinal cancer and other cancers at extrathoracic sites, as well as other lung disorders and diseases, have also been associated with asbestos exposure, although the consistency and magnitude of the excess risks of these
developing asbestos-induced mesothelial risk rises rapidly with time. Epidemiological studies suggest that exposure to chrysotile, amosite, and crocidolite can separately increase risk of mesothelioma and asbestosis. However, there is no evidence that smoking exposure can cause mesothelioma. Increased risk of mesothelioma and asbestosis have been observed in families of asbestos workers, presumably due to the dissemination of fibers in the home from contaminated work clothes. Mesotheliomas have also been documented in populations whose only identified exposure was living near asbestos mines or asbestos product factories, or shipyards with heavy asbestos use.

a. Lung cancer and mesothelioma. Lung cancer has been responsible for the largest number of deaths attributable to occupational exposure to all of the principal commercial asbestos mineral types: chrysotile, amosite, crocidolite, and anthophyllite. Excess lung cancers have been documented among workers involved in asbestos mining and milling and in the manufacturing and use of a variety of asbestos products. Lung cancer risk appears to increase with both the level and duration of exposure. The latency period for the disease is generally 20 years or more after exposure. This means that lung cancer usually does not manifest itself until 20 years after the disease-initiating exposure. Most persons who develop lung cancer die within 2 years of diagnosis. While both asbestos and cigarette smoking can separately increase risk of lung cancer, together they appear to interact synergistically to multiply lung cancer risk in humans. Commenters have suggested that smoking should be controlled to reduce the very high lung cancer risk due to combined asbestos exposure and smoking. However, even complete control of the smoking factor, if possible, would leave a substantial increases of lung cancers due to occupational exposure to asbestos.

Mesothelioma is a rare cancer of the lining of the lung (pleural mesothelioma) or abdominal cavity (peritoneal mesothelioma). Mesothelioma has been associated with occupational exposure to chrysotile, amosite, and crocidolite. Epidemiological studies suggest that mesothelioma risk rises rapidly with time from the onset of exposure. Risk also increases with both intensity and duration of exposure. The latency period for the disease is generally between 25 and 30 years. In almost all instances, the disease is rapidly fatal, with survival times of less than 2 years after diagnosis. There is no evidence that cigarette smoking increases the risk of developing asbestos-induced mesothelioma. Most epidemiological studies have been conducted on occupational populations exposed to high airborne concentrations of asbestos for relatively long periods of time. However, short-term occupational exposures have been shown to cause serious health effects. For example, one group of asbestos factory workers with less than 2 months of occupational exposure had a two-fold increase in lung cancer risk (Ref. 4). Also, many documented cases of mesothelioma have been linked to extremely brief exposures to relatively high concentrations of asbestos (Ref. 1).

There is also direct evidence of adverse health effects from non-occupational asbestos exposure. Increased risk of pleural abnormalities and mesothelioma have been observed in families of asbestos workers, presumably due to the dissemination of fibers in the home from contaminated work clothes. Mesotheliomas have also been documented in populations whose only identified exposure was living near asbestos mines or asbestos product factories, or shipyards with heavy asbestos use (Ref. 1).

Animal studies confirm the epidemiological findings regarding the health effects of asbestos exposure. All commercial forms of asbestos have been shown to produce lung tumors and mesothelioma in laboratory animals with no substantial differences between the form of asbestos forms in carcinogenic potency.

b. Gastrointestinal cancer. A number of epidemiological studies have documented significant increases in the incidence of gastrointestinal cancer due to occupational exposure to asbestos. Gastrointestinal cancers consist largely of cancers of the esophagus, stomach, colon, and rectum. However, the magnitude of the excess gastrointestinal cancer risk is lower than that of lung cancer or mesothelioma and no dose-response data are available.

A number of commenters argued that the evidence indicating a positive association between gastrointestinal cancer and asbestos exposure is weak and inconclusive. They indicated that unidentified facts may cause the excess gastrointestinal cancers. Commenters suggested that many of the excess cancers attributed to gastrointestinal cancer may be due to misdiagnosis of peritoneal mesotheliomas. Other commenters contended that in the absence of any positive experimental evidence, the epidemiology data alone do not support the conclusion that exposure to asbestos can cause gastrointestinal cancer.

EPA recognizes that the evidence supporting an association between gastrointestinal cancer and asbestos exposure is not as strong as that which is available to support an association between asbestos exposure and lung cancer and mesothelioma. However, after weighing available information, EPA believes that there is evidence of a strong causal relationship between asbestos exposure and gastrointestinal cancer excess. This evidence includes the following: (1) A statistically significant increase in gastrointestinal cancer was found in 10 of 23 epidemiological studies. (2) A consistent relationship exists between increased gastrointestinal cancer risk and increased lung cancer risk (approximately 10 to 30 percent of the lung cancer excess). (3) It is biologically plausible that asbestos could be associated with these tumor sites, because it is conceivable that the majority of fibers inhaled are cleared from the respiratory tract and subsequently swallowed, allowing the fibers to enter the gastrointestinal tract (Ref. 5). Additionally fibers may be swallowed directly. (4) One study demonstrated some evidence of carcinogenicity in male rats fed diets containing intermediate range size chrysotile asbestos (65 percent 10 microns in length) (Ref. 6).

Further, EPA does not accept the argument that all gastrointestinal cancers identified in the epidemiology studies described above are the result of misdiagnosis. Cancers of some gastrointestinal cancer sites (e.g., stomach and pancreas) could be the result of misdiagnosis of peritoneal mesotheliomas. However, this does not account for all of the excess cancers seen at sites such as the colon or rectum. OSHA, in its final rule lowering the asbestos PEL concluded that the studies conducted to date “constitute substantial evidence of an association between asbestos exposure and a risk of incurring gastrointestinal cancer. EPA agrees with this conclusion.

c. Cancers at other sites. Increased risk of cancers other than mesothelioma and lung and gastrointestinal cancers have been observed in populations occupationally exposed to asbestos. An excess of laryngeal cancer in asbestos workers has been reported in a number of studies (Ref. 2). Available data, however, indicate that there may be an interaction between smoking and asbestos exposure in the etiology of laryngeal cancer. Elevated risk of kidney cancer has also been observed in two epidemiological studies (Refs. 7 and 8). In addition, an increased incidence of
ovarian cancer has been found among female workers in three studies (Refs. 9, 10, and 11). Therefore, evidence suggests an association between asbestos exposure and cancers other than lung cancer, mesothelioma, and gastrointestinal cancer. However, because of study limitations, inconsistencies among studies, and the possibility of misdiagnosis of disease, the relationship between asbestos exposure and cancer at these extrathoracic sites is not clear. Because of this uncertainty, EPA did not calculate the risk of cancers at other sites for purposes of the quantitative risk assessment for this rule.

d. Asbestosis. Asbestosis is a disabling fibrotic lung disease that has been associated with high levels of occupational exposure to asbestos. Clinical signs and symptoms associated with asbestosis include shortness of breath, pulmonary functional changes, basal rales, and small, mainly irregular, opacities on chest radiographs. Asbestosis can both appear and progress many years after the termination of exposure. All types of asbestos have been associated with the development of asbestosis.

Epidemiological data indicate that the incidence rate increases and the disease becomes more severe with increasing dust level and duration of exposure. This has also been confirmed in animal studies via inhalation exposure. It is not clear whether an exposure threshold exists for asbestosis. However, there is no available evidence that disabling asbestosis is caused by non-occupational asbestos exposure or relatively low levels of occupational exposure. Therefore, the risk of disabling asbestosis from low levels of exposure to asbestos was not calculated for purposes of the quantitative risk assessment performed for this final rule.

e. Effect of fiber type. A number of commenters argued that chrysotile, the major commercial form of asbestos, is far less carcinogenic than the amphibole asbestos types (e.g., amosite and crocidolite) and thus, different carcinogenic potency values for chrysotile and amphiboles should be used for quantitative risk assessment.

For lung cancer, EPA finds the evidence supporting this argument to be inconclusive and inconsistent. Some of the lowest unit risk factors observed for lung cancer are among cohorts exposed to predominantly chrysotile asbestos (Refs. 12 and 13). However, some of the highest unit values are also from exposure to primarily chrysotile (Refs. 14 and 15). This suggests that chrysotile exposures can confer an extremely high risk of lung cancer. The cause of the observed variability in lung cancer unit risk for chrysotile in different studies is unknown, but some of the variabilities can be attributed to differences in the fiber characteristics associated with different processes, uncertainties due to small numbers in epidemiological studies, and incorrect estimates of the exposures of earlier years (Refs. 1 and 2).

For mesothelioma, EPA recognizes that peritoneal mesotheliomas have largely been associated with crocidolite exposure and that there is some epidemiological evidence suggesting that crocidolite is more potent than chrysotile in inducing pleural mesothelioma. However, definitive conclusions concerning the relative potency of various fiber types in inducing mesothelioma cannot be made on the basis of available epidemiological information. This is because: (1) Mesotheliomas are difficult to diagnose; (2) dose-response information for mesothelioma for individual fiber types is unavailable; (3) exposure data are inadequate; and (4) exposure to crocidolite fibers could be higher because they become airborne more easily than other fiber types. Further, numerous animal studies have demonstrated that chrysotile is at least as potent as amphiboles in inducing both mesothelioma and lung cancer by inhalation, as well as by injection or implantation.

Available information indicates that the combined epidemiological and animal evidence fail to establish conclusively differences in mesothelioma hazard for the various types of asbestos fibers. In view of the presence of the risk of disabling asbestosis, extrathoracic sites is not clear. Because of this uncertainty, EPA did not calculate the risk of cancers at other sites for purposes of the quantitative risk assessment performed for this final rule.

e. Effect of fiber dimension. A number of commenters stated that while long fibers (>5 microns) are associated with biological activity, fibers less than 5 microns in length may be innocuous. According to these commenters, short fibers to not contribute to any significant risk to humans and therefore EPA should base its cancer risk estimates on only fibers longer than 5 microns in length.

Injection or implantation studies in animals indicate that longer, finer fibers of the same asbestos fiber type appear to have greater carcinogenic potential than shorter, thicker fibers (Refs. 1, 2, and 3). Results of several recent inhalation studies also indicate that long fibers (>5 microns) are more carcinogenic than short fibers (<5 microns) (Ref. 14 and 15). However, studies performed to date have not established fiber dimensional thresholds for potency.

Although animal studies have provided an indication of the qualitative relationship between fiber dimension and carcinogenic potency, they are not used for quantifying dose-response relationships for humans because EPA believes that extrapolation of data from human exposures in the workplace to human exposure in non-occupational settings is more appropriate. EPA based most of its estimates of non-occupational exposure in terms of the total mass of asbestos released to air. To estimate health risk from the non-occupational exposure, the mass measurements need to be converted to the equivalent optical fiber concentration (fibers longer than 5 microns and greater than 0.25 μm in diameter) that are used as dose measurements in workplaces for which dose-response relationship has been developed. Some data exist that relate optical fiber counts to the total mass of asbestos. The range of conversion factors between optical fiber count mass concentration is large (5 to 150 μg/m³/f/ml) because these values vary with different environments and sampling techniques, and any average value derived from this range has a large uncertainty. Despite the uncertainties, they are the best data available for such assessments and therefore EPA believes that for the purpose of extrapolating to low mass concentration from fiber count, the approximate geometric mean, 30 μg/m³/f/ml is appropriate (Ref. 1). Additionally, uncertainty may be introduced in the assumption made in this assessment that the fiber size distribution is the same in both occupational and non-occupational air environments. The assumption is considered prudent in view of the fact that qualitatively, short fibers are found more predominantly than long fibers in both occupational and non-occupational settings. The same approach has been...
adopted by the National Academy of Sciences (Ref. 3) and the Chronic Hazard Advisory Panel (CHAP) on Asbestos (Ref. 2) in estimating human health risk associated with low-level non-occupational exposure to asbestos.

5. Potency values. Commenters stated that cancer risks vary from one industry segment to another and maintained that EPA should use different potency values for different industries in its quantitative cancer risk assessment for asbestos.

Most of the commenters singled out two segments of the asbestos industry, manufacturers of chrysotile friction products and A/C products made from chrysotile, in which the lung cancer risks were considerably lower than those in chrysotile textile production.

EPA has concluded that the data supporting this suggestion are not convincing because of significant methodological or statistical uncertainties in these studies. Further, when the 95 percent confidence limits on the potency factors for lung cancer are considered along with the uncertainties associated with estimates of exposures, there is considerable overlap of the unit risk estimates across industry segments and fiber types (Ref. 1). Accordingly, EPA believes that it's use of a geometric mean unit risk derived from 11 studies that cover all industrial processes (with the exception of mining and milling) and that provide a dose-response relationship is reasonable. This approach recognizes that lower cancer risks may exist in some industry segments because of uncertainties in the measurement of exposure or statistical variabilities, but the potency factor for asbestos is considered to be equivalent across industry segments. In fact, a follow-up study (Ref. 24) reported a lung cancer unit risk of 0.0076 for A/C production workers who were exposed predominately to chrysotile. This value is closer to the best estimate for the fractional increase in lung cancer, Klc, for asbestos exposure, 0.010. This study provides further support for the use of a single potency factor for all asbestos exposure scenarios.

2. Quantitative Risk Assessment. Risk assessment usually requires extrapolation between different routes of exposure, from animals to humans, and from test groups to the population at large. Despite uncertainties, risk assessment provides an estimate of the magnitude of risk for making decisions about controlling exposure to a hazardous substance. However, because health risk from asbestos exposure is estimated using direct evidence from a large number of epidemiological studies, the risk posed by asbestos exposure is far more certain than that posed by exposure to other hazardous substances for which only animal data and/or fewer, less conclusive human data are available.

Data from a study of U.S. insulation workers allow models to be developed for the time and age dependence of lung cancer and mesothelioma risk (Ref. 4). Thirteen other epidemiological studies demonstrate a linear dose-response relationship between cumulative occupational asbestos exposure and lung cancer. Although much less data are available regarding a dose-response relationship for mesothelioma, existing data suggest a linear response with dose and duration of exposure. To obtain dose-response estimates for current occupational and non-occupational exposures to asbestos, it is necessary to extrapolate the effects observed in occupational settings with historically high exposure to anticipated effects at low levels of exposure. This is based on a no-threshold linear extrapolation. The assumption of no-threshold low dose linearity for asbestos carcinogenicity is reasonable and well-supported because (1) cumulative dose-response relationship have been shown in several epidemiological studies over a wide range of exposure; (2) threshold dose has not been demonstrated; and (3) the concept is consistent with accepted theories of carcinogenesis.

Both the lung cancer and mesothelioma models used for this final rule have been adopted by OSHA (Ref. 16). The National Academy of Sciences (Ref. 3) also adopted a similar no-threshold model to estimate lung cancer risk to non-occupational populations from exposure to asbestos. No-threshold linear models have widespread support (Refs. 2, 3, 6, 18, 22, and 23). The derivation and validation of the models as well as the assumptions and uncertainties involved in the model, are discussed in detail in Refs. 1, 2, and 21.

\[ d_{10}= \text{duration of exposure from onset until } \text{10 years (minimum latency period) before present (years).} \]

\[ f = \text{intensity of exposure to fiber equivalents longer than } 5 \text{ microns (f/cc).} \]

\[ K_d = \text{dose response constant} = 0.010. \] (Refs. 1 and 21)

Because mesothelioma is a very rare form of cancer in the general population, an absolute risk model is used to estimate excess mesothelioma incidence due to asbestos exposure. According to this model, the added risk of mesothelioma is proportional to the cumulative exposure to asbestos and increases in proportion to the third power of time after onset of exposure. This model incorporates a delay of 10 years for the manifestation of disease (i.e., a minimum latency period of 10 years). Four epidemiological studies provided quantitative data suitable for calculation of potency factors for lung cancer and mesothelioma (Ref. 1). EPA (Ref. 1) selected an average value for \( K_m \) of 1.0 x \( 10^{-8} \) as the best estimate for environmental exposures. Although it was not possible to determine directly the 95 percent confidence limits on \( K_m \), a multiplicative factor of 5 was estimated for the average value of \( K_m \) and a multiplicative factor of 20 was estimated for its application to any unstudied exposure circumstance.

The absolute risk model for mesothelioma can be expressed as:

\[ K_{10}(t, d, f) = K_m f(t-t_0) \text{ for } t > t_0 + d \]

\[ K_{10} = K_m f(t-t_0) \text{ for } 10 + d > t > t_0 \]

\[ = 0 \text{ for } t < 10 \]

Lung cancer is best described by a relative risk model. According to this model, excess risk of lung cancer from asbestos exposure is proportional to the cumulative exposure (i.e., the duration of exposure times the intensity of exposure, in terms of fiber-year/cc) and the background risk in the absence of exposure. EPA used this model and data from 11 studies of workers exposed to asbestos in textile production, asbestos product manufacturing, and insulation application to calculate potency factors for lung cancer (Klc, the fractional increase in risk per fiber-year/cc of exposure) (Ref. 1). The geometric mean value of Klc for these studies, 0.010, was used as the best estimate for environmental asbestos exposure. The 95 percent confidence limits for this value are 0.0040 and 0.027 (multiplicative factor of 2.5) based on an analysis of variances in the 11 studies from which the Klc was calculated. The 95 percent confidence limits for Klc that might be applied in any unstudied exposure circumstances are estimated to be a multiplicative factor of approximately 10.

The relative risk model for lung cancer can be expressed as:

\[ I_l = I_k [1 + Kc f (d_{10})] \]

where:

\[ I_l = \text{age-specific lung cancer death rate with exposure to asbestos.} \]

\[ I_k = \text{age-specific lung cancer death rate without exposure to asbestos.} \]

\[ t = \text{time from onset of exposure until present (years).} \]

where:

\[ I_m(t, d, f) = \text{mesothelioma incidence at } t \text{ years from onset of exposure, from duration } d \text{ at concentration } f. \]
\( K_m = \text{carcinogenic potency expressed as the incidence of mesothelioma per unit of exposure in fiber-years } / \text{cc} \)

\( I = \text{intensity of exposure to fiber equivalents longer than } 5 \text{ microns } (f/\text{cc}) \)

\( t = \text{time after exposure in years} \)

\( d = \text{duration of exposure in years}, \text{(Refs. 1 and 21)} \)

In extrapolating rates of excess asbestosis-related deaths from gastrointestinal cancer, OSHA adopted the approach used by OSHA (Ref. 16) in assuming that excess gastrointestinal cancers will be equal to those for lung cancer in each time period. However, this approach may actually understate the rate of gastrointestinal cancers. OSHA noted that this approach could result in an underestimate, and EPA's analysis indicates that the excess gastrointestinal cancer rate could be as high as 30 percent of the lung cancer rate (Ref. 1).

There are inconsistencies in findings among different epidemiological studies with regard to excess mortality for cancers at sites other than the lung, mesothelial linings, and gastrointestinal tract (e.g., laryngeal, kidney, and ovary cancers). Also, there are uncertainties about the development of disabling asbestosis at low exposure. Therefore, EPA has not made numerical estimates of the risks for these asbestosis-related diseases for purposes of this analysis. Since estimates of these diseases are not included in the overall risk estimates, EPA believes that the total health risk posed by exposure to asbestos is underestimated.

A number of commenters contended that it is more meaningful to adhere to a linear, no-threshold dose-response model for estimating lung cancer and mesothelioma risk from asbestos exposure. They cited a number of epidemiological studies which they stated show that there is a threshold below which asbestos-related disease does not occur (Refs. 12, 13, 25, and 26). EPA has reviewed these studies and found that they are all insufficient to detect a threshold at low doses (Ref. 1).

Other commenters expressed concern about the low-dose linearity assumption because the shape of the dose-response curve at extremely low doses is subject to conjecture and that the use of no threshold linear model greatly overestimates true risk. Others believe that asbestos is a non-genetic carcinogen. As discussed above, EPA has concluded that the low-dose linearity assumption is reasonable because direct evidence for linearity of carcinogenic response associated with asbestos exposure is found in several epidemiological studies over a wide range of exposure. Whether the response is linear at very low doses is not known (Ref. 1). In the discussion of the choice of mathematical procedures in carcinogen risk assessment, the White House Office of Science and Technology Policy (OSTP) stated: "When data and information are limited, however, and when such uncertainty exists regarding the mechanism of carcinogenic action, models or procedures which incorporate low-dose linearity are preferred when compatible with the limited information" (Ref. 27). EPA generally concurs with this position as reflected in EPA's Guidelines for Carcinogen Risk Assessment (51 FR 33992). Thus, given the lack of complete understanding of the mechanisms by which asbestos induces cancer, and the goal of protecting human health, EPA believes that the choice of low-dose linearity is most prudent.

3. Magnitude of human exposure. Exposure to asbestos is discussed in more detail in the Asbestos Exposure Assessment (Ref. 29), the Asbestos Modeling Study (Ref. 30), and the Non-Occupational Asbestos Exposure Report (Ref. 31). Further responses to comments on this subject can be found in the Response to Comments document.

Most of the population of the United States is exposed to some level of airborne asbestos from asbestos-containing products. Asbestos products have been in wide use in the U.S. for decades. Although U.S. asbestos consumption has declined in recent years, thousands of tons of asbestos are still used annually in the manufacture in the U.S. of the products that are subject to this rule (Ref. 21). Fibers can be released to the air and exposure can occur at all stages of the life cycle of asbestos products, including mining, processing, and the transport, installation, use, repair, removal, and disposal of asbestos-containing products.

Once released, asbestos fibers exhibit a number of characteristics that tend to increase human exposure to them. They are odorless and fibers of respirable size are largely invisible, presenting risk to persons who are not aware of that they are being exposed. They are also extremely durable and possess aerodynamic properties that allow them to remain suspended in the air for a long time and to reenter the air readily after settling out. Asbestos, therefore, can persist for a very long time in the environment and can travel extended distances through the air. These factors increase the intensity, duration, and area of exposure and complicate attempts to control or reduce exposure.

EPA has quantified many of the life cycle exposures anticipated from the continued manufacture, importation, processing, and use of the asbestos products that are subject to this rule. EPA estimates that over 135,000 full-time equivalent (FTE) workers are exposed during the life cycles of these products to levels of asbestos carrying lifetime risks of between 7 in 10,000 and 7 in 1,000 (Ref. 29). At least 40 million consumers face a potential hazard as they install, use, repair, and dispose of these products (Ref. 31). In addition, the general population is exposed to asbestos that is released into the ambient air during all of these activities. Both consumers and members of the general population frequently incur individual lifetime risks of 1 in 1,000,000 or greater of developing cancer from these exposures (Ref. 31).

There are other exposures associated with the continued production of asbestos products that cannot be readily quantified, but which could pose a significant risk to large populations. As discussed in more detail below, many releases of asbestos from asbestos products take place intermittently and over long periods, making them difficult to measure. Because of the difficulty of obtaining accurate monitoring data for these releases, they have not been quantified for purposes of this rule's analyses, but qualitative evidence indicates that cumulatively, they are probably significant. Similarly, because it is difficult to quantify the tendency of asbestos to be reaerosolized in air, EPA has not quantified in its analyses the risk posed by asbestos that is repeatedly reentrained after settling out. However, some reentrainment certainly occurs, and asbestos may pose some threat years after its initial release from asbestos products. These exposures, although unquantified, have the potential to affect large numbers of people for long periods of time. Thus, in addition to the exposures quantified for this rule, they are a source of considerable concern.

a. Occupational exposures. Since EPA's proposed rule was issued, OSHA has promulgated new occupational exposure standards for asbestos, lowering the 8-hour Time Weighted Average (TWA) PEL from 2.0 to 0.2 f/cc (51 FR 23812). OSHA has also set an Excursion Limit (EL) of 1 f/cc as a half-hour TWA in a September 1988 amendment to the standards (53 FR 35610). The probable impact of the 0.2 f/cc PEL on workers' exposures to asbestos was discussed in the proposal. As noted both in that proposal and in OSHA's rulemaking, exposures at the
new PEL still pose significant risks, as do exposure at the EL. OSHA notes that the new PEL and EL do not represent "safe" levels of asbestos exposure, but are the lowest levels that industry can feasibly achieve during current control technologies. EPA estimates that under the new PEL, approximately 135,000 FTE workers engaged in the manufacture, processing, installation, repair, and disposal of the products to be banned are exposed to levels of airborne asbestos between 0.02 f/cc and 0.2 f/cc (Ref. 29). Assuming that workers are exposed to these levels over a 45-year working lifetime, they incur individual risks of between 7 in 10,000 and 7 in 1,000 of developing cancer (51 FR 22844).

A number of commenters criticized the occupational exposure data base used to support the proposal as being outdated and incomplete. Much of that data came from the 1982 TSCA section 8(a) reporting rule (40 CFR 763.60). In response to these comments and because of the passage of time since the proposal, EPA has updated and expanded its analysis of occupational exposures, making use of available literature and data bases and conducting surveys of asbestos use and exposure levels. Materials used by EPA in the updated analysis include OSHA and Mine Safety and Health Administration (MSHA) compliance inspection reports, National Institute for Occupational Safety and Health (NIOSH) studies, academic and industry studies, and public comments. In 1980 and 1987 EPA conducted the Asbestos Exposure Survey and gathered exposure and release information on the manufacture of most of the major asbestos product categories from primary and secondary manufacturers of asbestos products. EPA gathered data on populations engaged in manufacturing in the 1986-87 Asbestos Market Survey.

EPA was able to obtain extensive information on occupational exposures during primary and secondary manufacturing for many product categories. Air monitoring data for primary and secondary manufacturing were available for many products from the 1986-87 EPA Exposure Survey, OSHA inspections, and numerous studies. EPA has estimated that approximately 9,300 workers in the U.S. are exposed to asbestos during the primary and secondary manufacture of the products that are affected by this rule (Ref. 29). These exposures are listed in Table 1 of this Unit.

EPA also gathered information on occupational exposures from the installation, repair, and disposal of most friction and construction products, the two product groups for which exposures are likely to be highest during these life cycle stages. For the installation and removal of construction products (roofing felt and A/C pipe, sheet, and shingle), air monitoring data were available from several studies. Occupational populations (in terms of FTEs) were estimated on the basis of crew size, productivity, and total manufacture and import volumes of the products. Exposures associated with the replacement and repair of friction materials were estimated in a similar fashion. EPA estimates that 125,400 FTEs are exposed to asbestos during the installation, repair, and disposal of asbestos friction and construction products. More than 125,400 workers are actually exposed to asbestos during these processes (OSHA estimates that 355,383 persons were exposed), but many are exposed on a less than a full-time basis (Ref. 29). FTE exposures are listed in Table I of this Unit.

Very little monitoring data on occupational exposures during installation, repair, and disposal were available for the other asbestos products that are subject to this rule, and EPA's estimates therefore do not include exposures from the installation, repair, and disposal of these products. However, on the basis of the limited data that exist for these products and on the basis of data for similar products and processes, EPA believes that significant exposures during installation, repair, and disposal of these products do take place (Ref. 57). Therefore, EPA believes that its analysis underestimates exposures associated with these products. EPA conducted an analysis in order to gauge the possible impact of the absence of some occupational exposure data on calculations of the rule's benefits; the results of this analysis appear in Table II of this Unit and Table VIII of Unit V.D.

In general, when data relating to a certain type of exposure could not be obtained, EPA did not quantify that type of exposure, reflecting what EPA considers to be a reasonable approach to risk assessment. EPA finds the exposures quantified for this rule sufficient in themselves to support EPA's risk assessment conclusions for asbestos. However, EPA notes that if all exposures to asbestos from the products affected by this rule could have been quantified, the benefits calculated for this rule would probably have been significantly greater than noted in EPA's risk assessment, lending further support to EPA's unreasonable risk finding for asbestos.

Much of EPA's occupational exposure data base for this rule represents exposure that took place before OSHA's lowered PEL of 0.2 f/cc became effective in 1986. To estimate exposures taking place after the lowering of the PEL, EPA first lowered to 0.2 f/cc all data points which reported exposures above 0.2 f/cc. EPA then averaged these points with those points that were reported as lower than 0.2 f/cc for each job category in each product category. For purposes of this analysis, EPA considered it appropriate to assume that previously high exposures will probably not be lowered significantly below the PEL. OSHA determined that 0.2 f/cc, which is 10 times lower than the previous PEL, was the lowest PEL that most of the asbestos industry could feasibly achieve using work practices and engineering controls. The asbestos industry challenged OSHA's standards, arguing that a PEL of 0.5 f/cc was the lowest feasible standard, and OSHA acknowledged that some industry sectors might not be able to control exposures to 0.2 f/cc without the use of respirators. Thus, while EPA believes that it is possible that some companies are below the 0.2 f/cc PEL by some margin, it is probable that others are not and that some of these actually exceed the PEL. EPA believes that adjusting previously high exposure points to 0.2 f/cc is a reasonable means of adjusting for facilities that may be above the PEL.

In estimating the benefits of its 0.2 f/cc PEL, OSHA used somewhat different assumptions than EPA has in this rule to estimate the impact of the PEL on workplace exposure levels. OSHA's analysis adjusted all exposures in its data base that were at or above 0.2 f/cc to 0.15 f/cc in cases where OSHA assumed that engineering controls were used. In cases where OSHA assumed that respirators were used, OSHA reduced the exposure by a factor equal to the effective protection factor of the respirator. OSHA assumed that exposures below 0.2 f/cc would be reduced by 20 percent due to engineering controls. OSHA's approach assumes not only general compliance with its fiber level standards, but also that, on average, those subject to the PEL will reduce their workplace exposures significantly below the standards to ensure compliance. OSHA did not factor non-compliance into its analysis of the costs and benefits of the PEL because both costs and benefits decline in proportion to any non-compliance, leaving cost-benefit ratios for the OSHA rule unchanged.
On the other hand, EPA's assessment of the costs and benefits of this rule is affected by non-compliance with the OSHA PEL. EPA's approach assumes general compliance with the PEL, but also accommodates the possibility that some level of non-compliance with the standard exists. As is discussed further below, OSHA issued many citations for violations of the asbestos standards in the first year after they went into effect. Using OSHA's fiber level adjustment assumptions in place of EPA's to estimate the effects of this rule results in an approximately 20 percent lower estimate of cancer-cases-avoided for occupational settings. However, if a non-compliance rate of 2 percent (a relatively low rate based on non-compliance rates in other Federal health and environmental regulatory settings) is assumed in conjunction with the OSHA fiber level adjustments, the resulting estimated benefits are virtually the same as those estimated using EPA's assumption about fiber level average exposure (Ref. 21). Therefore, EPA believes that its assumptions are appropriate for purposes of calculating the benefits of this rule. In practice, given some level of non-compliance with OSHA's asbestos regulations, actual cancer cases that would have occurred as a result of that non-compliance will now be prevented by this rule's product bans.

One commenter maintained that EPA should base its analyses solely on the data collected before OSHA promulgated its asbestos standard and should not adjust the data to reflect compliance with the standard. However, EPA considers it reasonable to assume that previously high exposure levels have been reduced to some lower level as a result of OSHA's action, and as discussed above, EPA has selected the PEL as a logical approximation of this level. Other commenters contended that EPA's approximation of occupational exposures taking place after the lowering of the PEL was too high, arguing that because exposure levels vary considerably from day to day, industry keeps average exposures significantly below the PEL to guarantee constant compliance. These commenters made similar arguments during OSHA's rulemaking setting the new PEL. However, in that instance, the commenters used the variability argument to support a claim that the PEL was infeasible because average exposures could not be kept low enough to guarantee constant compliance. OSHA refuted this argument, noting that day-to-day variability can be reduced by employers and that while exposures might be above the PEL some of the time, a finding of technological feasibility does not require that employers be able to comply with a standard constantly (51 FR 22653).

Moreover, data from recent OSHA inspections do not support the assertion that current exposures are significantly below the PEL. OSHA cited employers for nearly 1,000 violations of its asbestos standards in the first year after the standards went into effect, and the violation most frequently cited was the failure of employers to institute engineering controls to maintain employee exposure at or below the PEL (Ref. 32). Personal monitoring data from recent inspections showed that 91 out of 655 establishments inspected had concentrations of airborne asbestos above the PEL, and the average concentration level for all establishments inspected was 0.29 f/cc, 45 percent higher than the PEL (Ref. 33). While respirators were in use in many of the establishments with air concentrations higher than the PEL, 20 percent of these establishments were cited for violations of respiratory protection provisions for the PEL (Ref. 49).

On a related issue, some commenters stated that EPA had ignored the effect of using best available control technology (BACT) to reduce exposures, arguing that industry-wide exposure values are "not relevant to determination of the consequences of an effective PEL and consistent use of good work practice. As is discussed more fully in Unit V.E. and in the Response to Comments document, EPA has analyzed the likely effectiveness of mandating the use of BACT and has concluded that this regulatory option would not sufficiently reduce exposures to asbestos from products affected by this rule. For calculating the cancer-cases-avoided through regulation, EPA considers existing rather than best-case exposures to be the appropriate baseline. The evidence discussed in the preceding paragraphs indicates that many workplaces do not utilize BACT and that the adjustments EPA has made to its exposure data account for the impact of the 0.2 f/cc PEL. Where BACT is utilized, EPA's analysis has taken it into account. For instance, in its analysis of exposures during brake repair, EPA estimated that 9.6 percent of brake repair shops used BACT, and EPA calculated an average of industry-wide exposures including the relatively low exposures from this group.

On September 14, 1986 (53 FR 35610), OSHA amended its Asbestos Standards to incorporate an EL, which limits allowable short-term exposures to 1 f/cc over a half-hour period. OSHA took this action after noting that controlling episodic exposures to asbestos would lower the significant risk posed by asbestos in the workplace. However, while the EL will probably reduce workplace exposures, EPA does not believe that this reduction will be very great. EPA bases its judgment on a number of observations regarding the nature of and circumstances surrounding episodic exposures.

First, many exposures that are episodic are also unpredictable, defying attempts to control them. In industrial settings, episodic exposures are likely to be associated with unexpected events such as equipment breakdown (53 FR 35620). In the maintenance and repair sector of the construction industry, episodic exposures take place when individuals who only occasionally come into contact with asbestos materials and who may not recognize such materials disturb them accidentally or unwittingly in the course of their work (53 FR 35624). OSHA directs employers to conduct initial monitoring of employees' exposures where they "may reasonably be expected" to exceed the excursion limit. However, if peak exposures cannot reasonably be expected, they are unlikely to be either monitored for or protected against.

Second, the initial monitoring required to measure short-term, peak exposures where they are expected to occur is subject to error. To obtain accurate estimates of short-term exposures, monitoring must be conducted using the strictest sampling strategies and analytical techniques. If the proper protocol is not observed precisely, violations of the EL can go undetected (53 FR 35618 and 35619).

Third, where violations of the EL are detected and control measures are implemented, these control measures will frequently be ineffective. OSHA expects that for many of the employees exposed to predictable bursts of airborne asbestos, including workers in industry and in building maintenance and repair, respirator use will prove the only feasible means of controlling exposure (53 FR 35618 and 35624).

Unfortunately, respiratory protection has not been found to be very reliable. OSHA ranked respirator use last in its recommended hierarchy of controls in its 1986 revision to the asbestos standards, observing:

Respirators are capable of providing adequate protection only if they are properly selected for the concentrations of airborne contaminants present, properly fitted to the employee, properly and conscientiously worn
by the employee, carefully maintained, and replaced when they have ceased to provide adequate protection. While theoretically it is possible for all of these conditions to be met, it is more often the case that they are not (51 FR 22962).

The drawbacks cited above are aggravated if those using the respirators are not accustomed to working with them or with asbestos. OSHA states in its amendment establishing the EL that it "is concerned about relying on respirator use to meet the EL in the maintenance and repair sector of the construction industry, where contact with asbestos is often only occasional (53 FR 35624). Finally, even if all the conditions mentioned above are met, respirators will do nothing to reduce the quantity of asbestos released into the immediate environment of respirator wearers. Thus, during the activity that generates the airborne asbestos, persons near the respirator wearer can be exposed to dust that remains airborne or that is reentrained by settling out.

Like respirators, other control measures may reduce some short-term exposures without having much impact on long-term exposures. Some control measures replace one opportunity for exposure with another. For instance, to reduce short-term exposures during brake repair, OSHA recommends that mechanics utilize either a solvent spray or a vacuum enclosure equipped with a High Efficiency Particulate and Aerossol (HEPA) filter. While both of these controls can be effective in reducing short-term exposures during the brake job, exposures can be high later if the asbestos-contaminated solvent is allowed to remain in the area to evaporate, or if care is not taken during the removal of the HEPA filter from the vacuum device (Ref. 29). Because establishments using HEPA vacuum enclosures are exempt from monitoring under the OSHA standard, high exposures during filter removal may not be detected. Again, as is the case for respirators, the effectiveness of the brake repair control measures in reducing overall exposures depends heavily on the knowledge and conscientiousness of the user. This is also true for shrouded tools, the control measure recommended by OSHA for reducing short-term exposures during the cutting of A/C pipe (53 FR 35622).

Fourth, the implementation of additional control measures will be difficult, expensive, and time-consuming for much of the regulated community, discouraging compliance with the EL. For instance, although some brake repair establishments servicing large government fleets utilize HEPA vacuum enclosures, smaller establishments repairing brakes less frequently are less likely to invest in these relatively expensive devices. Moreover, while employees in government brake repair shops are usually paid by the hour, employees in private establishments are often paid by the job, which discourages the use of time-consuming work practices and engineering controls (Ref. 50). A similar situation exists in the maintenance and repair sector of the construction industry where, as noted earlier, many smaller building firms may find it difficult to institute adequate respirator programs. In these industry sectors and others, limitations on resources and time may discourage the diligent use of control measures that is required to achieve substantial reductions in occupational exposures to asbestos. The record of compliance with OSHA's 0.2 f/cc PEL supports this projection. The provisions most frequently violated in the year after OSHA's 1988 PEL went into effect included the requirements to conduct initial and daily monitoring, institute engineering controls, and to institute a respirator program, all of which are as important to achieving the EL as the PEL. In fact, achievement of the EL requires stricter application of these requirements than does achievement of the PEL, making uniform compliance more difficult. Moreover, the structure of the brake repair and building maintenance and repair industries, in which numerous, small businesses are the norm, will also make enforcement of the EL difficult.

In summary, attempts to reduce short-term exposures are likely to have only a limited effect in eliminating the exposure risks posed by asbestos. Peak exposures are both unpredictable and difficult to detect. Efforts to control them must rely largely on respirators and work practice controls, control measures whose effectiveness is uneven, depending upon the conscientiousness of the user. Implementation of these control measures also requires resources that employers and employees may have difficulty investing, and the record of compliance with the 0.2 f/cc PEL indicates that in many cases, the investment will not be made. For these reasons, occupational exposures will probably not be greatly lowered as a result of the EL. Although the estimates given below may slightly overestimate occupational exposures in those cases where the impact of the EL is greatest, EPA believes that any overestimate is likely to be minor overall.

The following table summarizes EPA's estimates of occupational exposures to asbestos by product category and process. This table and the other tables in this Unit present exposure levels in terms of millions of fibers breathed per year (10⁶ f/yr), an index of exposure that accounts for varying breathing rates, air concentration levels, and frequencies and durations of exposure among workers, consumers, and the general population. Assuming an 8-hour workday, a 250-day work year (both conditions do not always hold in the industries below), and a breathing rate of 1.3 m³/hr, 100×10⁶ fibers/year = 0.038 f/cc. Assuming a 45-year working lifetime exposure, exposure to 100×10⁶ fibers/year carries a risk of 1.29×10⁻¹ (1.29 in 1,000) of developing cancer (51 FR 35610). In many cases, blank spaces in the table signify that information was not available, not that no exposure takes place. The high fiber levels and relatively low populations given for the industries below, and a breathing rate of 1.3 m³/hr, 100×10⁶ fibers/year carry a risk of 1.29×10⁻¹ (1.29 in 1,000) of developing cancer (51 FR 35610). In many cases, blank spaces in the table signify that information was not available, not that no exposure takes place. The high fiber levels and relatively low populations given for the repair and disposal of A/C shingle, A/C sheet, and roofing felt are a result of the FTE approach to the calculation of benefits (cancer-cases-avoided). In reality, per person fiber levels are lower and populations are higher. Except as noted, all exposure information presented in this Unit of the preamble dates from 1985, the most recent year for which a complete set of data was available in the Market and Exposure Surveys. In calculating the cancer-cases-avoided through the rule, however, EPA has assumed that exposed populations would decline at the same rate as production volumes.

### Table I—Occupational Exposures

<table>
<thead>
<tr>
<th>Product</th>
<th>Primary manufact.</th>
<th>Secondary manufact.</th>
<th>Install.</th>
<th>Repair/disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pop. 10⁶ f/yr</td>
<td>Pop. 10⁶ f/yr</td>
<td>Pop. 10⁶ f/yr</td>
<td>Pop. 10⁶ f/yr</td>
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<tr>
<td>Commercial paper</td>
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<tr>
<td>Rollboard</td>
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</table>
EPA was not able to quantify all occupational exposures to asbestos. As noted earlier, there are few data on exposures during the installation, use, repair, removal, and disposal of a number of products, although exposure is believed to take place during these processes for many of these products. Moreover, existing exposure data do not reflect the elevated levels of airborne asbestos that can result from unpredictable episodic events, such as the accidental disturbance of asbestos material by a maintenance worker. As a means of representing part of this recognized but unmeasured exposure, EPA estimated occupational exposures associated with the installation, repair, and disposal of certain products on the basis of the limited data that exist for these products and processes and on the basis of exposure data for similar products and processes. Populations (in terms of FTEs) were estimated on the basis of production volumes and the person-hours typically required for the activity of concern. These estimates are presented in the table below, and are used as indicated in this preamble to assess the possible impact of the absence of some occupational exposure data on calculations of the rule's benefits.

In view of the information presented in this Unit, EPA concludes that despite OSHA's recent promulgation of new, stricter standards for exposure to asbestos in the workplace, occupational exposures and risks remain unacceptably high. As noted earlier, OSHA has observed that risks at the 0.2 f/cc PEL remain significant but that feasibility constraints prevent OSHA from setting the PEL any lower. EPA's extensive database on occupational exposures, including information collected after OSHA's 0.2 f/cc PEL became effective, indicates that individual risk remains higher than 1 in 1,000 for tens of thousands of people who work with asbestos products.

Outside of the work environment, most of the U.S. population is exposed to asbestos that is released during the life cycle of asbestos products. Some of these people are consumers who are exposed to asbestos as they install, use, repair, remove, and dispose of asbestos products that they have purchased, such as roofing materials and automotive brakes. Others are exposed to asbestos released into the ambient air during the
manufacture, installation, use, repair, and disposal of asbestos products. Risks from non-occupational exposures are not only incurred by very large populations but occasionally can be quite high. EPA estimates that approximately 40 million consumers and 19 million of those exposed to ambient asbestos incur risks of 1 in 1,000,000 or more of developing cancer from their exposure. Approximately 223,000 of those exposed to ambient asbestos incur lifetime risks of 1 in 10,000 or greater of developing cancer (Ref. 30).

Historically, consumer exposures to asbestos have not received as much attention as occupational exposures to asbestos, but they are a source of significant concern. While consumer exposures are not likely to be as frequent for individual consumers as occupational exposures are for workers, they are likely to be more intense than occupational exposures because consumers generally lack the exposure-reducing equipment and expertise available to protect workers. For instance, consumers replacing their brakes are not likely to use either solvent spray or a HEPA enclosure, the two pieces of equipment recommended by OSHA for use in reducing exposures to asbestos during brake repair.

Consumers may in fact employ a shop or household vacuum cleaner to remove asbestos dust from brake assemblies, a technique that can lead to very high exposures because most vacuum cleaners fail to capture asbestos dust and simply force it back out into the air (Ref. 59).

Consumer exposures are also experienced by a much larger population than occupational exposures. According to two recent, independent consumer surveys, approximately 40 million consumers repair their own brakes once every 3 years, and other consumer surveys indicate that at least 840,000 consumers repair their own roofs every 4 years (Ref. 31). These figures do not include consumer populations exposed to asbestos from the installation, repair, and removal of gaskets, A/C sheet, and A/C shingle, other processing during which consumer exposures are likely, but not quantified. Populations annually exposed to asbestos during brake and roof repair are presented along with equivalent information for exposures to ambient asbestos in Table IV of this Unit. Air concentration levels were estimated from occupational data. This may result in underestimates because, as noted above, consumers are unlikely to have access to the exposure-reducing work practices and engineering controls used by workers.

The ability of asbestos to persist and to spread in the environment makes it a hazard to millions of people who may not have any direct occupational or consumer contact with asbestos products. Several tons of asbestos are released to the ambient air during mining and milling, during the manufacture of asbestos products, during brake use and repair, and during construction and demolition (Ref. 29). Additional asbestos is released from asbestos products during other parts of their life cycles. Once released, this asbestos accumulates and spreads in the environment. Air monitoring studies have demonstrated that urban areas, with their high concentrations of motor vehicles, construction, and demolition, generally have levels of airborne asbestos one or two orders of magnitude higher than rural areas. While urban background levels range between 0.01 and 0.1 jg/m³ readings in large cities range from 1 jg/m³ upward (Ref. 3). Thus, asbestos released during the life cycle of asbestos products is capable of elevating ambient levels of asbestos to several times the background level.

The release estimates and atmospheric modeling that EPA used to estimate ambient exposures capture at least part of the contribution of asbestos-containing products produced and used in the future to ambient levels. Under this modeling, EPA calculated ambient exposures attributable to releases from mining and milling, the manufacture of asbestos products, brake use and repair, and construction with asbestos products. Since the proposal, these calculations have been expanded and refined to include ambient exposures from brake repair, construction, and demolition.

To estimate ambient exposures attributable to mining and product manufacturing, EPA first estimated air emissions per facility in milling and in each product category, using production volumes and the efficiency of pollution control equipment for each product category. EPA then used atmospheric dispersion modeling based on site-specific meteorological data to estimate ambient concentrations and exposed populations. Because the number of plants involved in the manufacture of asbestos products is quite large, monitoring air concentrations around each plant is impractical. The atmospheric modeling used in EPA's asbestos exposure analyses has been tested on other pollutants and has been found generally to predict their concentrations within a factor of two (Ref. 47).

As explained in the Asbestos Exposure Assessment (Ref. 29), EPA's methodology to estimate asbestos air releases from manufacturing and processing plants is presented in the March 5, 1987 draft EPA report entitled National Emission Standards for Asbestos-Background Information for Proposed Standards (Ref. 46). This document presents emission scenarios based on the only published study on the efficiency of baghouses in the asbestos industry. For each industry, three emissions scenarios were presented for baghouses operating in normal, non-failure mode: minimum, maximum, and "best estimate" emissions. These scenarios were based upon three different assumptions regarding the sensitivity of the gravimetric analytical method used in the study. For all three scenarios, TWA efficiencies were also calculated taking into account occasional baghouse failures. Time-weighted efficiencies for various asbestos product categories range from between 99.965 and 99.659 percent under the maximum emission scenario with occasional baghouse failure assumed to 99.99 percent for all products under the minimum emission scenario with no baghouse failure assumed. Under the "best estimate" emission scenario with occasional baghouse failure assumed, efficiencies range between 99.968 and 99.888.

For the maximum emission scenario with no baghouse failure assumed, a normal operating mode consisting of two efficiencies, 99.95 percent for asbestos product categories with high inlet concentrations (greater than 0.1 gram/cu ft) and 99.67 percent for product categories with low inlet concentrations (less than 0.1 gram/cu ft) was used. The asbestos product categories with high inlet concentrations, for which an efficiency of 99.95 percent was used, are asbestos-cement sheet and pipe, friction materials, and reinforced plastics. Those with low inlet concentrations, for which an efficiency of 99.67 percent was used, are paper, coatings and sealants, gaskets, and textiles. For purposes of comparison, EPA presents some results in this preamble using both the maximum emissions scenario with no baghouse failure assumed and the "best estimate" emissions scenario with occasional baghouse failure assumed. However, in many cases, EPA presents results in this preamble using only the maximum emissions scenario with no baghouse failure assumed.

EPA estimates that 122 million people are exposed to ambient asbestos...
released during milling and product manufacturing. Under the maximum emission scenario with no baghouse failure assumed, a number of people would incur risks of at least 1 in 1,000 of developing cancer from a lifetime of exposure (Ref. 30). Under the “best estimate” assumption of baghouse efficiency with occasional baghouse failure assumed, many thousands of persons would incur risks of at least 1 in 10,000 of developing cancer from ambient exposure to asbestos from plant emissions.

Table III of this Unit, based on the maximum emissions scenarios with no baghouse failure assumed, lists the exposure levels and populations associated with plant releases for each product category. For each category, exposure levels have been averaged over the entire population exposed. As detailed in Unit V.F and in the Asbestos Modeling Study, actual exposures are much higher for some people and lower for others, but the total populations and average exposures presented here provide a general gauge of exposure for each product category and were used to calculate the benefits (cancer-cases-avoided) of the rule.

Averaging has no effect on EPA’s calculation of benefits because EPA uses a linear dose-response model to project cancer-cases-avoided. A linear dose-response model assumes that an individual’s risk of developing cancer increases at a constant rate with his or her exposure to asbestos. Thus, for populations of equal size, a given increment of exposure carries the same amount of risk regardless of any differences that may exist between the populations in the magnitude of the exposures that they experience in addition to it. For example, if half of a population is exposed to an asbestos concentration of 0.19 f/cc and half is exposed to an asbestos concentration of 0.21 f/cc, the expected incidence of cancer for the entire population can be calculated by “moving” for the purposes of the analysis, 0.01 f/cc of exposure from the 0.21 f/cc population to the 0.19 f/cc population, yielding an average exposure level of 0.2 f/cc for the entire population. For populations of the same size, the 0.01 f/cc carries the same risk whether it is associated with an additional exposure of 0.2 f/cc or of 0.19 f/cc. As long as the cumulative population exposure (the sum of the products of the various exposure levels and the populations exposed to each) remains constant, it can be distributed in any way among the population without affecting the calculation of expected cancer cases. The following Table III, based on the maximum emissions scenario with no baghouse failure assumed, lists the exposure levels and populations associated with plant releases for each product category.

**TABLE III—EXPOSURES TO AMBIENT ASBESTOS FROM PRIMARY AND SECONDARY MANUFACTURING**

<table>
<thead>
<tr>
<th>Product</th>
<th>Population exposed</th>
<th>Average exposure (10^5 f/cc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial paper</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Rollboard</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Millboard</td>
<td>5,747,875</td>
<td>0.0232</td>
</tr>
<tr>
<td>Pipeline wrap</td>
<td>4,847,937</td>
<td>0.0476</td>
</tr>
<tr>
<td>Beater-add gaskets</td>
<td>37,169,666</td>
<td>0.0373</td>
</tr>
<tr>
<td>High-grade electrical paper</td>
<td>254,772</td>
<td>0.405</td>
</tr>
<tr>
<td>Roofing felt</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Flooring felt</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Corrugated paper</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>V/A floor tile</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>3,313,602</td>
<td>0.167</td>
</tr>
<tr>
<td>A/C flat sheet</td>
<td>21,223,368</td>
<td>0.0218</td>
</tr>
<tr>
<td>A/C corrugated sheet</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A/C shingle</td>
<td>891,142</td>
<td>0.00386</td>
</tr>
</tbody>
</table>

**TABLE IV—EXPOSURES TO AMBIENT ASBESTOS FROM CONSTRUCTION AND BRAKE REPAIR AND EXPOSURES FROM CONSUMER BRAKE AND ROOF REPAIR**

<table>
<thead>
<tr>
<th>Process</th>
<th>Installation</th>
<th>Repair and disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>10^5 f/cc/yr</td>
<td>Population</td>
</tr>
<tr>
<td>Roofing felt</td>
<td>171,136,373</td>
<td>0.000098</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>171,136,373</td>
<td>0.0000264</td>
</tr>
<tr>
<td>A/C flat sheet</td>
<td>171,136,373</td>
<td>0.00000289</td>
</tr>
<tr>
<td>A/C corrugated sheet</td>
<td>171,136,373</td>
<td>0.00000043</td>
</tr>
<tr>
<td>A/C shingles</td>
<td>171,136,373</td>
<td>0.0000052</td>
</tr>
<tr>
<td>Drum brake linings (LMV)</td>
<td>183,793,774</td>
<td>0.0123</td>
</tr>
<tr>
<td>Disc brake pads (LMV)</td>
<td>170,871,494</td>
<td>0.00000597</td>
</tr>
<tr>
<td>Disc brake pads (HV)</td>
<td>170,871,494</td>
<td>0.0000171</td>
</tr>
<tr>
<td>Brake blocks</td>
<td>210,250</td>
<td>1.104</td>
</tr>
</tbody>
</table>

To calculate exposures to asbestos released into the ambient air through brake use, EPA first calculated the total amount of asbestos emitted from brakes in each of 24 American cities, using studies on brake emissions and...
estimates of miles traveled by vehicle type (because emissions vary by vehicle type) in each city. Second, EPA performed atmospheric dispersion modeling of these emissions to estimate concentrations in each city. Third, EPA grouped the cities together by population, obtaining average concentrations for each group. To estimate the populations exposed to each of these average concentrations nationwide, EPA added up the populations living in the U.S. cities similar in size to the cities of each group. Because none of the original 24 cities had fewer than 25,000 inhabitants and because vehicular traffic is less concentrated in rural areas than in cities, populations living in areas with fewer than 25,000 inhabitants were assumed to have no exposure to asbestos released during brake use. Finally, EPA averaged the estimated concentrations over all population groups from areas with more than 25,000 inhabitants, weighting each concentration by the population exposed to it. Using this technique, EPA estimates that 100 million people (the 1980 U.S. population living in areas of more than 25,000 people) are exposed to 8.7 \times 10^3 \mu g/m^3 of asbestos resulting from the use of asbestos brakes (Ref. 31). The individual risk of developing cancer from a lifetime of exposure to this concentration of asbestos is estimated at approximately 1 in a million, a level which is significant given the very large population exposed. Because populations living in areas with fewer than 25,000 people (55.5 percent of the U.S. population) probably are exposed to at least some asbestos from brake use, this estimate should be considered a lower bound.

In addition to the exposures quantified above, EPA believes that other significant ambient exposures occur that cannot be easily quantified. One type of unquantified exposure results from releases of asbestos that are difficult to measure, such as the gradual weathering and disintegration of construction products used outdoors. A number of studies indicate that these releases are probably significant. Indirect evidence of weathering comes from several studies of corrosion in A/C pipe: soft, acid water has been found to dissolve A/C pipe in some instances (Ref. 64). Because rainwater is likely to be both soft and acid, it is likely to be very corrosive to A/C materials.

Direct evidence of weathering supports this projection. A study of erosion in A/C shingle found visible differences in wear between areas of shingle that were exposed to the elements and areas that were protected, and inspection of the worn areas with a scanning electron microscope revealed a network of asbestos fibers at the shingle surface. In addition, concentrations of asbestos as high as 543 million fibers per liter (mFL) were found in runoff collected from roofs covered in A/C single. Ten mFL considered abnormally high (Ref. 51). Another study detected asbestos releases from construction materials after a shingle storm: several air samples taken after a heavy rain at a school with A/C walkways and roof panels showed significantly elevated asbestos concentrations (Ref. 1). Thus, in areas where there is widespread use of A/C sheet and A/C shingle, weathering is probably an important source of ambient asbestos.

Another type of unquantified exposure results from the tendencies of asbestos to persist in the environment and to reenter the air after settling out. Both the durability and aerodynamic properties of asbestos are well documented. The extraordinary ability of asbestos to survive for long periods under a variety of different conditions is often cited as an important reason for its incorporation into a number of products, including paper products used as insulation, friction materials, asbestos cement products, packings, and gaskets. Reentrainment is supported by studies finding high airborne asbestos concentrations not only near waste piles but upwind as well as downwind of point sources (Ref. 48), a finding most likely to result from the resuspension of asbestos deposited earlier by winds blowing in the opposite direction. This evidence indicates that over time, asbestos builds up to some degree in surface waters and soils and that some of this build-up is continuously reentrained to the environment. This process of build-up and reentrainment is referred to as environmental loading. Because the likelihood of reentrainment in the environment depends upon a number of factors that are difficult to measure, including the fraction of asbestos that is washed away by rainfall or burned under later soil deposits, reentrainment has not been included in EPA's atmospheric modeling. Thus, EPA has not quantified exposures attributable to environmental loading. Nonetheless, EPA is very concerned about the possible impact of this process on exposures to ambient asbestos. Given its durability, asbestos may persist in the environment for a decade or more after its original release, and environmental loading is likely to be most severe in urban areas, where large populations both create and come into contact with asbestos releases. In fact, the elevated concentrations of asbestos found by numerous studies in urban areas probably result at least in part from environmental loading. The potential longevity of the risk posed by environmental loading was a major factor in EPA's decision to eliminate that risk at its source by banning most asbestos products.

Some commenters argued that exposures to asbestos released into the ambient air by the manufacture, importation, processing, and use of asbestos-containing products are insignificant because the risks associated with such exposures are very small. However, individual risks from asbestos in the ambient air can be quite high for persons living near asbestos product plants, construction sites, or other sources of release. As noted earlier, under the maximum emission scenario with no baghouse failure assumed, a number of people would incur risks of at least 1 in 1,000 of developing cancer by living in such areas. Under the "best estimate" emissions scenario, many thousands of people would still incur a risk of at least 1 in 10,000 from ambient exposure to asbestos from plant emissions. Moreover, while most people exposed to ambient asbestos from asbestos-containing products incur individual risks smaller than 1 in 1,000, the number of people exposed is extremely large, making the total risk a concern.

c. Exposure from imported and exported asbestos products. EPA has determined that significant exposure is likely from imported asbestos products. Although some exposure to U.S. populations is avoided when asbestos products are manufactured abroad and imported rather than manufactured in the U.S. (foreign exposures and resulting cancer cases are not included in the estimates for this rule), significant exposures still occur after import of the products into this country. U.S. exposures occur during transport, installation, use, maintenance, removal, and disposal of the product. As noted above, large numbers of people are exposed to asbestos during these activities and the level of exposure is often quite high.

Significant exposures also occur during the U.S. portion of the life cycle of asbestos-containing products manufactured in this country for export. These exposures occur during the mining and milling of asbestos fiber and the processing of fiber into products. Families of workers and populations living near mining and manufacturing
sites are also exposed to asbestos as a result of these activities. Therefore, as is discussed in Unit III.B of this preamble, EPA finds under section 12(a)(2) of TSCA that the manufacture or processing for export of asbestos-containing products that are subject to the rule will present an unreasonable risk of injury to human health. Therefore, the manufacture and processing of asbestos-containing products for export is not exempted from this rule under section 12(a)(1), and is subject to the rule's bans.

d. Exposure conclusions. In conclusion, EPA finds the intensity, scope, and potential longevity of human exposure to asbestos released during the life cycles of the products subject to this rule cause for serious concern. In spite of efforts to control exposure, asbestos is released and inhaled at all stages of the life cycles of asbestos products; extensive exposures have been quantified for workers, consumers, and the general population. EPA estimates that thousands of asbestos workers and pharmaceutical products members of the general population incur individual risks near 1 in 1,000 from exposure to asbestos released from the products subject to this rule and that millions of people incur risks near 1 in 1,000,000 from such exposure. These risks are very large. Moreover, evidence indicates that significant exposures take place that cannot be quantified. EPA is especially concerned about exposures from environmental loading, which may occur long after the initial release of asbestos from a product.

B. Environmental Effects

The unreasonable risk finding for this rule is based on the risks to human health posed by exposure to asbestos. These risks are the most readily quantifiable consequences of the commercial use of asbestos and are sufficient to support the actions taken in this rule. However, EPA is concerned about the potential environmental effects of ambient loading due to continued manufacture, importation, processing, and use of commercial asbestos products. Exposure to asbestos fibers has been clearly shown in both human and animal studies to cause severe health effects. Effects on wildlife have not been counted for purposes of this rule. However, because asbestos fibers are extremely durable and transportable, EPA believes that continued asbestos use will leave a legacy of serious health and environmental effects due to unnaturally high concentrations of asbestos in the ambient air.

C. Asbestos Substitutes

This Unit discusses the relative availability of substitutes for asbestos in asbestos-containing products and the potential health hazards posed by such substitutes. EPA has found that suitable substitutes currently exist for most uses of asbestos. EPA believes that the benefits to society of asbestos-containing products are relatively small because of the current availability of many substitutes and the expected development of others after promulgation of this final rule.

1. Availability of substitutes. This subject is described in more detail in Volume III, Appendix F of the Regulatory Impact Analysis (RIA). Further responses to comments on these subjects can be found in the Response to Comments Document. The availability of substitutes for the various product groupings subject to this rule are discussed in Unit V.F of this preamble.

The following Table V lists currently-available major substitutes for asbestos-containing products that are banned by this rule and the market shares for each product category projected for the substitutes in the absence of asbestos. This breakdown does not take into account the development of new substitutes or new applications of existing substitutes since the preparation of the RIA. It also does not account for the likely development of new substitutes before the effective date of this rule's bans. EPA is aware that it may not have identified all substitutes for asbestos-containing products and that the costs of the rule may be overstated as a result.

<table>
<thead>
<tr>
<th>Product and substitute</th>
<th>Approximate Substitute Market Share (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/C pipe:</td>
<td></td>
</tr>
<tr>
<td>Polyvinylchloride (PVC)</td>
<td>27</td>
</tr>
<tr>
<td>Ductile iron</td>
<td>7</td>
</tr>
<tr>
<td>A/C flat sheet:</td>
<td></td>
</tr>
<tr>
<td>Calcium silicate</td>
<td>77</td>
</tr>
<tr>
<td>Non-calcium silicate</td>
<td>4</td>
</tr>
<tr>
<td>Laboratory sheet</td>
<td>20</td>
</tr>
<tr>
<td>A/C corrugated sheet:</td>
<td></td>
</tr>
<tr>
<td>Fiberglass reinforced plastic</td>
<td>98</td>
</tr>
<tr>
<td>Aluminum</td>
<td>32</td>
</tr>
<tr>
<td>Steel</td>
<td>11</td>
</tr>
<tr>
<td>Polyvinylchloride</td>
<td>9</td>
</tr>
<tr>
<td>A/C shingles:</td>
<td></td>
</tr>
<tr>
<td>Wood</td>
<td>32</td>
</tr>
<tr>
<td>Vortex and cellulose</td>
<td>27</td>
</tr>
<tr>
<td>Asphalt</td>
<td>20</td>
</tr>
<tr>
<td>Aluminum</td>
<td>9</td>
</tr>
<tr>
<td>Tile</td>
<td>2</td>
</tr>
<tr>
<td>Drum brake linings:</td>
<td></td>
</tr>
<tr>
<td>Non-asbestos organics</td>
<td>99</td>
</tr>
<tr>
<td>Semi-metallic</td>
<td>1</td>
</tr>
<tr>
<td>Disc brake pads (LMW and HMW):</td>
<td>100</td>
</tr>
<tr>
<td>Semi-metallic</td>
<td>100</td>
</tr>
<tr>
<td>Brake blocks:</td>
<td></td>
</tr>
<tr>
<td>Non-asbestos organics</td>
<td>99</td>
</tr>
<tr>
<td>Semi-metallic</td>
<td>1</td>
</tr>
<tr>
<td>Clutch facings:</td>
<td></td>
</tr>
<tr>
<td>European woven</td>
<td>50</td>
</tr>
<tr>
<td>U.S. woven</td>
<td>30</td>
</tr>
<tr>
<td>Molded aramid</td>
<td>10</td>
</tr>
<tr>
<td>Molded fiberglass</td>
<td>15</td>
</tr>
<tr>
<td>Automatic transmission components:</td>
<td>100</td>
</tr>
<tr>
<td>Cellulose</td>
<td>100</td>
</tr>
<tr>
<td>Other friction materials:</td>
<td>100</td>
</tr>
<tr>
<td>Fiberglass &amp; para-aramed</td>
<td>100</td>
</tr>
<tr>
<td>Millboard:</td>
<td></td>
</tr>
<tr>
<td>Standard board</td>
<td>80</td>
</tr>
<tr>
<td>Premium board</td>
<td>20</td>
</tr>
<tr>
<td>Specialty paper:</td>
<td></td>
</tr>
<tr>
<td>Earth and cellulose</td>
<td>50</td>
</tr>
<tr>
<td>Loose cellulose</td>
<td>50</td>
</tr>
<tr>
<td>Roof coatings:</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>87</td>
</tr>
<tr>
<td>Polyethylene</td>
<td>8</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
</tr>
<tr>
<td>Non-roof coatings:</td>
<td></td>
</tr>
<tr>
<td>Synthetic fibers</td>
<td>70</td>
</tr>
<tr>
<td>Clay and mineral</td>
<td>30</td>
</tr>
</tbody>
</table>

Substitutes for asbestos products are being developed and accepted in the marketplace. It should be noted that a number of products that are subject to this rule's bans are no longer manufactured or imported in the U.S. In these cases, viable substitutes have apparently forced asbestos-containing products from the U.S. market. An increasing rate of availability and acceptance of substitutes is evidenced by a more rapid decrease in asbestos use in most product categories than was predicted in the RIA for the proposal. Public comments have identified new substitutes and indicated that substitute prices have decreased substantially beyond the estimates generated in the RIA for this final rule. In addition, EPA believes that this rule will further spur
the development of substitutes, thereby increasing availability and decreasing costs.

2. Health risk review of fibrous asbestos substitutes. This Unit addresses the potential health risks caused by exposure to various fibers projected to replace asbestos in products banned by this rule. This subject is discussed in more detail in (1) "Review of Recent Epidemiological Investigations on Populations Exposed to Selected Non-asbestos Fibers" (Ref. 35); (2) "Durable Fiber Exposure Assessment" (Ref. 36); (3) "Durable Fiber Industry Profile and Market Outlook" (Ref. 37); and (4) "Health Hazard Assessment of Non-asbestos Fibers" (Ref. 38). Further responses to comments on this subject can be found in the Response to Comments document.

Based on available information and a public health policy regarding asbestos, EPA has more concern about the continued use and exposure to asbestos than it has for the future replacement of asbestos in the products subject to this rule with other fibrous substances. Available information about the fibrous substitutes under review for this rulemaking supports the conclusion that the fibrous substitutes appear to pose a lower human health hazard than asbestos (Ref. 38). However, due to limited data, EPA cannot quantify the risk that may be posed by asbestos substitutes. EPA believes it is prudent public health policy to regulate asbestos rather than to delay regulation until all risks of substitute products are definitively determined. This conclusion is based on a consideration of (1) Available data on the health hazards and exposures posed by asbestos and its substitutes; (2) the factors that enhance or mitigate fiber pathogenicity; (3) the degree of the deficiencies of the data available on health hazards and exposures of substitutes; and (4) EPA’s public health policy of reducing known, serious health risks.

a. Background. EPA, for the proposed rule, performed a review of the available hazard and exposure information on eight fibrous substances that could substitute for asbestos in Asbestos Substitutes and Related Materials" (Ref. 39). In response to public comments received on the proposal, EPA conducted an extensive review of available information and updated its hazard and exposure assessment of fibrous asbestos substitutes (see Refs. 35, 36, 37 and 39).

Specifically, this analysis included six man-made or synthetic fibrous materials (aramid fibers, carbon fiber, ceramic fibers, fiberglass, mineral wool, and polyolefin fibers), and two naturally-occurring fibers (attapulgite and wollastonite). These eight fibers were individually selected for review because (1) They are commercially important; (2) they are potentially the most fibrous substitutes; (3) they represent fiber types with broadly different physical and chemical characteristics; and (4) hazard and exposure data are available. EPA chose to place its emphasis on the review of fibrous substitutes because their morphological similarity to asbestos suggested that they may induce cancer. Other non-fibrous substitutes, specifically, wood and other cellulose products, cement, and bricks, appear to pose little or no health hazard and, for this reason, their potential health effects have not been analyzed in detail for purposes of this rule.

b. Health effects of fibrous substitutes. EPA conducted a comprehensive review of the experimental and epidemiological hazard data for the eight major substitutes (Refs. 35 and 38). Available epidemiological and toxicological data indicate that inhalation exposure to some fibrous substitutes may be associated with malignant and non-malignant diseases in humans. However, the evidence of carcinogenicity and fibrogenicity of these substitutes is more limited than for asbestos. Based on available data, EPA has concluded that, under similar experimental conditions, the fibrous substitutes are generally less biologically active and pathogenic than asbestos (Ref. 38). Unlike the fibrous substitutes, asbestos is a well-recognized, potent human carcinogen, which also causes non-malignant pulmonary effects. At this time, EPA cannot make a definitive assessment of the biological and pathogenicity of fibrous substitutes in comparison with asbestos because available data on the health effects of the substitutes are incomplete. EPA has not derived a carcinogenic potency for any of the fibrous asbestos substitutes suspected to pose a carcinogenic concern, because either available epidemiological data and/or animal inhalation data are inadequate to establish a quantitative exposure-response relationship or tumor response has only been observed in animals via non-physiological routes of administration, such as intraperitoneal injection (Ref. 38).

One commenter contended that a potency value could be derived for fibrous glass and mineral wool based on epidemiological data and concluded that the potency may be comparable to or exceed the potency established for asbestos. EPA has concluded that a potency value cannot be derived for fibrous glass because the epidemiological evidence for carcinogenicity of these substances is inadequate. The data cited by the commenter do not show consistent elevation of lung cancer risks in exposed workers or provide sufficient information to demonstrate a dose-response relationship (Ref. 35). Further, it is not appropriate to compute potency values from the available experimental data because the inhalation studies in animals did not produce tumorigenic responses (Ref. 38). Similarly, carcinogenic potency cannot be determined for mineral wool because dose-response information is not available from existing epidemiological studies (Ref. 35) and no tumorigenic responses were found in available inhalation studies (Ref. 38).

The commenter also stated that a unit cancer risk could be developed for aramid fibers using results from an animal inhalation bioassay for ultrafine para-aramid. The commenter made use of the linearized multi-stage procedure to calculate risk. In calculating the unit cancer risk value, the commenter only considered a subset of the bioassay data (Ref. 50). Consequently, EPA does not believe that the analysis presented by the commenter adequately reflects the results of the bioassay (Ref. 50). EPA is continuing to gather additional information to evaluate potential cancer risk of respirable aramid fibrils. Additionally, EPA is assessing the appropriate model to use to extrapolate cancer risk for aramid fibrils.

Unprocessed commercial-grade para-aramid, a type of aramid fiber, is manufactured in sizes that are too large to be respirable (Ref. 36). In addition, not all types of aramid fibers are expected to produce fibrils (e.g., continuous para-aramid) (Ref. 36). The para-aramid used in the cited animal study was a highly respirable material made specifically for the study (Ref. 36). Although the commenter cited-grade of para-aramid is believed to have the potential to generate respirable fibers as the small fibrils peel off from the non-respirable core matrix, exposure data are too limited to determine if fibril formation poses a significant concern. Limited monitoring data (combined area samples and personal samples) indicate that exposures to para-aramid fibrils range from not detectable to a maximum of 7.6 f/cc (Refs. 36, 34, and 55). According to a commenter, during manufacture, a maximum likely 8-hour TWA of 0.1 f/cc was recorded. According to the same commenter, during production and processing of
friction materials, the maximum likely 8-hour TWA was less than 0.1 f/cc. Due to the way that the monitoring data were presented, it is difficult to determine if these data are representative of occupational exposure (Refs. 52 and 53). In addition to the limited monitoring data, exposures were only monitored at a few industrial operations which are suspected of producing respirable fibers (Ref. 52). Additionally, it is not known if these operations are representative of the industry (Ref. 53). Based on available information, EPA believes that neither commercial-grade aramid products nor fibrils formed from such products may pose major occupational, consumer, and ambient exposures. Generally, it appears that aramid fibrils tend to curl and clump together, thus reducing their tendency to become airborne. Fibril formation appears to be a by-product of aramid manufacture and processing. Fibrils are not expected to become an integral component of aramid products. In contrast, asbestos becomes airborne easily and can remain airborne for long periods of time.

c. Respirability. A basic property which allows a fiber’s potential toxicity to be expressed is its respirability, i.e., the ability to penetrate into the lower respiratory tract. Respirable fibers are generally defined as fibers with actual diameters of less than about 3.5 microns or an aerodynamic diameter of less than about 10 microns. Once in the lower respiratory tract, other factors such as fiber length and diameter, surface, and chemical properties are thought to influence biological activity (Ref. 38).

According to available information, a large percentage of the production volume of these fibrous substitutes consists of non-respirable fibers (Ref. 36). Because non-respirable fibers are unlikely to enter and penetrate the lung, such fibers pose minimal risk of inhalation toxicity. However, some portion of the production volume for many of these substitutes contains fibers of respirable size. Such fibers are of concern to EPA. However, available information indicates that fibers in the respirable size range are generally manufactured for specialty uses, such as high-temperature insulation materials, filtration media, ear defenders, spacecraft, and aircraft insulation (Ref. 36). Specialty uses may be of concern in terms of risk to individuals but do not have as great a potential for broad population exposures.

d. Exposure of fibrous substitutes.

EPA conducted an analysis of the durable fibers industry which included information about producers, uses, and future trends of the eight fibrous substitutes (Ref. 37). EPA also developed an exposure profile of durable fibers (Ref. 36). To this end, EPA conducted a search of the literature and surveyed industry sources. This analysis focused primarily on activities and applications most likely to generate airborne fibers of respirable size. Exposure data for fibrous substitutes, although very limited, were available for all fibers except polyolefins. Most exposure data available in the literature are for fiber manufacture. Exposures during man-made and synthetic fiber production are typically less than 1.0 f/cc because processes are highly automated and often enclosed, meaning that operators are rarely in contact with the fiber (Ref. 36). Many of the packaging operations are also automated and ventilated, and the exhaust is sent to dust collection equipment (Ref. 36). Often the fiber size composition of airborne material is not noted. When fiber size distinctions have been made, respirable fibers can constitute 50 percent or more of airborne fibers. However, as noted above, airborne fibers typically measured less than 1.0 f/cc. Much of the airborne occupational exposure data available to EPA is outdated. Since many of these data were developed, the industry has become increasingly automated (Ref. 36). Therefore, current exposure levels may be lower.

Production of naturally-occurring substitute fibers presents a different exposure scenario than man-made fibers since the former are mined and milled. Mining and milling have traditionally been “dusty” operations where the use of engineering controls or personal protective equipment is difficult to integrate into the routine operations of the industry. Mining operations are labor intensive and exposures are likely; however, they can be performed in open pits which allows for some ventilation. Milling operations use mechanical grinding and screening machines and exposure occurs to workers who run these machines. Both dust and fiber concentrations have been shown to significantly exceed OSHA’s nuisance dust standards (Ref. 36).

During wollastonite milling, a limited study found fiber concentrations ranging from 30 to 80 fibers/cc (Ref. 36). While worker exposure to attagapulite and wollastonite may be high during certain mining and milling activities, available information indicates low hazard for wollastonite or short fiber attagapulite (Ref. 38). Attagapulite mined in the U.S. is of the short fiber variety (Ref. 36). The U.S. supplies over 90 percent of the world-wide demand for attagapulite (Ref. 37). Based on EPA's analysis (See Unit V.C.1 of this preamble), neither attagapulite or wollastonite are expected to be important asbestos substitutes.

Some commenters cited exposure data for various fibrous products and concluded that the exposures sometimes exceeded the asbestos PEL. These commenters were concerned that exposures may pose a significant risk. In general, production and use of respirable man-made fibers and mining and milling of the naturally-occurring mineral fibers, may potentially result in some exposures that exceed exposures from asbestos (Ref. 36). While the data on certain fibrous substitutes indicate that occupational exposure may range from not detectable to levels that exceed the asbestos PEL, levels in excess of the asbestos PEL alone will not lead to significant risks unless the substitutes present a health hazard of a magnitude approaching that of asbestos. As explained above, available information on the hazards of the fibrous substitutes indicate that they are less biologically active and pathogenic than asbestos.

Given the scarcity of exposure data, the numerous types of processes or activities involved, and the variable characteristics of the many fibrous materials, EPA has concluded that reliable projections cannot be made about exposures to fibrous asbestos substitutes. This is contrasted with asbestos manufacturing, processing, and use practices, about which much is known and such conclusions or reasonable projections about exposure can be made.

e. Risk of fibrous substitutes.

Some commenters stated that EPA should perform risk analyses of the same depth for the non-asbestos substitutes as EPA performed for asbestos. Commenters also stated that EPA’s substitute analysis should consider the entire life cycle of the substitute, including the risk associated with non-asbestos raw materials, by-products, contaminants, and energy production. Additionally, some commenters stated that EPA should consider other health and environmental effects in addition to cancer associated with the substitutes, including silicosis and death due to trauma.

For reasons described previously, EPA believes that the available data base on the hazards and exposure to substitute fibers is not sufficient for EPA to perform a quantitative risk analysis. While EPA adopted a life cycle approach to its risk analysis for asbestos, EPA did not include in that
analysis additional risks that may result from: (1) Exposure to raw materials, byproducts, or contaminants associated with production and use of asbestos-containing products; (2) accidents; or (3) energy production and consumption required to produce asbestos products. EPA quantified, to the extent possible, only risks of cancer associated with exposure to asbestos fibers. EPA adopted a similar life cycle approach in its review of substitutes and only evaluated the potential that the fiber itself may cause cancer or non-malignant lung effects. In summary, the review approach adopted for substitutes is comparable to the approach used for asbestos and is only limited by the availability of data.

Some commenters stated that EPA could not conclude, based on available data, that substitutes pose lower risk than asbestos. EPA agrees that the data base is insufficient to quantify the risk of substitutes; however, in spite of the deficiencies of the data base, information is available to indicate that: (1) Some non-fibrous asbestos substitutes pose little or no health risk concern; (2) the inherent biological activity or pathogenicity of the substitute fibers appears to be less than asbestos; (3) a large percentage of the total production volume of fibrous substitutes is non-respirable, and thus does not pose a risk concern; and (4) the diameter size of man-made and synthetic fibers may be controlled, thus enhancing efforts to reduce the presence of contaminant asbestos.

1. Policy approach to asbestos and asbestos substitutes. Regulatory decisions about asbestos which poses well-recognized, serious risks should not be delayed until the risk of all replacement materials are fully quantified. EPA believes that this is a prudent policy since: (1) Asbestos is a human carcinogen and poses a serious risk to health; (2) substitute fibers appear to pose less hazard; (3) years are likely to pass before experimental toxicological data are available to quantify or adequately evaluate the possible health effects of substitutes; (4) a decade or more may pass before epidemiological data of the quality that exists for asbestos may be available to confirm asbestos hazards of substitutes identified in experimental data; (5) evolving fiber technology and the advances within the chemical industry are likely to create new substitutes, thus making it quite difficult to ever fully analyze the risks of all possible major substitutes; and (6) risks associated with man-made and synthetic fibers appears easier to control than the risks resulting from asbestos use because fiber diameter size can be technologically controlled.

EPA will control to evaluate hazards and exposures posed by fibrous materials and will determine appropriate regulatory action to mitigate any unreasonable risks that may be identified. EPA may consider regulation of fiber diameter and length of substitute fibers if it is determined that such risk reduction action is needed. EPA recommends, that, whenever feasible, manufacturers, processors, and users avoid the production and use of respirable fibers. EPA also strongly encourages manufacturers and processors of fibers to institute quality control practices that minimize if not eliminate the inadvertent production of respirable fibers.

D. Economic Effects of the Rule

EPA has prepared a Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products (Ref. 21) which analyzes the potential economic impact of the rule. EPA’s assessment of the “reasonably ascertainable economic consequences of the rule,” pursuant to section 6(c)(1)(D), is summarized below. The methodologies used by EPA to estimate the costs and benefits of this rule comport with widely-accepted cost-benefit techniques. The methodologies used and the data on which costs and benefit estimates are based have been updated to reflect public comments. Further responses to comments on this subject can be found in the Response to Comments document.

1. Estimated costs. Estimated costs were derived using the Asbestos Regulatory Cost Model (ARCM), which is described in the RIA and which primarily used information collected during telephone surveys conducted by an EPA contractor during 1986 and 1987. EPA also used some data obtained under the TSCA section 8(a) asbestos rule to estimate costs. Some information was adjusted to reflect more current data obtained through public comments and from other sources. The sources of information are noted in the record for this rule.

The costs represent the net present value of costs incurred due to changes in asbestos production volume between the years 1987 and 2000, using a social rate of discount of 3 percent. The 13-year time period serves as a reasonable endpoint for the analysis at a point well after all the actions taken in the rule have become effective. The 3 percent rate used to discount costs (and benefits, as discussed below) is a reasonable rate set by consensus by EPA economists. This figure falls within the range of social discount rates suggested by the economics literature.

In estimating the costs of this rule, allowance is made by the economic model to estimate declines in the prices of substitutes. In practice, the cost of a product, in real terms, declines over its production as experience is gained in the manufacturing process. In addition, experience under other regulations has shown that the number of substitutes will increase as a result of product regulation. Some of the new substitutes will be of lower cost than some of the existing substitutes or they will not capture market share from the existing substitutes. Both of these effects will lower the prices of substitutes. Neither of these effects can be fully quantified. However, as the cost of substitutes decreases, the overall cost of this rule will also decrease.

The economic model does not take into account the cost reduction benefits of using substitutes which currently have lower costs than the asbestos-containing products. In other words, the analysis assumes that the price of substitutes, after being adjusted for product life and performance, is always greater than or equal to the price of the comparable asbestos-containing product. This was done to account for differences in the characteristics of asbestos and non-asbestos substitute products that cannot be captured in cost differences. For example, because asbestos-containing products have been traditionally used in these markets, a bias may exist toward the use of asbestos products rather than similarly-priced substitutes. However, this assumption overstates the costs imposed by the rule whenever the substitute actually costs less than the asbestos-containing product and there is no significant difference in product performance characteristics.

EPA attempted to gauge the possible effects of expected declines in the price of substitutes on the overall cost of the rule. The analysis of costs of the actions taken in this rule assumes that the prices of substitutes for asbestos products will decrease by 1 percent annually over the life of the 13-year period analyzed in the ARCM. However, the analysis also assumes that the cost of individual substitute products will always remain greater than or equal to the price of the comparable asbestos-containing product, for the reasons described in the preceding paragraph.

EPA believes that the assumption of a limited 1 percent decline in the price of substitutes is a reasonable "best
estimate" in light of the effects of the growing markets for such products, increasing competition and production know-how in these markets, and the likely development of new, more cost-effective substitutes that have not been quantified for the ARCM.

Costs estimated in the RIA include costs to consumers and costs to producers. Consumer losses due to the rule result from increases in costs incurred for asbestos products or substitutes for asbestos products or from inferior performance of substitutes, to the extent that these latter costs could be quantified. It is estimated that consumers will incur $375.4 million in losses as a result of the actions taken in this rule, for the period of the analysis, spread across the retire consumer population.

Producer losses due to this rule would accrue when producers are forced to forego the portion of the return on their capital stock used to produce asbestos products. This occurs when the capital stock used in the production and processing of asbestos-containing products either cannot be used or cannot be used as efficiently in the production of substitute products. It is estimated that the rule will result in $83.49 million in total producer costs.

The rule will also result in some transition costs to workers who are displaced by product bans. These losses are incurred in the form of lost wages and job search costs. EPA believes that these transition costs will be relatively low compared to consumer and producer costs because of: (1) The amount of time allowed for companies to plan before the effective dates of most bans and (2) the already occurring transition to non-asbestos substitutes by many former producers of asbestos products.

The total costs of the rule were estimated first with costs discounted at 3 percent and benefits not discounted (hereafter 3 percent/0 percent) and then with both costs and benefits discounted at 3 percent (hereafter 3 percent/3 percent). The results of both analyses will be cited throughout the text of this preamble. Both analyses support the actions taken in this rule. The total estimated cost of the rule is $458.89 million. This cost will be spread over 13 years and a large population. Therefore, the impact on most persons will be negligible.

Estimated total costs of individual product bans are set forth in the following Table VI:

<table>
<thead>
<tr>
<th>Product</th>
<th>Total cost (in $ million, discounted at 3 percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos/ceament (A/C) sheet</td>
<td>2.66</td>
</tr>
<tr>
<td>A/C shingles</td>
<td>23.57</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>128.03</td>
</tr>
<tr>
<td>Products not currently in U.S. production (asbestos protective clothing and vinyl/asbestos floor tile)</td>
<td>0</td>
</tr>
<tr>
<td>Paper products (commercial paper, rollboard, millboard, corrugated paper, and specialty paper)</td>
<td>2.73</td>
</tr>
<tr>
<td>Felt products (flooring and roofing felt and pipeline wrap)</td>
<td>8.30</td>
</tr>
<tr>
<td>Gaskets</td>
<td>207.72</td>
</tr>
<tr>
<td>Disc and drum brake pads for original equipment market (OEM) and brake blocks</td>
<td>12.73</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>12.73</td>
</tr>
<tr>
<td>Other asbestos friction products (automatic transmission components, clutch facings, and commercial and industrial friction products)</td>
<td>15.20</td>
</tr>
<tr>
<td>Coatings (roof coatings and nonroof coatings)</td>
<td>48.29</td>
</tr>
</tbody>
</table>

Does not include specialty industrial gaskets.

EPA also analyzed the costs of the rule without the assumption about the declining price of substitutes that is described in the preceding paragraphs. Under this scenario, the total cost of the rule would rise from $458.89 million to $806.51 million. Estimated total costs of individual product bans under this scenario are set forth in the following Table VII:

<table>
<thead>
<tr>
<th>Product</th>
<th>Total cost (in $ million, discounted at 3 percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos/ceament (A/C) sheet</td>
<td>3.35</td>
</tr>
<tr>
<td>A/C shingles</td>
<td>34.18</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>227.33</td>
</tr>
<tr>
<td>Products not currently in U.S. production (asbestos protective clothing and vinyl/asbestos floor tile)</td>
<td>0</td>
</tr>
<tr>
<td>Paper products (commercial paper, rollboard, millboard, corrugated paper, and specialty paper)</td>
<td>4.66</td>
</tr>
<tr>
<td>Felt products (flooring and roofing felt and pipeline wrap)</td>
<td>10.67</td>
</tr>
<tr>
<td>Gaskets</td>
<td>263.01</td>
</tr>
<tr>
<td>Disc and drum brake pads for original equipment market (OEM) and brake blocks</td>
<td>31.68</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>25.15</td>
</tr>
</tbody>
</table>

Does not include specialty industrial gaskets.

The costs in both of these analyses are likely overstated for a number of reasons. The methodology used in this analysis for dealing with a lack of information tends by design towards overestimating costs and underestimating benefits. This "cautious" approach is taken to ensure that the analysis provides a strong basis for the regulatory decision made in this rule.

A commenter stated that EPA, in the analyses used to support the proposed rule, underestimated the costs of banning the manufacture, importation, and processing of asbestos-containing products. The commenter argued that EPA overestimated the rate of development of asbestos substitutes, underestimated future asbestos consumption rates, and erred in a number of other ways, discussed in more detail in the Response to Comments document, in estimating the costs associated with the various options described in the proposed rule.

For the final rule, EPA has updated the data base used to support its analysis of the costs and benefits of the rule and has modified its analytical approach in response to comments. In addition, the decline in the rate of consumption of asbestos in the U.S. has been more rapid in recent years than was predicted in EPA's models. There were more rapid than predicted declines in asbestos consumption rates in the U.S. from a high of 240,000 metric tons in 1985 to a low of 185,000 metric tons in 1987. This change suggests that the use of asbestos substitutes has increased markedly since the proposed rule was published.

EPA has adopted several conservative assumptions to ensure that the rate of substitution is not overstated in the analysis of the rule's costs. The analysis embodies a low-decline baseline consumption approach. This approach assumes that substitutes have already
been adopted for those market sectors for which substitution for asbestos was relatively uncomplicated. It also assumes a constant rate of asbestos consumption unless EPA is aware of specific instances in which substitution has been made. In addition, the analysis assumes that the price of a substitute for an asbestos product will not fall below the price of the asbestos product for which it is being substituted. Therefore, the analysis adopts a number of assumptions that likely overestimate the costs of the actions taken in this rule rather than underestimate them.

2. Estimated benefits. The costs described above will be offset to some extent by a number of avoided costs. While EPA did not attempt to place a value on the loss of life itself, or on associated costs such as “pain and suffering,” “loss due to leisure time, or other similar factors, EPA has estimated that the actions taken in this rule will result in the avoidance of at least 202 quantifiable cases of lung and gastrointestinal cancer and mesothelioma when benefits are not discounted and at least 148 cancer cases when benefits are discounted at 3 percent from the time of exposure.

These estimates assume the occupational exposure levels based on other analogous exposure scenarios discussed in Unit V.A.3 of this preamble. These estimates do not, for reasons discussed in Unit V.A. of this preamble, include the number of asbestosis cases and cases of other diseases avoided. In addition, EPA did not estimate losses due to lost work days or medical care costs. Thus the benefits of the rule (costs avoided by this rule) represent prudent estimates that likely understates actual benefits. The cancer-cases-avoided by individual product category are set forth in the following Table VIII:

### Table VIII—Cancer-Cases-Avoided by Product Category Assuming Analogous Exposure for Selected Product Categories

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Discount Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 percent</td>
</tr>
<tr>
<td>Asbestos/cement</td>
<td>0.96</td>
</tr>
<tr>
<td>A/C shingles</td>
<td>0.23</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>3.17</td>
</tr>
<tr>
<td>Products not currently in U.S. production (asbestos protective clothing and vinyl/asbestos floor tile)</td>
<td>0</td>
</tr>
<tr>
<td>Paper products (commercial paper, rollboard, millboard, corrugated paper, and specialty paper)</td>
<td>0.52</td>
</tr>
</tbody>
</table>

Analogous exposures could not be assumed for a number of exposures. Therefore, benefits are understated to the extent that these exposures are not included. For example, some exposures result when asbestos fibers are released to air due to weathering of A/C products and other products used in exterior uses.

Also, the analysis did not quantify the increased risk due to high concentration, episodic exposures to asbestos for many products. Further, additions to ambient loading caused by the activities affected by this rule and the resultant risk reduction from this rule’s actions could not be adequately quantified. The effect these factors would have on the calculation of benefits is difficult to determine because of technological difficulties in quantifying the extent of these releases and the resultant exposures. However, the effect could be significant because releases via these routes are frequent and, on aggregate, broad-ranging.

EPA also analyzed the benefits that accrue due to the actions taken in this rule if the analogous exposure analysis described in Unit V.A.3 of this preamble are not assumed. In this analysis, in all instances where exposure is believed to exist, but specific exposure data are not available, EPA assumed no exposure. The figures in the following chart, therefore, understate the actual number of cancer-cases-avoided due to this rule to the extent that available monitoring data used in the exposure analysis understates actual exposure to asbestos. In this analysis, estimates of cancer-cases-avoided decrease from 202 cases to 164 cases if benefits are not discounted and from 148 cases to 120 cases if benefits are discounted at 3 percent. The cancer-cases-avoided by individual product category using this analysis are set forth in the following Table IX.

### Table IX—Cancer-Cases-Avoided by Product Category Without Analogous Exposure Assumptions

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Discount Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 percent</td>
</tr>
<tr>
<td>Asbestos/cement</td>
<td>0.96</td>
</tr>
<tr>
<td>A/C shingles</td>
<td>0.23</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>2.25</td>
</tr>
<tr>
<td>Paper products (commercial paper, rollboard, millboard, corrugated paper, and specialty paper)</td>
<td>0</td>
</tr>
<tr>
<td>Felt products (flooring and roofing felt and pipeline wrap)</td>
<td>0.43</td>
</tr>
<tr>
<td>Disc and drum brake pads for original equipment market (OEM) and brake blocks</td>
<td>1.45</td>
</tr>
<tr>
<td>Gaskets</td>
<td>2.62</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>6.68</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>88.37</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>0.43</td>
</tr>
<tr>
<td>Gaskets</td>
<td>0.68</td>
</tr>
<tr>
<td>Felt products (flooring and roofing felt and pipeline wrap)</td>
<td>0.68</td>
</tr>
<tr>
<td>Disc and drum brake pads for original equipment market (OEM) and brake blocks</td>
<td>14.55</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>88.37</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>1.45</td>
</tr>
<tr>
<td>Gaskets</td>
<td>1.29</td>
</tr>
</tbody>
</table>

As stated earlier, EPA decided for this rulemaking to estimate potential risk from plant emissions using an assumption of baghouse efficiency of 99.95 percent for some product categories and 99.67 percent for other product categories (the maximum emission scenario with no baghouse failure assumed). However, EPA also estimated the number of cancer-cases-avoided using the assumptions of 99.968 to 99.988 percent efficiency (the best estimate scenario with occasional baghouse failure assumed). These estimates, assuming the occupational exposure levels based on other analogous exposure scenarios discussed above, are 183 cases if benefits are not discounted and 134 cases if benefits are discounted at 3 percent. The cancer-cases-avoided by individual product category using these estimates are set forth in the following Table X.
TABLE X—CANCER-CASES-AVOIDED BY PRODUCT CATEGORY ASSUMING ALTERNATIVE EXPOSURE SCENARIOS

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Discount Rate 3%</th>
<th>Discount Rate 0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>asbestos/cement (A/C)</td>
<td>0.48</td>
<td>0.59</td>
</tr>
<tr>
<td>shingles</td>
<td>0.22</td>
<td>0.31</td>
</tr>
<tr>
<td>A/C pipe</td>
<td>2.10</td>
<td>2.90</td>
</tr>
<tr>
<td>Products not currently in U.S. production (asbestos protective clothing and vinyl/asbestos floor tile)</td>
<td>0.16</td>
<td>0.25</td>
</tr>
<tr>
<td>Paper products (commercial paper, rollboard, millboard, corrugated paper, and specialty paper)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Disc and drum brake pads for original equipment market (OEM)</td>
<td>2.20</td>
<td>2.72</td>
</tr>
<tr>
<td>Disc and brake pads for aftermarket (AM)</td>
<td>25.83</td>
<td>26.41</td>
</tr>
<tr>
<td>Other asbestos friction products (automotive transmission components, clutch facings, and commercial and industrial friction)</td>
<td>12.72</td>
<td>17.27</td>
</tr>
<tr>
<td>Coatings (roof coatings and non-roof coatings)</td>
<td>95.38</td>
<td>117.98</td>
</tr>
</tbody>
</table>

Does not include specialty industrial gaskets

The different assumptions about baghouse efficiency do not have a significant effect on the estimates of cancer-cases-avoided. Under both the best and worst exposure scenarios with occasional baghouse failure assumed and the maximum emission scenario with no baghouse failure assumed, EPA believes that the maximum emission scenario with no baghouse failure assumed is generally result in death after relatively short periods of treatment or hospitalization. In addition, this total would be further lowered when due to the fact that most asbestos-related diseases appear only after a long latency period.

Continued manufacture, importation, processing, and use of the asbestos-containing products banned by this rule would result in environmental loading of asbestos. The effect of environmental loading is discussed in more detail in Unit V.A.3 of this preamble. The actions taken under this rule will reduce the incremental increase in ambient concentrations of asbestos and thus reduce the risk of asbestos exposure faced by the general population. EPA has attempted to quantify these benefits, due to the difficulty and probable imprecision of some changes. However, EPA believes that the long-term benefits derived from this incremental decrease in ambient concentrations of asbestos will result in substantial health benefits for the general population. EPA has also concluded that these benefits can be attained through the source reduction actions taken in this rule, rather than by use of other options considered.

Further, due to the rule’s bans, the substantial future costs associated with removal and disposal of asbestos-containing products that would have otherwise been produced and used will be avoided. These included higher removal, demolition, and disposal costs for asbestos products than those for non-asbestos products, as well as higher health risk expenses for asbestos products. Future removal, demolition, and disposal of asbestos construction products will likely be higher because the increased use of asbestos for building materials. These costs can be substantial, but they have not been estimated for purposes of this decisionmaking because estimates of the timing and frequency of building removal or renovation would be speculative.

Also, the continued use of asbestos will likely exacerbate the heavy burden on courts and workman’s compensation boards that have, in recent years, been inundated with claims related to harm caused by asbestos exposure. This rule, by reducing the occurrence of asbestos-related diseases, will eventually reduce the costs related to claims arising out of illnesses and deaths caused by asbestos exposure.

Since the proposal, EPA has observed a rapid development of substitutes for asbestos-containing products. EPA believes that this rule will further stimulate technological innovation in the development of substitutes for asbestos and that this strong trend toward use and acceptance of substitutes will continue.

Different health benefits were estimated in support of the proposal than those development for the final rule. The number of cancer-cases-avoided estimated for the proposal (approximately 1,000 cases and more, depending on the regulatory option) is higher than the estimate for the final rule (202 and 146 cases if analogous exposures are assumed) for a number of reasons:

1. Several product categories are not included in this final rule analyses because they are no longer manufactured or imported in the U.S. (e.g., vinyl-asbestos floor tile). This change accounts for approximately 475 of the cancer-cases-avoided quantified in the proposal rule. (2) The production and exposure data support the rulemaking were updated for the final rule. U.S. asbestos consumption has decreased and substitute use had increased since the publication of the proposed rule. Therefore, the proposal's estimates of cancer-cases-avoided were higher than those for the final rule because consumption rates and resulting exposure totals were higher at the time of the proposal.

3. Updated exposure assessments were used in the health benefits model. The updated data were lower for some products than those used for the proposal, meaning that the proposal's estimates of cancer-cases-avoided were higher than those for the final rule. (4) The time frame used for estimating health benefits for the proposal was 15 years: for the final rule, the period is 13 years. Therefore, the final rule analysis covered 2 fewer years of exposure, resulting in fewer estimated health benefits. (5) Some modifications were made to the health effects model used for the final rule, including minor modifications, including quantification of gastrointestinal cancer risk, and the use of a lower dose response constant for mesothelioma (using an average of the dose response constants from a number of studies, rather than the constant from one large study) that resulted in an estimate of benefits that was approximately 20 percent lower for the final rule than for the proposal.

Several commenters stated that EPA underestimated the benefits associated with the product bans described in the proposed rule. These commenters asserted that the analysis of benefits underestimated risks because it did not take into account diseases other than lung and gastrointestinal cancer and...
mesothelioma or exposures to families of asbestos workers, and failed to quantify factors like avoided pain and suffering and increased worker productivity. EPA agrees that the benefits of the rule may be understated, possibly to a significant extent, in the supporting analysis due to technological or other limitations. These factors, however, have been considered qualitatively in EPA’s analysis.

One commenter argued that EPA significantly overestimated the benefits of the rule by overstating asbestos potency and exposure levels. The lung cancer and mesothelioma potency values used by EPA in its analysis of benefits are well-supported and are consistent with those used by OSHA in reducing its PEL to 0.2 f/cc. The potency values for lung cancer represent the mean of the results of 11 human epidemiological studies on the effects of asbestos exposure. The potency values for mesothelioma represent the mean of the results of 4 human epidemiological studies on the effects of asbestos exposure. In addition, the exposure estimates used in this analysis underestimate actual exposure for a number of reasons, as explained in Unit V.A.3 of this preamble. Therefore, EPA may have actually understated, not overstated, the benefits of this rule.

Some commenters argued that EPA, in the proposal, improperly failed to discount benefits to be derived from the rule, and in support documents for a final rule, only discounted benefits until the time of the exposure that results in cancer rather than until the occurrence of the disease. Other commenters argued that EPA should not discount benefits, stating that discounting the benefit of saving human life is inapposite methodology for this rulemaking.

This final rule provides estimated benefits both with and without discounting. Arguments can be made that estimating benefits without discounting is preferable in cases like this one where the primary benefits derived is the avoidance of human cancer cases. However, arguments also can be articulated supporting the discounting of benefits. EPA believes that if benefits in the form of cancer-cases-avoided are to be discounted, they are properly discounted to the time when risk is reduced or avoided. Since the benefit of a regulation to control a hazardous substance occurs at the time of the reduced exposure, EPA has concluded that the appropriate period over which to discount is until the time of exposure reduction. This approach was used in this case after extensive review of applicable literature and an examination of the inherent bases and features of other approaches.

3. Small businesses. EPA has, pursuant to section 6(c)(1)(D) of TSCA, also analyzed the economic impact of this rule on small businesses. The rule will not have a significant effect on small businesses because there are few such businesses affected by the rule and individual company producer losses are not expected to be substantial since capital equipment for the production of asbestos-containing products has little remaining useful life, is inexpensive, or can generally be converted at low cost to manufacture of alternative products. A small fraction of the manufacturers, importers, and processors subject to this rule are small producers and some could be adversely affected by the rule. In addition, a number of small governments may be affected by the ban of some asbestos products, for example A/C pipe. However, the economic impact of this rule is generally spread widely throughout the economy and any concentrated effect will not be focused on specific market sectors or on small businesses.

4. Evaluation of the rule’s economic impact. The overall costs of this rule are significant. However, the overall benefits of the rule are also significant, although many of the benefits cannot be easily quantified.

The analysis performed to ascertain the economic consequences of the rule likely overstates the costs of the actions. However, the analysis points out several important factors: (1) the societal benefit, or "essentiality", of asbestos has decreased, and continues to do so, as asbestos consumption declines and substitutes for the mineral are developed for many applications; (2) most of the costs associated with the rule are short-term and spread over a relatively large population; (3) the continued development of price- and performance-comparable substitutes for asbestos indicates that the rule will not lead to either dramatic increases in consumer prices or decreases in the availability of products affected by this rule; and (4) the producer and consumer costs imposed by this rule are offset by the rule’s benefits (e.g., cancer-cases-avoided, medical costs, and lost productivity avoided), although many of these benefits are difficult to quantify or to express in monetary terms.

EPA, therefore, finds that, under the standards of section 6 of TSCA, the costs of the rule to be reasonable in light of the unreasonably large number of asbestos-related deaths and serious illnesses that would occur if the actions in this rule were not taken.

E. Other Options Considered

Section 6 of TSCA requires EPA to select the least burdensome means to reduce an unreasonable risk. This Unit describes EPA’s evaluation of options that would reduce or eliminate the unreasonable risk to human health posed by exposure to asbestos. Further responses to comments on this subject can be found in the Response to Comments document.

The options considered include the one selected for the final rule, a staged-ban of the manufacturing, importation, processing, and distribution in commerce of a number of categories of asbestos products. EPA selected a staged-ban for this final rule rather than one of the other regulatory options discussed in the proposal or identified in comments because these other options would either fail to adequately reduce the unreasonable risk posed by asbestos exposure or impose an excessive burden. Conversely, the final rule’s staged-ban approach prohibits, at different times, the manufacture, importation, processing, or distribution in commerce for uses of asbestos that pose an unreasonable risk. Timing of these bans is based largely on the availability of suitable available or anticipated non-asbestos substitutes for the banned products. Therefore, the staged-ban approach takes into account the potential economic effects of the various bans, while still eliminating the sources of the risk. Other options were discussed in the proposed rule or identified in comments, but were not selected for the reasons described below.

Under two proposed rule alternatives, some product categories would be banned soon after the effective date of the rule and the remaining product categories would be "phased down." This would be accomplished by instituting a permit system which would create limits on the U.S. mining of asbestos and the importation of asbestos and asbestos-containing products. These limits would be based on previous volumes of the affected activity and would be managed by a system of issuing permits allowing gradually declining levels of the indicated activities. The permits would be transferable. This system would, over time, restrict the total amount of asbestos available for use in the U.S. and limit the amount used in imported products until the rule’s objective of a complete phase out was achieved.
In the analysis performed for this rulemaking, EPA concluded that a permit system approach would not be the least burdensome means of reducing the unreasonable risks posed by asbestos and would not adequately control asbestos exposure for all the products analyzed under the rule. Most commenters who rendered an opinion on the issue opposed the permit system options. Commenters stated that the implementation of these options could create significant administrative costs for EPA and industry, particularly in the area of imported asbestos products. EPA found that implementing the proposal’s permit system options for all of the product categories in the rule would result in high administrative costs. EPA also believes that a permit system involving all of the products affected by this rule would be difficult to enforce.

EPA concluded that some uses of asbestos and some product life cycle stages pose a substantially greater risk than others and that the permit systems described in the proposed rule would not necessarily control the highest risk exposures (e.g., persons that produced or used products with high levels of asbestos exposure could purchase permits). Therefore, EPA concluded that the proposed rule’s permit system would not adequately control asbestos exposure for the rule’s product categories.

Despite EPA’s conclusion based on currently available information that a permit system approach is not viable for regulating all of the products analyzed under this rule, EPA recognizes that there are a number of inherent conceptual advantages to employing an economic incentive approach in regulating the risks posed by chemicals. Therefore, as a follow-up to EPA’s review of the applicability of a permit system as a regulatory option in this rule, EPA will perform several extensive analyses of the advantages and disadvantages of using various economic incentive approaches, including marketable permit system alternatives, as possible mechanisms for reducing human health and environmental risks from chemicals. These studies will review in greater detail the viability of employing such approaches under regulatory authorities such as section 6 of TSCA.

One study will focus on economic incentive programs that could be applied under TSCA and other authorities, rather than, for example, concentrating on air-emission issues, as does the bulk of the available theoretical literature. The study will identify and evaluate criteria for determining which chemicals or chemical products would be appropriate candidates for the use of economic incentive approaches under TSCA and other authorities. Factors considered in identifying these criteria will include determinants of a chemical’s market, such as its production and use, that would make the chemical a viable candidate for a permit system rather than a deposit system. The study will also examine these criteria in the context of specific candidate chemical substances.

Another study will analyze administrative problems associated with economic incentive approaches with the aim of devising methods that provide equitable and efficient regulation of these chemical substances. For example, the study will examine issues related to imports which complicate implementation and enforcement of economic incentive approaches. The study will also examine mechanisms to overcome complications caused by these factors and evaluate the type and level of assistance to EPA from other agencies (e.g., U.S. Customs Service) that would be necessary to implement and enforce an economic incentives approach.

Based on the analyses performed during this and other rulemakings, there is a continuum in the risks and benefits associated with product categories. Some product categories on the continuum have some characteristics (e.g., a large number of specialized uses or a lagging rate of substitute development) that make the products amenable to regulation through use of an economic incentive approach. Based on the criteria developed in the studies described in the preceding paragraphs, upon completion of these studies, EPA will review this rule and other rules, based on the identified criteria and on then-available information about products and markets. For example, with respect to this rule, this review could determine whether (1) any product categories not included within the rule’s bans should be phased out by use of an economic incentives approach, (2) any products banned in Stage 3 for which a significant number of exemptions are likely might be more efficiently phased out via an economic incentives approach, and (3) substitute development could be more efficiently compelled by an economic incentive approach for any products that are the subject of an active exemption. EPA’s review will determine whether any of these products exhibit characteristics that lead EPA to conclude that exposures could be more efficiently phased out by use of an economic incentive approach. If, after review of this or any other rule, EPA determines that an economic incentive regulatory approach is warranted for some of the categories, EPA may in the future undertake rulemakings under sections 6 and 8 of TSCA to amend such rules to implement an economic incentive approach.

Even within the staged-ban approach, EPA has considered a number of possible options for the number of stages, the number of years between the stages, and the scheduling of product bans at various stages. The final rule follows the 3-stage ban approach of the proposed rule. EPA has modified the timing of the ban from soon after promulgation and 5 and 10 years after the effective date of the final rule, as discussed in the proposed rule, to 1, 4, and 7 years, respectively, after the effective date of the final rule. This was done because of the passage of time since the proposed rule was published and because EPA’s analysis of available data and comments indicates that marked advances have been made in the development of and conversion to suitable substitutes for asbestos in most product areas. The timing for the stages in the final rule are reasonable in terms of the current or anticipated availability of suitable substitutes, based on EPA’s analyses. EPA rejected the option in the proposal of a limited 2-stage ban with a TSCA section 8(a) reporting requirement because that option would not sufficiently reduce the unreasonable risk posed by asbestos exposure. In addition, the final rule does not include a ban on the mining and import of bulk asbestos because not all asbestos-containing products are included within the bans on manufacture, importation, processing, and distribution in commerce. However, the risks posed by these activities are expected to decline as the demand for asbestos decreases due to the actions taken in this rule.

Also, in scheduling products for the staged-ban, EPA has analyzed the relative risks posed by the different asbestos-containing products and the probable availability of non-asbestos substitutes. In the rule, the various asbestos products are scheduled to be banned at times when it is likely that suitable non-asbestos substitutes will be available. For example, bans on asbestos-containing brakes pads and drum brake linings are divided into a Stage 2 ban on the original equipment market and a Stage 3 ban on the aftermarket because suitable substitutes might not be available for some aftermarket products until Stage 3. The final rule’s approach balances the need
for a reduction in the unreasonable risk of exposure to asbestos with the economic effects of bans on manufacture, importation, processing, and distribution in commerce.

The inclusion in the final rule of a provision allowing for exemptions in limited circumstances is a means of taking into account the size and diversity of the asbestos industry. EPA realizes that, despite EPA's projections, technology might not advance sufficiently by the time of a ban to produce substitutes for a few specialized or limited uses of asbestos in some product categories. In addition, other unforeseeable circumstances may occur that would make a ban on a discrete product inappropriate at the scheduled date. In these circumstances, an exemption from the rule's bans may be appropriate if an applicant can show that one is appropriate following the procedures described in Unit III.E of this preamble. However, EPA believes that granting exemptions will not be the norm. The procedures should be used only in exceptional cases and should not be viewed as a means of attempting to postpone a person's share of the economic consequences of the actions dictated by the rule.

Another option considered would involve an immediate ban of the manufacture, importation, processing, or distribution in commerce of all asbestos products.

Section 6 of TSCA requires that a range of factors, including the availability of substitutes and the relative costs of regulatory options, be considered in addressing the reasonable risks posed by a chemical substance. EPA rejected an immediate ban option because it would result in potentially severe economic and societal effects. An immediate ban would not account for the current unavailability of viable substitutes for some asbestos-containing products that provide significant benefit and would result in high costs in those markets. Therefore, an immediate ban would not be the least burdensome means of reducing the unreasonable risk posed by asbestos.

EPA also considered requiring asbestos-containing products to be labeled as a means of reducing the risk posed by asbestos exposure. However, EPA has determined that the risk-reduction benefits from a labeling requirement for asbestos-containing products would not be substantial. For example, many of those that would potentially be exposed to asbestos from the labeled products would not have access to the warning labels. In addition, many asbestos products are used in caustic or dynamic environments in which labels cannot survive. Commenters also argued that labels directly applied to products can inhibit product performance. For example, if gaskets were required to be labeled, those who came into contact with the product packaging could have access to the labels. However, many gaskets are too small to be effectively labeled. In addition, it would be unlikely that those exposed to the product during use or removal would have access to the label because it might not survive in a hot, fluid environment. The aim of the final rule's labeling requirement is not to serve as a warning, but rather only to facilitate compliance with and enforcement of the rule. The drawbacks of labeling described above do not affect the use of labeling as a compliance and enforcement tool. The labels required by this rule are applied to product wrapping or packaging and are not intended to survive through the entire product life cycle.

Several commenters suggested the consideration of options that would require "controlled use" of asbestos rather than bans on manufacture, importation, processing, or distribution in commerce. These commenters argued that exposure to low levels of asbestos is not an unreasonable health hazard and that EPA should undertake actions in a number of areas to require exposure controls (e.g., workplace controls for brake replacement and repair) rather than enacting a product ban. Commenters also suggested that chrysotile fibers pose a lower hazard than other asbestos fiber types and that controlled-use actions would be more appropriate for chrysotile than would be source reduction actions.

Controlled-use options were rejected because they would be ineffective in reducing exposure at many points in the life cycle of asbestos products. As is discussed in Unit V.A of this preamble, EPA has found that exposure to even low levels of asbestos poses an unreasonable health hazard. In addition, some of the exposures of concern are not amenable to controls (e.g., ambient releases from asbestos friction products during use, from brake replacement and repair work performed by consumers, or from weathering of asbestos products exposed to an outdoors environment).

In other instances, controlled-use approaches create new exposures or move exposure from one stage of the product life cycle to another. For example, even if asbestos is vented from a workplace, although workers are subject to lower exposure levels, asbestos is still released to the outside ambient air, thereby creating potential exposures for passersby and surrounding populations.

Further, many engineering controls either fail to reduce exposures to asbestos to levels that do not pose a significant risk or create workplace inefficiencies that lead them to not be used. For example, respirators are difficult to fit properly and are often uncomfortable. Poor fit and intermittent use because of discomfort lead to unprotected workers. The problems are especially prevalent in negative pressure respirators, the type most commonly used in workplaces because of their low cost (Ref. 16).

Other agencies and EPA offices have or are currently establishing asbestos exposure control requirements for the workplace. However, because of the extent and nature of the risks posed by asbestos and limitations on available technology and the jurisdictions of the regulatory entities, EPA believes that even those control standards that are based on the best available technology leave an unreasonable level of residual risk in some occupational and non-occupational settings.

Therefore, EPA has concluded that source reduction actions, like those taken in this rule, rather than controlled use approaches are necessary to reduce the unreasonable risk posed by asbestos exposure. In addition, pursuant to the discussion in Unit V.A of this preamble regarding the relative hazards posed by the various asbestos fiber types, EPA has also concluded that this rule's source reduction actions are more appropriate than controlled use approaches for products containing chrysotile fibers.

Some commenters expressed a concern that if EPA bans the manufacture, importation, or processing of some asbestos-containing products, the governments of other countries will be compelled to take similar actions, although suitable non-asbestos substitutes may not be available in those countries. The unreasonable risk finding in this rule is based on a detailed analysis of the risks posed throughout the entire life cycle in the U.S. of the future manufacture, importation, processing, distribution, use, and disposal of the specified asbestos-containing products. The findings which support this rule are not directly applicable to other countries in which factors relating to risk and cost may be significantly different.
**Summary of Individual Product Categories**

This Unit describes EPA's unreasonable risk finding for each individual category of asbestos-containing products identified for this rule. It summarizes for each individual product category available information regarding exposure, individual risk levels, the development of substitutes, the results of EPA's analysis of the costs and benefits of a ban, and other qualitative factors that were considered in EPA's unreasonable risk analysis for each category. These discussions reflect public comments received on these subjects. Further responses to comments on these subjects can be found in the Response to Comments document.

In the product category discussions below, information regarding costs, benefits, and product substitutes is derived primarily from the RIA (Ref. 21), which is discussed in Unit V.D of this preamble. Information regarding exposure levels is derived from EPA's Asbestos Exposure Assessment (Ref. 29), Asbestos Modeling Study (Ref. 30), and Non-Occupational Asbestos Exposure Report (Ref. 31), which are discussed in Unit V.A.3 of this preamble.

Based on available information, EPA finds that the manufacture, importation, processing, and distribution in commerce of asbestos for use in each of the following product categories, except those discussed in Unit V.F.1 of this preamble, presents an unreasonable risk of injury to human health. The discussions of EPA's findings, below, summarize: (1) The estimated benefits of the actions taken in this rule for each product category, (2) quantifiable asbestos exposure and lifetime risk levels for the product, (3) the projected availability of product substitutes, (4) a description of qualitative factors that were considered in reaching EPA's unreasonable risk conclusion for the product, (5) the estimated costs of the actions taken, and (6) an explanation of any changes in EPA's approach to regulating the product since the proposal.

The individual risk levels quantified for the product categories that are subject to this rule are very high. An individual lifetime risk level of 10⁻³ or greater has been quantified for many persons who are exposed during the primary and secondary manufacture of most of these products. Some other phases of these products' life cycles also result in very high levels of individual risk. An individual lifetime risk level of 10⁻³ means that members of the populations exposed to this level of risk stand a 1 in 1,000 chance of developing cancer during their lifetime as a result of the exposures. EPA considers the risk levels quantified for this rule for asbestos exposures to pose a substantial concern. EPA also believes that the risk levels quantified for this rule represent an underestimate of the actual risk posed by asbestos exposure from these products. A number of exposures to asbestos and the resultant risks, for example, the risks posed by incremental increases in environmental loading caused by the continued manufacture and importation of the asbestos products banned by this rule, are believed to be significant, but could not be quantified for purposes of this rule, often because of limits in exposure monitoring technology. Despite this cautious approach to estimating risk, the exposure and risk that can be quantified are sufficient to make an unreasonable risk finding for purposes of this rule.

The costs and benefits cited below include assumptions regarding anticipated declines in substitute prices (discussed in Unit V.D of this preamble) and exposures estimated by analogy for recognized, but unquantifiable, exposures (discussed in Unit V.A.3 of this preamble). EPA believes that this approach presents a prudent, representative analysis of the costs and benefits of the actions taken in this rule with some reasonable adjustments made for unquantifiable exposures or market changes. However, even if these assumptions are not used, EPA has concluded that the continued manufacture, importation, and processing of the asbestos-containing products that are identified in the rule poses an unreasonable risk of injury to human health.

b. Felt products. This grouping consists of the flooring felt, roofing felt, and pipeline wrap product categories. All of these categories will be banned in Stage 1. The benefits (in terms of cancer cases-avoided) of the actions taken in this rule on these product categories are set forth in the following Table XI:

<table>
<thead>
<tr>
<th>TABLE XI—CANCER-CASES-AVOIDED FOR ASBESTOS FELT PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>Flooring felt</td>
</tr>
<tr>
<td>Roofing felt</td>
</tr>
<tr>
<td>Pipeline wrap</td>
</tr>
</tbody>
</table>

No current U.S. manufacture or import.

Primary routes of exposure to asbestos from these products occur during primary manufacture, and product installation, repair, removal, and disposal. Quantifiable lifetime risk for these products from occupational exposure ranges from an average of 7.4 x 10⁻⁴ for secondary manufacture of flooring and roofing felt to an average of 2.5 x 10⁻³ for the primary manufacture of roofing felt. EPA estimates that as many as 1,652 workers may be exposed to asbestos during the installation and removal of roofing felt, incurring individual risks comparable to those for manufacturing. These exposure estimates do not take into account high peak exposure to which homeowners or others may be unknowingly subjected during removal or repair of these products. EPA determined that accurately quantifying these exposures and the resultant risks would be difficult and that sufficient other exposure and risk information is available regarding these products to make a finding of unreasonable risk.

Effective substitutes currently exist for all three of these product categories. These products are largely no longer produced in the U.S., and flooring felt is no longer imported in this country. In the proposal, flooring and roofing felt would have been subject to the Stage 1 ban and pipeline wrap would have been banned at Stage 3 or covered by the permit system. However, EPA received comments indicating that the product categories are not easily distinguishable from one another and that suitable substitutes are currently available for pipeline wrap. EPA therefore concluded that a Stage 1 is appropriate for all three product categories.

The total cost of the actions taken on these product categories are set forth in the following Table XII:

<table>
<thead>
<tr>
<th>TABLE XII—COST OF THE RULE FOR ASBESTOS FELT PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>Flooring felt</td>
</tr>
<tr>
<td>Roofing felt</td>
</tr>
<tr>
<td>Pipeline wrap</td>
</tr>
</tbody>
</table>

No U.S. manufacture or import.

EPA has concluded that a Stage 1 ban is appropriate for these product categories for the following reasons: (1) Relatively high quantifiable exposure and individual risk levels exist for these products; (2) these products pose a high potential for ambient release during a number of life cycle stages, for example, during manufacture, installation, removal, and repair work; (3) homeowners and workers are
potentially subject to uncontrolled exposures during removal and repair work; (4) the cost of taking these actions is reasonable because suitable substitutes exist for all of these products; and (5) while the quantified benefits of banning these products are relatively small, compared to other product categories banned by this rule, these products are likely both to lead to a number of serious exposures that could not be readily quantified for this rule and to contribute significantly to environmental loading.

b. A/C sheet. This grouping consists of the flat and corrugated A/C sheet product categories. These categories will be banned in Stage 1. These products were proposed for a Stage 1 ban. The benefits (in terms of cancer-cases-avoided) of the actions taken in this rule on these product categories are set forth in the following Table XIII:

### TABLE XIII—CANCER-CASES-AVOIDED FOR A/C SHEET

<table>
<thead>
<tr>
<th>Product</th>
<th>Discount rate</th>
<th>3 percent</th>
<th>0 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/C flat sheet</td>
<td>0.05</td>
<td>1.05</td>
<td>1.06</td>
</tr>
<tr>
<td>A/C corrugated sheet</td>
<td>0.12</td>
<td>0.14</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Primary routes of exposure to asbestos from these products occur during manufacture, installation, and repair. Approximately 53 workers are exposed to asbestos during primary manufacture of A/C flat sheet. EPA estimates that as many as 735 workers may be exposed to asbestos during the installation, repair, and disposal of A/C flat sheet, and that as many as 109 workers may be exposed during installation and repair of A/C corrugated sheet. Quantifiable risk posed for these products from occupational exposure is estimated to range from an average of 6.2 \times 10^{-3} for the primary manufacture of A/C flat sheet to 6.7 \times 10^{-4} for repair and disposal of flat and A/C corrugated sheet. Quantifiable risk from non-occupational, lifetime exposures to asbestos released during the manufacture of A/C sheet is estimated at 1 \times 10^{-5} for approximately 4,500 people and at greater than 1 \times 10^{-6} for over 200,000 people.

EPA believes that the exposures quantified for these product categories are understated. Ambient release of asbestos occurs due to weathering of these products during outdoor uses. Cutting, drilling, and sanding take place during secondary processing, installation, repair, and maintenance of these products and result in significant release of asbestos. Homeowners or others may be unknowingly exposed to significant levels of asbestos when they sand these products in preparation for repainting or removing them. Worker exposure estimates for this rule assume compliance with OSHA restrictions, but EPA believes, based on some public comments, that there may be some cutting of A/C products with power saws in violation of OSHA restrictions. Asbestos releases to the ambient air due to weathering of these materials during outdoor uses were not calculated and high peak exposures occurring during cutting or scraping of these products were not quantified for purposes of the rule. EPA determined that accurately quantifying these exposures and the resultant risks would be difficult and that sufficient other exposure and risk information is available regarding these products to make a finding of unreasonable risk.

Effective substitutes exist for all uses of these products. The total costs of the actions taken in this rule for these product categories are set forth in the following Table XIV.

### TABLE XIV—COST OF THE RULE FOR A/C SHEET

<table>
<thead>
<tr>
<th>Product</th>
<th>Total cost in $ million, discounted at 3 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/C flat sheet</td>
<td>2.37</td>
</tr>
<tr>
<td>A/C corrugated sheet</td>
<td>0.29</td>
</tr>
</tbody>
</table>

EPA has concluded that a Stage 1 ban is appropriate for these product categories for the following reasons: (1) relatively high quantifiable exposure and individual risk levels exist for these products; (2) these products pose a high potential for ambient release during a number of life cycle stages; (3) homeowners and workers are potentially subject to uncontrolled, high peak exposures during installation, repair, and removal; (4) the cost of taking these actions is reasonable because suitable substitutes exist for all of these products; and (5) while the quantified benefits of banning these products are relatively small, compared to other product categories banned by this rule, these products are likely to lead to a number of serious exposures that could not be readily quantified for this rule and to contribute significantly to environmental loading.

c. A/C shingles. This product category covers roof shingles and siding composed of a mixture of cement and asbestos fiber. This category will be banned in Stage 3. This product was proposed for a Stage 1 ban. The benefits (in terms of cancer-cases-avoided) of the actions taken in this rule on this product category is as follows: 0.32 cases if benefits are not discounted and 0.23 cases if benefits are discounted at 3 percent.

Currently, A/C shingles are rarely used in new building construction and are used primarily for replacement, maintenance, and historical restoration. Primary routes of exposure to asbestos from products in this category occur during manufacture, installation, repair, removal, and disposal. Quantifiable risk posed by these products from occupational exposure is estimated to range from a lower bound of 3.7 \times 10^{-4} for installation to an average of 6.1 \times 10^{-4} for primary manufacturing. Quantifiable risk from non-occupational, lifetime exposure to asbestos emissions released during manufacturing is estimated at 2.1 \times 10^{-4} for approximately 1,500 people and at greater than 1.0 \times 10^{-6} for approximately 6,800 people. EPA believes that a number of factors contributed to exposure being underestimated for this category. Ambient releases result from weathering of these products and high peak exposures potentially occur during cutting, sanding, scraping, and hammering of these products. EPA is concerned about unknowing, inadvertent high peak exposures for homeowners or others during replacement or repair of existing shingles and siding. Such exposures can result from sanding, chipping, cutting, or other activities that result in substantial fiber release. Asbestos releases to the ambient air due to weathering of these materials during outdoor uses were not calculated and high peak exposures occurring during repair of these products were not quantified for purposes of the rule. EPA determined that accurately quantifying these exposures and the resultant risks would be difficult and that sufficient other exposure and risk information is available regarding these products to make a finding of unreasonable risk.

The traditional appeal of A/C products is their durability and their ability to be fabricated. A number of non-asbestos products are available that are effective substitutes from the perspective of performance. Suitable substitutes, including wood, aluminum, and vinyl sidings and asphalt, cedar wood, and tile shingles, exist for many applications of the products in this category. However, suitable substitutes are not currently available for some products in this category. Therefore, EPA has scheduled the ban of this
product for Stage 3 rather than Stage 1, as originally proposed, to allow for the development of cost-effective substitutes while still addressing risks in a timely manner.

The total cost of the actions taken in this rule for this product category is $23.57 million. EPA believes that this cost estimate may be overstated. This is because the cost analysis for this product category assumed that wood substitutes would capture 32 percent of the A/C shingle market if the asbestos products were banned. This assumption was made largely because wood is more physically attractive than other substitutes, although it is much more expensive and does not perform significantly better.

EPA has concluded that a Stage 3 ban is appropriate for this product category for the following reasons: (1) Relatively high quantifiable individual risk levels exist for these products; (2) these products pose a high potential for ambient release during a number of life cycle stages; (3) homeowners and workers would be potentially subject to uncontrolled exposures; (4) suitable substitutes exist for many of these products and are likely to exist for others by the time of the ban; (5) the cost of taking these actions is reasonable, especially in light of the assumption made regarding the portion of the market substituted for by wood shingles in the estimate of the costs, the time provided for substituting development, and the level of ambient exposure posed by products in this category; and (6) while the quantified benefits of banning these products are relatively small, compared to other product categories banned by this rule, these products are likely to lead to a number of serious exposures that could not be readily quantified for this rule and to contribute significantly to environmental loading.

d. Other product categories that are currently out of production. This grouping consists of the vinyl/asbestos floor tile and asbestos clothing categories. These categories will be banned in Stage 1. These products were proposed for a Stage 1 ban.

These products are no longer produced in the U.S. and are currently imported in, at most, only small quantities. In instances in which these products are still imported, EPA is concerned about the potential for uncontrolled consumer exposure, for example, the sanding, cutting, and removal of vinyl/asbestos floor tile. The fact that these products are no longer in commerce in the U.S. indicates that effective substitutes are available.

Therefore, the cost of banning these products is minimal.

EPA has concluded that a Stage 1 ban is appropriate for this product category for the following reasons: (1) Relatively high quantifiable individual risk levels would exist for these products were significant U.S. manufacture or importation to begin again; (2) these products pose a high potential for ambient release during a number of life cycle stages; (3) homeowners and workers would be potentially subject to uncontrolled exposures which were significant U.S. manufacture or importation to begin again; (4) the cost of banning these products is negligible because there is no current significant manufacture or import of these products and because suitable substitutes exist for them; and (5) these products are included within the ban to ensure that their U.S. manufacture, importation, processing, or import does not resume.

1. Vehicular brakes. This grouping includes drum brake linings, disc brake pads and brake blocks used in new and existing motor vehicles. The manufacture or import of 1994 or later model year motor vehicles containing asbestos drum brake linings or asbestos disc pads (hereafter referred to as the original equipment market, or OEM) will be banned in Stage 2. Asbestos brake friction material manufactured, imported, or processed as replacement drum brake linings or disc brake pads for light- and medium-weight (LMV) motor vehicles with brake systems designed to use non-asbestos friction material will also be banned in Stage 2. The manufacture, import, or processing of asbestos brake blocks for heavy-weight (HV) motor vehicles will be banned in Stage 3. In addition, all friction material containing asbestos manufactured, imported, or processed as replacement parts for vehicles designed to use asbestos friction material (hereafter referred to as the aftermarket, or AM) will be banned in Stage 3.

The benefits (in terms of cancer-cases avoided) of the actions taken in this rule on these product categories are set forth in the following Table XV-

<table>
<thead>
<tr>
<th>TABLE XV-CANCER-CASES-AVOIDED FOR ASBESTOS VEHICULAR BRAKES—Continued</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Brake blocks (OEM &amp; AM)..........................</td>
</tr>
</tbody>
</table>

In the proposal, EPA discussed two approaches for regulating asbestos vehicular friction material, either banning all such material in Stage 2 or via the operation of a permit system. EPA stated that it would consider a class exemption for replacement parts under the proposal's staged-ban option.

Asbestos brake friction products are some of the most widely-used asbestos products and are a source of broadly ranging exposures to asbestos. EPA has quantified exposures to asbestos from the manufacture, installation, use, and repair of brake friction products. During the life cycle of these products, both occupational and non-occupational exposures to asbestos pose a lifetime risk of cancer mortality. The population at risk from these products is larger than that at risk from any other asbestos product category for which exposure has been quantified for this rule.

Occupational exposure to asbestos from the primary and secondary manufacture of friction products is high and affects many people. The 8-hour TWA exposure level quantified for the primary manufacture of all friction products is 0.145 f/cc (Ref. 29). The lifetime risk from this exposure is estimated to be $5.0 \times 10^{-3}$ with 2,779 workers exposed. The exposure level from secondary manufacture is considerably less than from primary manufacture, because secondary manufacture of friction products does not involve cutting, grinding, and fitting of brake material. However, the TWA exposure level for secondary manufacture is still high, ranging upward from 0.48 f/cc (Ref. 29). The lifetime risk from secondary manufacture ranges from an average of $1.6 \times 10^{-8}$ for drum brake linings to an average of $1.9 \times 10^{-3}$ for disc brake pads, with 3,038 workers exposed.

Quantifiable risk from non-occupational, lifetime exposure to asbestos released during the manufacture of drum brake alone is estimated at $1.0 \times 10^{-4}$ for 62,008 people and greater than $1 \times 10^{-6}$ for 2 million people.

Occupational exposure from the installation and repair of asbestos brake pads/linings/blocks may result in significant exposure. The 8-hour TWA exposure level for the servicing of disc
and drum brake systems is estimated to average 0.05 f/cc (Ref. 29). The lifetime risk from this exposure is $1.68 \times 10^{-5}$. There are an estimated 325,000 brake repair facilities where an FTE population of 1,391,000 mechanics may be exposed to asbestos during installation and repair of asbestos brake friction products. Exposure and, thus, risk have not been quantified for the disposal of asbestos brake friction material.

EPA estimated that approximately 13 million do-it-yourself brake installation and repair jobs are done annually by consumers (Ref. 31). Exposure from consumer brake repair varies depending upon the technique used to repair the brakes, whether the repair is done in a garage or outdoors, and other factors. Release of asbestos fibers into the ambient environment resulting from the braking action of asbestos vehicular brakes contributes to the significant risk of cancer mortality for members of the general population. EPA has quantified the non-occupational exposures from the use of these friction materials: drum brake linings, disc brake pads (LMV), and brake blocks.

EPA estimates that the lifetime risk is one in one million for 101 million Americans, on average. EPA received a large number of comments concerning exposure associated with the use of asbestos-containing brakes. Several commenters stated that there is very little risk of exposure to asbestos fibers released from brakes, because the asbestos is transformed to forsterite by the high heat generated from the use of brakes. EPA recognizes that only a small percentage of the asbestos in brakes is eventually emitted into the air. The remainder is either trapped in the brake assembly or is transformed into minerals such as forsterite by the heat of abrasion before release. However, asbestos is definitely released from brakes during brake use. The three studies of brake emissions, which EPA relied upon in developing its exposure estimates, all used electron microscopy to obtain positive mineralogical identification of the emissions' components. The studies found that between 0.017 and 0.216 percent of the material released was asbestos.

Although these percentages are quite small, the total amount of asbestos released from friction use (approximately 7 tons per year) is large because the total volume of brake emissions is large. There are devices which can control the release of asbestos during the normal replacement of brakes. These devices, the enclosed cylinder/HEPA vacuum system and the compressed air/solvent spray system, are recommended, but not required, by OSHA as means for reducing exposures below OSHA's PEL and action level (Ref. 10). The OSHA standard prohibits the use of air hoses during brake repair. Under ideal conditions these controls may significantly reduce exposure. However, controls must be used consistently to be effective and additional controls can be created during the disposal of asbestos-contaminated solvent or during replacement of HEPA vacuum filters. If the devices are used properly and exposures are reduced to the PEL or lower, EPA believes that the residual exposure can still result in an unreasonable risk. The efficacy of controlled use as an approach to risk reduction is discussed in more detail in Units V.A. 3 and V.E. of this preamble.

Several commenters stated that EPA should not ban asbestos friction products, arguing that engineering controls can provide sufficient protection from the risks of asbestos exposure. EPA believes that while these controls, if used consistently, can reduce exposure to the OSHA PEL, EPA's analysis indicates that exposure at levels even below OSHA's 0.1 f/cc action level still pose significant risk. In computing workplace exposures, EPA assumed compliance with the OSHA standard when actual monitoring data was either unavailable or above the OSHA PEL. For example, the EPA exposure data for brake repair facilities estimate asbestos exposure at 0.05 f/cc (Ref. 29). Even at this level, which is one half the OSHA action level of 0.1 f/cc, EPA, using the risk table in the 1986 OSHA rule, calculates a lifetime risk of $1.6 \times 10^{-4}$. Given the substantial lifetime risk and EPA's concern regarding the consistent and proper use of these controls by mechanics (Ref. 50), EPA does not believe that use of controls during brake repair will sufficiently reduce risk.

Additionally, a controlled use approach as an alternative to a ban of asbestos in friction material would not reduce general population exposures to asbestos originating from brake use. In addition, these controls would not typically be available to the estimated 13 million consumers who annually perform do-it-yourself brake jobs (Ref. 31).

EPA has assessed the current availability of non-asbestos friction material for disc and drum brake system in various vehicle weight classes. This assessment can be found in Volume III of the Regulatory Impact Analysis (Ref. 21). To summarize briefly, use of non-asbestos friction materials in recently-manufactured vehicles is increasing rapidly. There is nearly complete substitution for asbestos in disc pads used in recently-manufactured motor vehicles. Almost 100 percent of disc pads for newly manufactured heavy-weight vehicles are asbestos-free. For light- and medium-weight vehicles, 85 percent of the disc pads used in new vehicles are asbestos-free. Several producers estimate that by 1990, 90 to 100 percent of the disc pads for new vehicles will be asbestos-free.

Evidence also indicates that significant progress is being made in the development of substitutes for drum brake linings used in recently-manufactured motor vehicles. As noted by some commenters, substitution for asbestos in drum brake linings and brake blocks in new model vehicles appears to be more difficult than for disc brakes in new model vehicles. However, according to some commenters, much research is ongoing and some substitutes are currently available for drum brakes in newly-manufactured vehicles. Several commenters stated that asbestos substitutes are more readily available than EPA has estimated and that full conversion to asbestos-free brakes in newly-manufactured vehicles would be feasible in the near future. Some commenters pointed to the rapid conversion to asbestos-free brake friction material in the European market as proof of the technical feasibility of banning similar products in the U.S. For example, Sweden, the Federal Republic of Germany, Switzerland, Austria, Denmark, and Norway have either banned or are phasing out the use of asbestos friction material.

Primary substitutes include semi-metallic materials for disc brakes and non-asbestos organic materials (including fiberglass, para-aramid, mineral fibers, steel wool and fibers, and resins) for drums. Opinions from commenters vary greatly concerning the availability of effective and economical substitutes for brake friction products. While some commenters stated that there are substitutes currently available for most, if not all, brake friction products, other commenters felt that substitutes would be available within 5 to 10 years of the time of the proposal for most, if not all, brake friction products. Several commenters were more pessimistic about the future availability of substitutes. Other commenters indicated that adequate asbestos-free brake blocks may be difficult to develop for new model heavy-weight vehicles because the
weight of the vehicle puts greater demands on the braking system.

While many opinions were offered in comments and elsewhere about the progress being made toward the use of asbestos-free brake friction material, EPA did not receive analytical or quantitative data from commenters documenting technical difficulties encountered regarding substitution for asbestos in brake friction material. EPA acknowledges the inherent research and development variability associated with technological innovation. As a result, EPA decided to delay the ban on asbestos disc brake pads and drum brake linings in new light- and medium-weight vehicles and in replacement disc pads and drum brake linings for light- and medium-weight vehicles with brake systems designed to use non-asbestos until Stage 2. Manufacture, import, and marketing of brake blocks for use in either new heavy-weight vehicles or as replacements will not be banned until Stage 3. These dates are within the range of time frames suggested by comments and the American Society of Mechanical Engineers (ASME) expert panel's recommendations for new vehicles (Ref. 40). Specifically, ASME stated that "at the present rate of technical progress, most new passenger cars can be equipped with totally new non-asbestos frictional systems by 1981, and most light trucks and heavy trucks with 5-cam brakes, by 1982. However, a few low-volume new vehicle applications may not have acceptable non-asbestos friction materials at that time. Heavy truck wedge brake blocks, medium drum brake linings and many off-road vehicle brake linings may not be developed by 1982. Comments submitted to EPA in 1986 in response to its proposal described various lead time frames that would be necessary to permit the transition to non-asbestos frictional systems. These schedules varied between 2 and 10 years. The most common time frame pointed to was 4 to 6 years for most friction products, with special considerations given to brake blocks and disc pads for heavy vehicles. Several commenters requested time frames in excess of 10 years be considered for these heavy vehicles. Keeping in mind that these comments were made in 1986, EPA believes that it is reasonable to assume that OEM brake friction material for light- and medium-weight vehicles and heavy-weight vehicles can be asbestos-free by the dates prescribed in the rule.

Commenters generally agreed that it is easier to develop replacement asbestos-free friction materials for use in vehicles that are intentionally designed to use such materials than it is to develop asbestos-free friction materials for use as aftermarket replacement products in vehicles currently in use that have brake systems designed to use asbestos. A number of commenters addressed the current availability and efficacy of asbestos-free aftermarket replacements for vehicles designed to use asbestos friction materials. Some of these commenters maintained that substitutes are currently available for all friction material aftermarket applications. Some of the major producers of brake friction products, including aftermarket friction materials, no longer produce asbestos brake friction material. One commenter stated that asbestos replacements for heavy-weight vehicles are no longer available from reliable U.S. producers. On the other hand, some commenters stated that it would be infeasible, primarily for economic reasons, to develop effective asbestos-free substitutes for the aftermarket, while others indicated, in 1986 comments, that it would take 10 years to develop adequate aftermarket substitutes. These comments about the technical infeasibility of replacing asbestos friction material with asbestos-free friction material were not based on performance data, but rather theoretical discussions and anecdotal information. Due to the lack of analytical information, EPA cannot estimate quantitatively the rate at which asbestos-free substitution is occurring for the aftermarket products. EPA has delayed until Stage 3 the ban on aftermarket friction materials manufactured, imported, or marketed for use in brake systems designed to use asbestos. EPA believes this delay will permit time to address technological difficulties in developing aftermarket substitutes for vehicles designed to use asbestos. By the effective date of the Stage 3 ban, many of the vehicles on the road will be asbestos-free because of the Stage 2 ban and the prior manufacture of asbestos-free vehicles. EPA believes that it is important to force technology to develop asbestos-free replacements as rapidly as possible on the basis of marketability to avoid further asbestos replacement in brake systems designed to use asbestos. By the effective date of the Stage 3 ban, many of the vehicles on the road will be asbestos-free because of the Stage 2 ban and the prior manufacture of asbestos-free vehicles. EPA believes that it is important to force technology to develop asbestos-free replacements as rapidly as possible on the basis of marketability to avoid further asbestos replacement in brake systems designed to use asbestos. By the effective date of the Stage 3 ban, many of the vehicles on the road will be asbestos-free because of the Stage 2 ban and the prior manufacture of asbestos-free vehicles. EPA plans to monitor the progress of substitute availability for aftermarket products, thus encouraging substitute producers and aftermarket manufacturers to report progress or technological difficulties that may necessitate modification of certain provisions of the ban.

Comments described technological replacement difficulties or economic disincentives associated with developing asbestos-free friction material replacement parts for older and antique cars or for specialty cars such as race cars. EPA will consider a class exemption for such vehicles if one is requested.

Some commenters stated that a ban on asbestos use in the aftermarket for brake systems designed for asbestos friction products will compromise the performance of braking systems designed for asbestos brakes. Some commenters went so far as to predict that there may be more deaths in vehicle accidents due to poor performance caused by premature substitution than from the health risk posed by continued use of asbestos in friction products. Several commenters stated that EPA has ignored the impact of an asbestos friction product ban on highway safety and that risks associated with substitution should have been considered as part of the rule's analysis of costs and benefits. One commenter urged EPA to confer with the National Highway Traffic Safety Administration (NHTSA) regarding possible motor vehicle safety considerations associated with use of non-asbestos friction materials in vehicular brake systems. EPA and NHTSA have met and discussed potential effects on vehicle safety if asbestos friction materials were banned (Refs. 61, 62, and 63). NHTSA has no objection to the staged ban and technical review approach adopted for this rule (Ref. 28).

Evaluation of the safety concern regarding asbestos substitution voiced by these commenters is complicated by the fact that there are no federal safety standards governing the performance of aftermarket brake friction products. While the NHTSA promulgated safety performance standards in 1968 for brakes in new vehicles, no similar standards exist for replacement parts. NHTSA received two petitions requesting that NHTSA promulgate safety standards for the aftermarket. These petitions noted the present use of inferior grade asbestos and non-asbestos friction materials and the infeasibility of aftermarket friction material to individual brake systems; the petitioners argued that there is a compelling need to establish performance standards for the aftermarket. NHTSA granted a petition requesting that NHTSA propose a standard requiring that all heavy truck brake linings be rated and marked in
While some controversy may continue with dates proposed and time frames that are generally consistent, brake adoption in this rule represents benefit. The 2-stage ban for asbestos was concerned that a complicated commenters. Some commenters variable rate of development noted sequential ban accommodates the vehicles will be banned in Stage 1 and the OEM for cars and light trucks will be banned in Stage 2 and the OEM for aftermarket brake performance. In light of the controversy surrounding the availability of effective substitutes for aftermarket friction products, coupled with the rapid development and current use of some asbestos-free substitutes and the lack of definitive evidence to resolve the controversy, EPA has decided to delay the ban on asbestos in aftermarket brake friction products until Stage 3 to allow sufficient time to develop adequate substitutes. In spite of the relatively low economic impact associated with an immediate ban of asbestos in the brake friction products category and the high risk associated with asbestos exposure originating from asbestos friction products, EPA believes that it is important to provide this 7-year lead time for the industry to develop and produce safe and effective asbestos-free substitutes. Such an approach is consistent with some comments received by EPA.

The ban on asbestos friction products will become effective in two stages: the OEM for cars and light trucks will be banned in Stage 2 and the OEM for heavy vehicles and the AM for all vehicles will be banned in Stage 3. This sequential ban accommodates the variable rate of development noted by commenters. Some commenters proposed many more stages than EPA actually adopted in this final rule. EPA was concerned that a complicated schedule of effective dates for the bans would be burdensome without any real benefit. The 2-stage ban for asbestos brakes adopted in this rule represents time frames that are generally consistent with dates proposed by commenters. While some controversy may continue to exist over the dates when substitutes will be available for different vehicle types, EPA believes that this rule provides sufficient lead time for the development of effective non-asbestos substitute brakes.

In light of these facts and the extensive risk posed by exposure to asbestos from vehicular brakes, EPA believes that it is appropriate and necessary to ban asbestos in vehicular friction material. Nonetheless, as described above, EPA, in consultation with NHTSA, will monitor the pace of substitute development and undertake a technical review 5 years after the effective date of the rule, to ensure the availability of suitable non-asbestos aftermarket brake products. After considering all of these issues, EPA believes that this is the best approach in light of the high risk posed by asbestos, the rapid development of replacement friction materials, the current use of non-asbestos brakes in European countries, the controversy concerning substitute availability and performance, and the current consideration, by NHTSA, of aftermarket safety standards.

The total costs of the actions taken in this rule for these product categories are set forth in the following Table XVI:

<table>
<thead>
<tr>
<th>Table XVI—Cost of the Rule for Asbestos Vehicular Brakes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Drum brake linings (OEM)</td>
</tr>
<tr>
<td>Drum brake linings (AM)</td>
</tr>
<tr>
<td>Disc brake pads, LMV (OEM)</td>
</tr>
<tr>
<td>Disc brake pads, LMV (AM)</td>
</tr>
<tr>
<td>Disc brake pads, HV (OEM &amp; AM)</td>
</tr>
<tr>
<td>Brake blocks (OEM &amp; AM)</td>
</tr>
</tbody>
</table>

**Other friction products.** This grouping includes clutch facings, automatic transmission components, and the industrial and commercial friction products categories. These products will all be banned at Stage 2. The benefits (in terms of cancer-cases-avoided) of the actions taken in this rule on these product categories are set forth in the following Table XVII:

<table>
<thead>
<tr>
<th>Table XVII—Cancer-Cases-Avoided for Other Friction Products—Continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Industrial and commercial friction products</td>
</tr>
</tbody>
</table>

Primary routes of exposure to asbestos from these products occur during manufacture and repair. Quantified occupational risk posed by the manufacture and repair of these products ranges from an average of $1.46 \times 10^{-2}$ for the primary manufacture of automatic transmission components to an average of $5.2 \times 10^{-3}$ for the primary manufacture of friction materials. Approximately 517 workers in primary and secondary manufacture and 116 FTEs in installation, repair, and disposal are exposed to asbestos. In addition to these occupational risks, EPA has quantified significant non-occupational releases from the primary manufacturing of these three products. Monitoring data are not available for the exposure resulting from the use of these products, although EPA does believe additional exposures from clutches and industrial and commercial friction products are likely.

After assessing the current availability of substitutes and expert opinions concerning the predicted availability of substitutes, EPA believes that suitable substitutes will be available for clutch facings, automatic transmission components, and commercial and industrial friction products by the effective dates of the bans. Over the last several years, EPA has noted the increased use of non-asbestos parts for these products, and believes further development is likely.

The total cost of the actions taken in this rule for these product categories are set forth in the following Table XVIII:

<table>
<thead>
<tr>
<th>Table XVIII—Cost of the Rule for Other Friction Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Clutch facings</td>
</tr>
<tr>
<td>Automatic transmission components</td>
</tr>
<tr>
<td>Industrial and commercial friction products</td>
</tr>
</tbody>
</table>

The economic impact on this ban will be limited by the fact that most major primary manufacturers of asbestos friction products also produce asbestos-
free substitute products. In fact, all of the U.S. manufacturers of asbestos-containing automatic transmission components also produce asbestos-free products. Currently, asbestos-containing automatic transmission components currently comprise only one quarter of the present market. Considering the rapid substitution in this area and the present market. The manufacture of automatic transmission products now comprises only one quarter of automatic transmission components. Currently, asbestos-containing products also produce asbestos-free substitutes. In fact, all of these products are asbestos-free.

Manufacturers of asbestos-free products have developed many substitute products that pose a high potential for ambient release during a number of life cycle stages; workers and the general population are potentially subject to uncontrolled exposures; suitable substitutes exist for many of these products and are likely to exist for others by the time of the ban; and the cost of taking these actions is reasonable. Gaskets. This group includes most of the beater-add and sheet gasket product categories. These products, except for specialty industrial applications, will be banned in Stage 2. Specialty industrial gaskets are not banned under this rule (see discussion at Unit V.F.I.x below). The benefits (in terms of cancer-cases-avoided) of the actions taken in this rule on these product categories are set forth in the following Table XIX.

<table>
<thead>
<tr>
<th>Product</th>
<th>Discount rate 3 percent</th>
<th>Discount rate 0 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beater-add gaskets</td>
<td>21.48</td>
<td>26.34</td>
</tr>
<tr>
<td>Sheet gaskets</td>
<td>10.76</td>
<td>14.20</td>
</tr>
</tbody>
</table>

Does not include specialty industrial gaskets.

Gaskets are materials used to seal one compartment of a device from another in applications such as engine and exhaust manifolds. Asbestos gaskets are used mainly to seal connections and prevent leakage of fluids between solid surfaces. Primary routes of exposure to asbestos from these products occur during manufacture, repair of machinery containing an asbestos gasket, replacement of the gasket itself, and disposal. Exposure estimates (but not cost or benefit estimates) used in this Unit reflect exposures quantified for all gasket applications, including the small specialty industrial gasket segment of the gasket market that is not banned by this rule. An estimated 2,583 workers are exposed to asbestos during primary and secondary manufacturing of asbestos gaskets. Quantifiable risk of occupational exposure to these products ranges from an average of 7.35 x 10^-4 for the secondary manufacture of beater-add gaskets to an average of 3.56 x 10^-3 for the secondary manufacture of sheet gaskets. Quantifiable risk from non-occupational, lifetime exposures to asbestos released during the manufacture of beater-add gaskets alone is estimated at 1 x 10^-4 for approximately 47,000 people and at greater than 1 x 10^-4 for approximately 6 million people. EPA believes that the exposures quantified for these products are underestimated. Exposures that occur during gasket replacement and machinery repair, including activities like scraping of gaskets or on-site fabrication of gaskets, were not quantified by EPA. EPA determined that accurately quantifying these exposures and the resultant risks would be difficult and that sufficient other exposure and risk information is available regarding these products to make a finding of unreasonable risk.

According to comments, production of asbestos-containing sheet and beater-add gaskets has dropped significantly in most applications in recent years and non-asbestos substitutes already possess a large share of both gasket markets. Also, commenters indicated that the majority of the gasket market will be asbestos-free before the end of 1989. The economic impact of this ban will be limited by the fact that significant progress has been made in the development and availability of non-asbestos substitutes for most gasket applications and that most, if not all, major manufacturers of asbestos gaskets also produce non-asbestos substitute products. Due to the insufficiency of available price data, these recent trends, and the resultant decreases in the costs of banning this product, are not fully taken into account in the analysis of the benefits of banning these categories. However, EPA believes that the actual cost of the actions taken on these categories is less than that indicated below.

Gaskets were proposed for either a Stage 3 ban or a ban via the operation of a permit system. However, EPA has received comments indicating that the development of suitable substitutes has been more rapid than projected for most applications. EPA is also concerned that consumers and others may be subject to uncontrolled exposures during the repair and replacement of consumer applications of these products.

The total costs of the actions taken in this rule for these product categories are set forth in the following Table XX.

<table>
<thead>
<tr>
<th>Product</th>
<th>Total Cost in $ million (discounted at 3 percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beater-add gaskets</td>
<td>111.20</td>
</tr>
<tr>
<td>Sheet gaskets</td>
<td>96.52</td>
</tr>
</tbody>
</table>

Does not include specialty industrial gaskets.

EPA has concluded that a Stage 2 ban is appropriate for these product categories (except for specialty industrial gaskets) for the following reasons: (1) Relatively high quantifiable exposure and individual risk levels exist for these products; (2) these products pose a high potential for ambient release during a number of life cycle stages; (3) homeowners and workers are potentially subject to uncontrolled exposures during replacement of gaskets; (4) the overall cost calculated for taking these actions is relatively high, but is likely to be an overestimate because, according to commenters, suitable substitutes exist for many of these products and are likely to exist for others by the time of the ban; and (5) the scheduling of these products for a Stage 2 ban allows for the continued development of substitutes. Delaying the ban on these gaskets until Stage 3 or not banning the use of asbestos in these products could hurt the efforts of the large numbers of firms that have already made significant progress in developing substitutes because some substitutes are more expensive than asbestos-containing gaskets.

Specialty industrial gaskets are excluded from this rule's bans. These applications are not banned because of the high costs of a ban, due to the lack of suitable substitutes for a number of specialized industrial uses, the relatively small benefits derived from a ban, and a number of other factors described in Unit V.F.I.x.

h. A/C pipe. This category will be banned in Stage 3. The benefits (in terms of cancer-cases-avoided) of the actions taken in this rule on this product category are as follows: 3.17 cases if benefits are discounted at 3 percent and 4.38 cases if benefits are not discounted. A/C pipe is a product composed of cement and asbestos fibers and used primarily to convey potable water in water mains, sewage in force main sewers, and various materials in...
the continued use of capital equipment currently used to produce A/C pipe. This would substantially reduce the costs and societal impact of banning A/C pipe.

Some commenters have argued that if A/C pipe is banned, pressure may be brought to replace or discontinue use of existing A/C pipe. EPA does not believe that installed A/C pipe should be replaced or that its use should be discontinued. EPA's evaluation of the risk posed by A/C pipe, and by all products subject to this rule, is of absolute risk posed over the entire life cycle of products to be produced in the future, not just risk posed by existing products during product use. EPA's primary concern, for purposes of this rule, is the risk posed by exposures during the life cycle stages of A/C pipe from manufacture through installation. Expected risks later in the product life cycle, for example those engendered from exposures due to eroding pipe, have not been quantified. Therefore, actions to remove or discontinue use of existing A/C pipe in response to this rule are not justified.

Other commenters argued that if A/C pipe is banned in the U.S., other countries, including those where viable substitutes for A/C pipe are not readily available, would be pressured to ban the product. EPA's unreasonable risk analyses for this rule for A/C pipe is based not only on the risk posed during the life cycle of the product in the U.S., but also on the availability of viable substitutes in the U.S. and other factors. Therefore, the fact that EPA finds in this rule that future A/C pipe production and use in the U.S. poses an unreasonable risk does not imply that a similar finding could be made outside of the U.S.

A commenter argued that PVC and ductile iron pipe as primary substitutes for A/C pipe pose greater health risks than those posed during the life cycle of A/C pipe. EPA acknowledges that the individual lifetime cancer risk associated with the production of PVC may be equivalent to that associated with the production of A/C pipe. EPA could not calculate individual lifetime cancer risk for the production of ductile iron pipe. Instead EPA could only compute population cancer risk for ductile iron pipe production because of the manner in which available risk data were presented. The population cancer risk for the production of ductile iron pipe could be comparable to the population cancer risk for production of A/C pipe. While available information permitted EPA to quantify the risks associated with the installation of A/C pipe, cancer risks from installation of ductile iron pipe or to PVC dust from installation of PVC pipe have not been identified. While individual lifetime risks have been quantified for vinyl chloride (VC) leachate in drinking water, individual lifetime risks associated with asbestos in drinking water have not been specifically quantified. While the supporting data are limited, based on a consideration of life cycle risks, EPA believes that the available evidence suggests that substitution of A/C pipe with PVC and ductile iron pipe will present lower population cancer risks.

1. Polyvinylchloride pipe. For the proposed rule, EPA concluded that PVC pipe does not appear to present a health hazard comparable to asbestos, although VC, the monomer used to produce PVC, is a carcinogen. EPA also concluded that while VC is a human carcinogen, it does not appear to present a greater hazard than asbestos in the workplace or ambient environment.

The PVC product itself presents little risk and workplace exposures are apparently adequately controlled (Ref. 39).

EPA based this determination, for the proposed rule, on several factors including the individual lifetime cancer risk of 10^-4 for occupational exposure due to inhalation of VC in the manufacture of PVC pipe (Ref. 39). In response to the proposal, a commenter stated that workers exposed via inhalation to VC at the OSHA's PEL of 1 ppm would have a potential individual lifetime cancer risk of 4 x 10^-3. The commenter noted that this individual lifetime cancer risk is based on EPA's Carcinogen Assessment Group's (CAG) published unit cancer risk of 2 x 10^-4 (mg/kg/day)^-1 for VC based on animal inhalation data. The commenter questioned the discrepancy between the individual lifetime cancer risk estimation for VC of 4 x 10^-3 and the lifetime cancer risk of 10^-4 cited in EPA's support document for the proposed rule.

The commenter is correct that CAG has published a unit risk number for inhalation exposure to VC. This unit risk number was derived from animal inhalation data. The individual lifetime cancer risk number, 10^-4 cited in the support document for the proposal, was derived from epidemiological data analyzed and reported by Nicholson et al. 1982 (Ref. 39). In summary, EPA believes that the expected individual lifetime cancer risk associated with the manufacture of PVC pipe may be equivalent to the individual lifetime cancer risk posed by manufacture of A/C pipe. However, as noted in
Asbestos Institute at the 1986 legislative hearing, production of A/C pipe is significantly more labor intensive than production of PVC pipe. Even if one assumes that the lifetime cancer risk for production of A/C pipe and inhalation of VC in the manufacture of PVC pipe are comparable, the number of expected cancer cases (population risk) from production of PVC pipe will most likely be lower than the expected number of cancer cases associated with the production of an equivalent amount of A/C pipe.

EPA recognizes that VC inhalation exposure in the workplace, is the most significant exposure. Other potential exposures that could be present but are difficult to evaluate include: (1) VC leachate in drinking water, (2) VC emissions from PVC plants, and (3) inhalation of PVC dust. A commenter noted that "exposure to VC by ingestion in drinking water (via leaching from the PVC water pipe or as a contaminant in the water supply from disposal of PVC/ PVC waste products) also occurs. Additionally, the commenter noted that EPA should update its unit cancer risk value for ingestion given a more recent calculation by EPA's Office of Drinking Water.

EPA acknowledges the presence of detectable levels of VC in drinking water; however, the amount of VC expected to leach into drinking water from PVC pipe is considered to be minimal (Ref. 43). It is estimated that nearly all individuals (99 percent) using public water supplies are exposed to less than 1.0 µg/l of VC from all sources. At 1.0 µg/l, the excess lifetime cancer risk is about 5 × 10⁻⁶ (Ref. 44). Since leaching of VC from PVC drinking water pipe is estimated to be minimal, the risks associated with any increase in the amount of VC leachate in drinking water as a result of a ban of A/C pipe is also expected to be minimal.

Exposure to respirable PVC dusts and fumes may occasionally be encountered in the production of PVC or in the manufacture of PVC pipe. Exposure to PVC dust is associated with fibrotic lung changes and nonfatal lung conditions, such as bronchitis and pneumococcosis (Ref. 45).

Analogous to its analytical approach to asbestos and fibrous substitutes, EPA limited its PVC assessment to health effects directly associated with VC or PVC. Effects from exposure to other chemicals (such as solvents, byproducts, intermediates, and adhesives) involved in the manufacture, installation, use or disposal of PVC pipe were not considered. For the proposal, EPA evaluated hazard and exposure data on some other chemicals associated with pipe production and use. However, as noted by a commenter, the hazard and/or exposure data for these other chemicals are too limited to assess risk.

On the basis of available evidence, on balance, EPA believes that the population risk associated with A/C pipe life cycle exposures are likely to exceed the population risks associated with life cycle exposures to PVC pipe. A/C pipe presents risks throughout its product life cycle during manufacture, installation and repair, use and disposal because of the especially hazardous properties inherent in asbestos, the environmental persistence of asbestos fibers, and the larger populations exposed. In contrast, PVC pipe presents risks largely during the manufacturing phase of PVC pipe.

For the proposed rule, EPA concluded that ductile iron pipe, as a substitute for A/C pipe, would not present a health hazard comparable to that of asbestos (Ref. 39). Based on EPA's revised analysis of lifetime exposure associated with A/C pipe, one could argue that the number of excess cancer deaths associated with the production of ductile iron pipe and A/C pipe may be similar (Ref. 42). However, the excess cancer deaths that may be attributed to ductile iron pipe may be overestimated (Ref. 42). The estimate of excess cancers was derived from epidemiological data gathered on steel and iron foundry workers who may have had more diverse and higher exposures to toxic agents. Nevertheless, even if the cancer risk associated with ductile iron foundries is similar to steel foundries, the estimate of cancer risk for ductile iron pipe is most likely an overestimate for current exposure since historical exposures upon which the risks were based were probably much greater. In contrast, ductile iron pipe is manufactured from scrap metal which is not expected to result in exposures similar in magnitude to those found in the steel and iron foundries. Given that the number of workers exposed to particular agents in particular job categories cannot be determined, a precise occupational cancer risk comparison cannot be made. In addition, available evidence suggests that risks during non-manufacturing stages of the product life cycle are greater for A/C pipe than for ductile iron pipe. Thus, EPA believes that fewer cancer cases would be expected from the substitution of ductile iron pipe for A/C pipe than from the continued manufacture, processing, and use of A/C pipe.

Regulatory approach. The total costs of the actions taken in this rule for this product category is $128.03 million. This cost is likely an overestimate of actual cost in that it does not quantify the effect of the development of substitute fibers in cement pipe production. Use of a substitute fiber is expected to substantially reduce the costs and societal impact of banning this product.

EPA has concluded that a Stage 3 ban is appropriate for this product category for the following reasons: (1) relatively high quantifiable exposure and individual risk levels exist for these products; (2) these products pose a high potential for release of asbestos fibers during a number of life cycle stages; (3) workers and surrounding populations are potentially subject to uncontrolled exposures, especially during installation; (4) while this category was proposed for a Stage 1 ban, EPA has concluded that it is appropriate to delay the ban until Stage 3 to allow more time for further substitute development; (5) the cost of taking these actions is reasonable because performance and price suitable substitutes exist. Prior to the effective date of the Stage 3 ban, EPA will undertake a technical review to determine the availability of non-asbestos substitutes for A/C pipe. EPA believes that this is the best approach in light of the significant risk posed by asbestos; the possible risks posed by the current major substitutes, PVC and ductile iron pipe; and the development of further substitutes for A/C pipe.

1. Coatings. This grouping includes the roof coatings and cements and non-roofing adhesives, sealants, and coatings product categories. These products will be banned in Stage 3. The benefits (in terms of cancer-cases-avoided) of the actions taken in this rule on these product categories are set forth in the following Table XXI:

<table>
<thead>
<tr>
<th>Product</th>
<th>Discount rate</th>
<th>Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roof coatings</td>
<td>1.08</td>
<td>1.09</td>
</tr>
<tr>
<td>Non-roof coatings</td>
<td>1.33</td>
<td>1.84</td>
</tr>
</tbody>
</table>

These products are used for a wide variety of functions. Roof coatings uses include waterproofing, sealing, and repair of roofs. Non-roof coatings uses include adhesives, sealants, and coatings used in the building
construction, automotive, and aerospace industries.

Primary routes of exposure to asbestos from these products occur during manufacture, installation, or removal. A total of 582 workers is estimated to be exposed to asbestos during primary manufacture of asbestos roof coatings, and 553 workers are exposed during the primary manufacture of asbestos non-roof coatings. Quantifiable risk posed by these products is estimated to range from 1.22×10⁻⁵ for the removal of roof coatings in built-up roofing (a lower bound that assumes less than full-time exposure) to an average of 3.92×10⁻⁵ for the primary manufacture of non-roof coatings. Quantifiable risk from non-occupational, lifetime exposures to asbestos released during the manufacture of roof coatings is estimated at 6.27×10⁻⁵ for approximately 1,000 people and at greater than 1×10⁻⁶ for approximately 450,000 people.

However, EPA has concluded that the exposure quantified for this grouping are underestimated. EPA did not quantify exposures that occur during application, maintenance, and repair, including activities like spray application of coatings and sanding or removal of existing coatings or caulking. EPA also did not quantify releases to the ambient air due to the weathering of products used in outdoor, sometimes harsh environments. Many products in this category that are used in outdoor environments eventually wear off or chip or flake, resulting in difficult to monitor ambient releases. If, as a means of representing the possible effect of underestimated exposure during installation and removal, it were assumed that as little as one-tenth of 1 percent of asbestos consumed for these uses were released over the life cycle of the product and exposure were assumed based on analogous product operations, the estimate of benefits would be more than double for roof coatings (benefits would be 3.57 cases at 0 percent and 2.59 cases at 3 percent) and would increase for non-roof coatings (benefits would be 2.07 cases at 0 percent and 1.50 cases at 3 percent).

According to comments, non-asbestos substitutes possess growing shares of both coatings markets. Available evidence suggests that suitable substitutes should be available for most applications by Stage 3. One commenter, a major producer of roof coatings, indicated that it had replaced asbestos in all of its formulations. Trends toward the greater use of non-asbestos substitutes and probable decreases in the cost of substitutes are not fully taken into account in the analysis of the benefits of banning these categories because of the unavailability of suitable substitute use information at the time the analysis was performed. Therefore, EPA believes that the actual cost of the actions taken on these categories is less than that indicated below.

Both coatings categories were proposed for either a Stage 3 ban or a ban via operation of a permit system. EPA has received comments indicating that progress has been made in the development of suitable substitutes.

The total costs of the actions taken in this rule for these product categories are set forth in the following Table XXII:

<table>
<thead>
<tr>
<th>TABLE XXII—COST OF THE RULE FOR COATINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Roof coatings</td>
</tr>
<tr>
<td>Non-roof coatings</td>
</tr>
</tbody>
</table>

EPA has concluded that a Stage 3 ban is appropriate for these product categories for the following reasons: (1) Relatively high quantifiable exposure and individual risk levels exist for these products; (2) these products pose a high potential for ambient release during a number of life cycle stages, including ambient releases due to weathering during outdoor use; (3) homeowners and workers are potentially subject to uncontrolled exposures during product application, maintenance, and removal; (4) the cost of taking these actions is reasonable because suitable substitutes are expected to exist for all of these products by the time of the ban; and (5) while the quantified benefits of banning these products are relatively small, compared to other product categories banned by this rule, these products are likely both to lead to a number of serious exposures that could not be readily quantified for this rule and to contribute significantly to environmental loading.

1. Paper products. This grouping includes the commercial paper, corrugated paper, millboard, rollboard, and specialty paper product categories. These products will be banned in Stage 3. The benefits (in terms of cancer cases-avoided) of the actions taken in this rule of these product categories are set forth in the following Table XXIII:

<table>
<thead>
<tr>
<th>TABLE XXIII—CANCER-CASES-AVOIDED FOR ASBESTOS PAPER PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
</tr>
<tr>
<td>Millboard</td>
</tr>
<tr>
<td>Specialty paper</td>
</tr>
</tbody>
</table>

Commercial and corrugated paper and rollboard are no longer commercially imported or produced in the U.S.

The products in these categories are used for a wide variety of functions. They are frequently very similar in form, but differ primarily by specific end use. Product uses include thermal insulation, fireproofing, and fill for a variety of applications, such as beverage and other filter. Asbestos paper products are also used as a component of other products, such as gaskets (discussed above).

Primary routes of exposure to asbestos from these products occur during manufacture, installation, repair, removal, and disposal. A total of 668 workers is estimated to be exposed to asbestos during primary and secondary manufacture of asbestos paper products. Quantifiable risk posed by these products is estimated to range from an average of 7.35×10⁻⁴ for the secondary manufacture of all paper products to an average of 1.87×10⁻³ for the primary manufacture of millboard. There is potential for episodic, peak exposure during manufacturing activities. Respirators and strict workplace and cleaning practices must be observed to meet the existing OSHA PEL for these products. Quantifiable risk from non-occupational, lifetime exposure to asbestos released during the manufacture of millboard is estimated at 1×10⁻⁴ for approximately 2,256 people and at greater than 1×10⁻⁴ for approximately 840,000 people. EPA has concluded that the overall exposures quantified for this grouping are underestimated. EPA did not quantify exposures that occur during installation, repair, and removal, including activities like cutting, drilling, and tearing performed by hand during installation, maintenance, removal, and disposal of existing products. EPA determined that accurately quantifying these exposures and the resultant risks would be difficult and that sufficient other exposure and risk information is available regarding these products to make a finding of unreasonable risk.

According to EPA’s analysis and comments, three of the five paper products in this grouping, commercial and corrugated paper and rollboard, are no longer commercially imported or
produced in the U.S. In addition, low-cost substitutes exist for products in the millboard and the specialty paper categories. Therefore, available evidence suggests that suitable substitutes should be available for most applications by the effective date of the Stage 3 ban. The total costs of the actions taken in this rule for these product categories are set forth in the following Table XXIV.

<table>
<thead>
<tr>
<th>Product</th>
<th>Total cost in $ million (discounted at 3 percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Millboard</td>
<td>3.73</td>
</tr>
<tr>
<td>Specialty paper</td>
<td>0</td>
</tr>
</tbody>
</table>

The paper product categories were proposed for either a Stage 3 ban or a ban via the operation of a permit system. Many of these products are no longer used in the U.S. and suitable substitutes are rapidly being developed, although the development of reasonably-priced substitutes for some specialty uses might take a number of years. EPA is also concerned that consumers may be subject to uncontrolled exposures during installation, maintenance, repair, and removal of products such as millboard. In addition, many of these paper products are very similar in form and bans would be difficult to enforce were the products in this grouping banned at different times.

EPA has concluded that a Stage 3 ban is appropriate for these product categories for the following reasons: (1) Relatively high quantifiable exposure and individual risk levels exist for these products; (2) these products pose a high potential for ambient release during a number of life cycle stages; (3) consumers and workers are potentially subject to uncontrolled exposures, especially during installation, maintenance, repair, and removal of these products; (4) the cost of taking these actions is reasonable because several of these products are no longer produced or imported in the U.S. and because suitable substitutes are expected to exist for all of these products by the time of the ban; and (5) while the quantified benefits of banning these products are relatively small, compared to other product categories banned by this rule, these products are likely both to lead to a number of serious exposures that could not be readily quantified for this rule and to contribute significantly to environmental loading.

One asbestos paper product category, high-grade electrical paper, is not included within the rule’s bans (see Unit V.F.1.v). This product is not included for a number of uses of the product, thereby making the cost of a ban very high relative to other products analyzed for this rule. In addition, high-grade electrical paper is reasonably discernable from other paper products.

k. New commercial asbestos products.

This grouping covers all new asbestos-containing products whose commercial manufacture, importation, or processing commences after the effective date of this rule. All such new uses will be banned from manufacture, importation, processing, and distribution in commerce as of Stage 1, unless EPA grants an exemption application for the product or use. In view of the following factors, EPA finds that the use of asbestos in new products whose commercial manufacture, importation, or processing is initiated after the effective date of this rule's bans poses an unreasonable risk of injury to human health: (1) The development of substitute fibers, (2) the potential for high lifetime risks related to exposure to asbestos due to the manufacture, importation, processing, and use of new asbestos products, (3) the likely escalation of environmental loading of asbestos if the manufacture, importation, processing, or distribution in commerce of new asbestos products were allowed, (4) the speculative benefits of new uses of asbestos, and (5) the absence of cost related to modification of existing capital equipment. Therefore, EPA finds that the benefits of banning new commercial asbestos products outweigh the costs of such a ban. Should a new use of asbestos be developed which meets the criteria applied to exemptions for existing asbestos products, set out in Unit II.E of this preamble and § 763.173, an exemption should be applied for and may be granted.

i. Acetylene cylinder filler. These products are used as filler in steel cylinders used to store acetone in oxyacetylene torches. Benefits derived by banning this product would total less than one-tenth of a cancer-case-avoided. Exposures during primary manufacture are likely to be limited, relative to other product categories, because the product is enclosed and there is little exposure during product repair or disposal compared to other products analyzed for this rule.

EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) Current substitutes are more expensive than asbestos products and little information is available on the relative performance characteristics of substitutes; therefore, reasonable cost, suitable substitutes may not be available for all applications of these products; (2) this product category accounts for only a minuscule portion of U.S. asbestos consumption (approximately 584 tons in 1985); and (3) a ban on this product category would result in only minimal benefits because asbestos exposure is limited in most life cycles stages, relative to other products analyzed for this rule.

ii. Arc chutes. These products are used to guide electric arcs in products including motor starter units in electric generating plants. The benefits derived from a ban on this product would total only a small fraction of a cancer-case-avoided. Although EPA has no data on exposure for products in this category, exposures in product life cycle stages beyond primary manufacture are likely to be limited, relative to other product categories, because the asbestos is bound in ceramic in the end use product.

EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) Insufficient information was available regarding exposure to determine the benefits of banning this product; (2) this product category accounts for only a minuscule portion of U.S. asbestos consumption (approximately 13.5 tons in 1985).

iii. Asbestos diaphragms. These products are used primarily in the chloralkali industry in the production of chlorine, caustic soda, and other
EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) Insufficient information was available regarding product substitutes to determine the costs of banning this product, although available information indicates that the costs of a ban would be high; (2) this product category accounts for only a minuscule portion of U.S. asbestos consumption (approximately 1 ton in 1986); and (3) a ban on this product category would result in only minimal benefits because asbestos exposure is limited in most life cycle stages, relative to other products analyzed for this rule.

iv. High-grade electrical paper. These products are used as electrical paper insulation, primarily for high-temperature, low-voltage applications such as motors, generators, transformers, and other heavy electrical apparatuses. The benefits derived from a ban on this product would total approximately 0.4 of a cancer-case-avoided. The cost of banning this product would be high because reasonably priced suitable substitutes do not exist for all applications and a number of existing substitutes are very expensive. The total cost of banning this product is estimated to total over $51 million.

EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) this product category accounts for only a small portion of U.S. asbestos consumption (approximately 125 tons in 1985); (2) the costs per unit of banning this product would be relatively high for the amount of benefits derived, due to the absence of substitutes of similar cost or performance characteristics for a number of applications; and (3) a ban on this product category would result in only minimal benefits because asbestos exposure is limited in most life cycle stages, relative to other products analyzed for this rule.

vii. Packings. Packings are used to seal fluids in devices where motion is necessary. Benefits derived from banning this product category would total less than one tenth of a cancer-case-avoided. Exposures in the product life cycle stages beyond primary and secondary manufacture are likely to be limited, relative to other product categories, because asbestos in packings is generally saturated with lubricant during packing formation and with fluid during use and removal. In addition, there are many specialized uses of asbestos packings, including advanced technology and military applications. The cost of banning this product would be relatively high on a per unit basis because suitable substitutes do not exist and are unlikely to soon be developed for a significant number of packings applications and a number of existing substitutes are very expensive. The total cost of banning this product is estimated at $50.55 million.

EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) this product category accounts for only a small portion of U.S. asbestos consumption (approximately 744 tons in 1985); (2) the costs of banning this product would be very high, due to the absence of reasonably priced substitutes; and (3) a ban on this product category would result in minimal benefits.

viii. Reinforced plastic. These products are used primarily for electromagnetic parts in the automotive and appliance industries and high-performance specialty plastics. Benefits derived by banning this product category would total approximately four tenths of a cancer-case-avoided. Exposures in product life cycle stages beyond primary manufacture are likely to be limited, relative to other product categories, because asbestos is encased in plastic in the end use products. In addition, the cost of banning this product would be high because suitable substitutes do not exist for a significant number of plastics applications and a number of existing substitutes are very expensive. The total cost of banning this product is estimated at almost $35 million.
EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) This product category accounts for only a minuscule portion of U.S. asbestos consumption (approximately 812 tons in 1985); (2) the costs of banning this product would be too high, due to the absence of a number of applications of substitutes of similar cost or performance characteristics; and (3) a ban on this product category would result in minimal benefits because asbestos exposure is limited in most life cycle stages, relative to other products analyzed for this rule.

ix. Sealant tape. These products are used primarily to seal windows and automotive windshields, in aerospace applications, and in the manufacture of insulated glass. Benefits derived by banning this product would total less than one tenth of a cancer-case-avoided. Exposures in the product’s life cycle stages beyond primary manufacture are likely to be limited, relative to other product categories, because asbestos is contained in rubber in the end use products. In addition, the cost of banning this product would be high because suitable substitutes do not exist for a number of non-automotive applications. A number of existing substitutes are very expensive and others do not perform as well as asbestos-containing products. The total cost of banning this product is estimated at almost $35 million.

EPA does not believe that a ban is appropriate for this product category for the following reasons: (1) This product category accounts for only a minuscule portion of U.S. asbestos consumption (approximately 700 tons in 1985); (2) the total cost of banning this product would be significant because of the absence of suitable substitutes for some uses; and (3) a ban on this product category would result in minimal benefits because asbestos exposure is limited in most life cycle stages, relative to other products analyzed for this rule.

Specialty industrial gaskets. The production of most asbestos-containing gaskets is banned in Stage 2 (see Unit V.F.g). Excluded from the rule’s bans are gaskets that are manufactured, imported, processed, or distributed in commerce for specialty industrial uses. This exclusion is limited to asbestos-containing gaskets that are designed for industrial uses in either (a) environments where temperatures are 750 degrees Fahrenheit or greater, or (b) corrosive environments. An industrial gasket is one designed for use in an article which is a “consumer product” within the meaning of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2052 or for use in a “motor vehicle” or “motor vehicle equipment” within the meaning of the National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. 1381. A corrosive environmental is one in which the gasket is exposed to concentrated (pH less than 2), highly oxidizing mineral acids (e.g., sulfuric, nitric, or chromic acid) at temperatures above ambient. For example, gaskets used in automobiles or consumer products would not be excluded from the rule’s bans, even if a particular application was designed for use in a corrosive environment or an environment of greater than 750 degrees Fahrenheit. On the other hand, gaskets used in industrial machinery would be excluded from the rule’s bans if the gasket application were designed for use in a corrosive environment or in one of greater than 750 degrees Fahrenheit.

Gaskets are used to seal one compartment of a device from another in static applications. This portion of the beater-add and sheet gasket product categories is not being banned because: (1) According to commentators and the RIA, industrial applications above 750 degrees Fahrenheit and industrial uses in corrosive environments contain many specialized uses of asbestos gaskets, including advanced technology and military applications, and available information indicates that substitutes for these industrial applications are less likely to be available than for lower temperature, non-corrosive, or consumer (e.g., automotive) applications, (2) due to the nature of their applications, the potential hazards created by failure of specialty industrial gaskets might be greater than for other categories, (3) these applications account for only a small portion of the gasket product categories and a very small portion of U.S. asbestos consumption, (4) industrial applications have relatively lower overall exposure levels and smaller exposed populations than do uses with potential consumer exposures, (5) the benefits resulting from a ban of these applications (approximately 0.6 cancer cases) would be small relative to the benefits derived from including the rest of the gasket categories in the ban. The cost of banning these portions of the gasket categories would be high because available evidence indicates that suitable substitutes do not exist and are unlikely to soon be developed for a significant number of applications and a number of existing substitutes are very expensive. The total cost of banning these applications is estimated at approximately $85 million.

xi. Textile products. These products are primarily intermediate textile products used in end products covered by other categories banned by this rule, including friction products and gaskets. Because exposures related to the production of these products are largely eliminated by other actions taken in this rule, EPA has determined that separate action on this category to be unnecessary.

VI. Other EPA Statutes

Section 6(c) of TSCA requires that if EPA 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 statute administered by EPA, EPA may not promulgate a rule under section 6(a) of TSCA unless EPA finds that it is in the public interest to protect against the risk by action under TSCA. EPA finds that no other law administered by EPA will eliminate or reduce to a sufficient extent the risks posed by asbestos exposure and that it is in the public interest to use TSCA.

Several EPA statutes have been used to limit asbestos exposure. On April 16, 1973, EPA used the authority of the Clean Air Act (CAA) to list asbestos as a hazardous air pollutant, establish a "no visible emission" standard for manufacturers, and ban the use of spray-applied, asbestos-containing material as insulation in buildings. EPA amended this regulation to ban asbestos-containing pipe lagging, by a rule published in the Federal Register of October 12, 1975 (40 FR 48292); and in 1978, extended the ban to all uses of sprayed-on asbestos by a rule published in the Federal Register of June 19, 1978 (43 FR 26372). The CAA rule, which was last amended on April 5, 1984 (49 FR 13058), also regulates the removal of asbestos from buildings and the disposal of wastes generated by removal. EPA proposed amendments to the rule in the Federal Register of January 10, 1989 (54 FR 912) to enhance and promote compliance with the current standard.

However, the CAA has limitations. The CAA does not apply directly to indoor air in the workplace or home. Consequently, some additional uses of that statute may leave many workplace or home exposures inadequately controlled.

Another EPA statute that could be used to reduce asbestos exposure is the Safe Drinking Water Act (SDWA). Under the 1986 SDWA Amendments, EPA is required to set a National Primary Drinking Water Regulation for asbestos. In the Federal Register of May 22, 1989, EPA proposed an SDWA.
containing respirable asbestos. The CPSC took these actions based on findings that the use of those products in the household would result in an increased risk of cancer. Earlier, the Food and Drug Administration under the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261) banned "general-use garments containing asbestos other than garments having a bona fide application for personal protection against thermal injury and so constructed that the asbestos fibers will not become airborne under reasonably foreseeable conditions of use" (16 CFR 1500.17). The FHSA is now administered by the CPSC.

In 1980, CPSC issued a general order requiring persons to submit information on the use of asbestos in certain consumer product categories. CPSC has also measured potential consumer exposure to asbestos from such products as asbestos millboard, asbestos paper products, and stove door gaskets. CPSC submitted those data to EPA as part of this rulemaking. On September 24, 1986 (51 FR 35911), CPSC issued labeling requirements for "household products containing intentionally added asbestos that, under any reasonable foreseeable conditions of handling and use are likely to release asbestos fibers." In 1986, in light of the EPA propose rule to ban certain asbestos products immediately and phase out others over 10 years, CPSC decided not to ban any additional consumer products containing asbestos under statutes that it administers.

OSHA began to regulate asbestos in the workplace in 1971 under the Occupational Safety and Health Act (29 U.S.C. 51, OSHA) (Re). Since the first workplace standard setting a limit of 2 f/cc was promulgated in May 1971, the workplace standard has been periodically lowered, to 5 f/cc in 1972 and to 2 f/cc in 1976. An Emergency Temporary Standard (ETS) establishing a PEL of 0.5 f/cc was published in the Federal Register of November 4, 1983 (48 FR 51086), but the ETS was found invalid by a court. OSHA proposed a revised standard in the Federal Register of April 10, 1984 (49 FR 14116). OSHA, issued a final rule on June 23, 1988 (51 FR 22912), lowering the PEL to 0.2 f/cc and establishing new work practice requirements for both general industry and the construction sector. Both asbestos industry groups and unions challenged various provisions of the new OSHA rule. On February 2, 1988, the United States Court of Appeals for the District of Columbia Circuit issued its decision in the consolidated appeals. The court upheld OSHA's finding that asbestos exposure poses a significant risk and the feasibility of the new PEL and specifically rejected the asbestos industry groups' challenges to OSHA's risk assessment. However, the court found that there was not substantial evidence supporting OSHA's: (1) Ban on the spraying of asbestos containing products. (2) rejection of a lower PEL for certain major subgroups of industry, (3) rejection of a short-term exposure limit (STEL), and (4) rejection of certain specific provisions recommended by participants in the rulemaking (e.g. smoking control provisions, bilingual labels, and more stringent respiratory protection requirements). The court ordered OSHA to establish a STEL to consider a lower PEL for certain industry sectors where it may be feasible, and to consider several other specific changes suggested by rulemaking participants. In response to this court decision, OSHA amended its Asbestos Standard to incorporate an Excursion Limit (EL). This amendment, which was published in the Federal Register of September 14, 1988 (53 FR 35910), limits short-term exposures to 1 f/cc over a half-hour period. OSHA has not either finalized or proposed any other changes in its Asbestos Standards.

The Mine Safety and Health Administration (MSHA), acting under the Mine Safety and Health Act, has adopted workplace standards designed to protect workers engaged in pit and underground mining and milling (30 CFR 71.202). The MSHA standard was last amended in 1976 and calls for a PEL of 2 f/cc.

State and local public employees are generally excluded from coverage under the OSHAct. However, under section 19 of the OSHAct, OSHA has promulgated State plans for 23 States and 2 territories, thus effectively extending OSHA protections to State and local government employees in those jurisdictions. EPA has promulgated a rule to establish requirements similar to those of the OSHA Asbestos Construction Standard for State and local public employees not covered under a State plan who conduct asbestos abatement work. However, other public employees, such as fire fighters, are not covered by that rule.

B. EPA's Determination Under Section 9(a) of TSCA

EPA is not required under section 9(a) to submit a report to other agencies on the asbestos risks described in this document since EPA has determined that such risks cannot be prevented or reduced to a sufficient extent taken under a Federal law not administered by EPA. Certain activities involving asbestos present risks that fall under the
jurisdiction of a number of different Federal laws such as the OSHA Act, the CPSA, and the CAA, but no one statute, other than TSCA, can adequately address all the risks posed throughout the life cycle of asbestos. Referral would result in fragmented assessment and control of risks and potentially duplicative regulatory efforts. Furthermore, even if EPA were to refer asbestos exposure risks to other agencies, taken by those other agencies would still leave a substantial residual risk, resulting in an adverse effect on public health. Only EPA under TSCA can stop the build up of asbestos in the environment. EPA’s reasons for reaching these conclusion are set forth below.

1. Interpretation of section 8(a) of TSCA. The comprehensive nature of TSCA has long been recognized. TSCA allows regulation of a chemical substance based on all of its risks and, thereby, allows the Government to remedy the deficiencies in other statutes that can deal only with parts of the risk. (Statement of the President on signing S. 3149 Into Law, October 12, 1976, Weekly Compilation of Presidential Documents, vol. 12, No. 42, Oct. 18, 1976, at 1488; S. Rep. No. 94-698, 94th Cong., 1st Sess. at 2). The need for a total exposure, multi-media approach to chemical regulation, and the dangers of a fragmented regulatory approach were recognized even during the early Congressional hearings on TSCA. See, for example, the 1973 Senate Hearings at 212–214 and the 1972 House Hearings at 65–67. No other single law provides authority to deal comprehensively with multi-media hazards.

In particular, Congress designed TSCA to deal with chemical substances for which the most appropriate remedy would be a total ban on their manufacture, importation, processing, and distribution in commerce. In this regard, Congress focused on the risk of asbestos and the dangers of fragmented regulation of asbestos during the legislative hearings. See the 1971 Senate Hearings and 1973 Hearings. Asbestos risks were described in the workplace and in over 3,000 uses that could present risks to the general population (H.R. Rep. No. 94–1341, 94th Cong., 2d Sess., at 5 (1976). Members of Congress believed it intolerable that no agency could deal comprehensively with chemical risks, including the risk from asbestos. See 1973 Senate Hearings at 319–320 (Letter from Senator Tunney to Dow Chemical Company); 1975 Senate Hearings at 131–132 (Remarks of Senator Tunney).

2. Capability of other Federal authorities to deal with the combination of asbestos activities. EPA’s analysis of the jurisdiction over the risks presented by asbestos among a number of agencies and statutory authorities is set out below. OSHA has authority under the OSHA Act to control risk presented to private sector manufacturing, construction, and service employees from workplace exposures, and may approve State plans covering State and local public employees. CPSA has authority under the CPSA and FHSA to control risk presented to consumers from consumer products. The Mine Safety and Health Administration has authority under the Mine Safety and Health Act concerning risk presented during the mining and milling of asbestos. State and local public employees in about half the States (such as fire fighters who may wear asbestos clothing) are not covered by either OSHA regulations or OSHA-approved State plans.

EPA has concluded that asbestos is appropriate for TSCA action rather than referral to other agencies. It is a substance for which there is broad exposure to populations in numerous situations—in the workplace, through long- and short-term ambient concentrations, and from consumers products. With the exception of TSCA, there is no single authority to deal with all of these multiple exposures. No one of the other potential Federal regulatory authorities, in looking at its specific part of the overall exposures, can either evaluate or deal with the totality of the risk presented. OSHA may set exposure limits for workers, but there may be venting of asbestos from the workplace into the atmosphere. EPA, under the CAA, may regulate ambient emissions, but not workplace or consumer exposures. In each case, only a fraction of the risk is controlled. Only EPA under TSCA can look across the range of asbestos use to evaluate whether exposure presents an unreasonable risk. There is no other Act that affords such authority. Further, only action under TSCA can stop the build up of asbestos in the environment.

3. Residual risks. Even if other Federal agencies took additional action to reduce the risk associated with asbestos during the various stages of the life cycle of asbestos products, a substantial and unreasonable residual risk would still remain.

Large populations outside of OSHA jurisdiction are at risk from exposure to asbestos. State and local public employees, such as fire fighters, are not protected by OSHA regulations in about half of the States. The general population is exposed to asbestos into the ambient air as a result of release during the manufacture, processing, use, repair, and disposal of asbestos products. As discussed more fully in Unit V.A.3 of this preamble, asbestos released into the ambient air can build up in the environment. EPA is concerned about this environmental residual risk.

Further, even if OSHA achieves strict compliance with its PEL of 0.2 f/cc and its new EL of 1 f/cc, a substantial and unreasonable residual risk would remain. OSHA recognized that a substantial risk remained with a PEL of 0.2 f/cc. OSHA estimated that persons exposed to this level over a working lifetime of 45 years would face a risk of 7 m 1,000 of developing cancer. However, OSHA concluded that this was the lowest exposure level that was technologically feasible in asbestos workplaces. As stated above, OSHA has been ordered to consider a lower PEL for certain general industry sectors where it may be feasible. However, technical limitations on asbestos exposure monitoring seem to limit OSHA from establishing a PEL lower than 0.1 f/cc. Indeed, the union groups that asked the court to order OSHA to adopt a lower PEL only requested a PEL of 0.1 f/cc. Workers exposed to a level of 0.1 f/cc still face a substantial risk. OSHA calculates that such workers face a risk of 3 in 1,000 of developing cancer when exposed over a 45-year working lifetime.

In addition, it is likely that the OSHA PEL of 0.2 f/cc and EL of 1 f/cc will be exceeded in many cases since it is particularly difficult to apply the PEL in the construction and service sectors. Many of the workplace exposures to asbestos occur downstream in the construction and service sectors rather than the manufacturing sector. Over 80 percent of workers exposed to asbestos are in the construction and service sectors. Employees in those sectors often do not know when they are exposed to asbestos because they do not know that they are working with asbestos products (Ref. 34). Attempts at compliance and OSHA’s compliance inspections are also difficult in the construction and service sections since employees frequently do not have a fixed work site. Between July 1, 1986 and June 30, 1987 OSHA cited 534 alleged violations of the asbestos rule for general industry and 427 alleged violations of the rule for the construction sector. OSHA inspection data show that 81 of the 655 asbestos monitoring samples taken by OSHA from July 1, 1986 through April 30, 1988, had exposure values above the OSHA PEL of 0.2 f/cc. While respirators were in use in many of the establishments
with air concentrations higher than the PEL. Twenty percent of these establishments were cited for violations of respiratory protection guidelines or for violations of the PEL (Ref. 49). As stated earlier, OSHA amended its Asbestos Standards to incorporate an EL on September 14, 1988. EPA does not believe that the EL will have a significant effect on the significant risk posed by asbestos in the workplace. A more detailed discussion of this may be found in Unit V.A.3 of this preamble. Finally, many asbestos control measures, in particular, the use of respirators or increased workplace ventilation, only shift the asbestos exposure to another population for which no exposure controls exist. For example, if ventilation is used, substantial quantities of asbestos would be released to the ambient environment where it would continue to present a risk both to other workers and the general population.

Similarly, CPSC cannot evaluate or deal with the totality of the risk presented by asbestos. CPSC may ban or require safety standards for asbestos-containing consumer products based exclusively on risk to consumers. CPSC is unable to consider risk to other groups from releases of asbestos during the life cycle of those products. In addition, CPSC has indicated that it does not plan to enact further bans on asbestos-containing products.

After carefully analyzing other Federal authorities, EPA concludes that action under TSCA is appropriate to reduce the unreasonable risk to human health posed by asbestos. Use of other Federal authorities cannot reduce risk to a reasonable level because: (1) Even together, they cannot reduce the total volume of asbestos or asbestos products in commerce or limit the ongoing buildup of asbestos in the environment, (2) Even together, they cannot protect all of the many population groups at risk, and (3) They all have jurisdictional gaps, both individually and collectively.

VIII. Enforcement

Section 15 makes it unlawful to fail or refuse to comply with any provisions of a rule promulgated under section 8 of TSCA. Therefore, any failure to comply with this rule would be a violation of section 15. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) Fail or refuse to permit access to or copying of records, as required by TSCA; (3) Fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation. Each day of operation in violation of this rule could constitute a separate violation. Knowing or willful violations of this rule could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment of up to 1 year. In addition, other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violations of this rule and seizing any chemical substance or mixture manufactured or imported in violation of this rule.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

IX. Confidentiality

Section 14(a) of TSCA allows a person who submits information to EPA to assert a claim of confidentiality if release of the information would reveal trade secrets or confidential commercial or financial information. Under this rule, claims of confidentiality can be asserted only at the time information is submitted in an exemption application and only in the manner specified in § 763.179. EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR Part 2, Subpart B.

Any person who claims information contained in an exemption application as confidential is required to provide two copies of its application: a complete copy of the application including all information as confidential in exemption applications must respond in detail to substantiation questions in § 763.179(d) at the time the application is submitted to EPA. If a claim is not accompanied by the required substantiation at the time it is submitted to EPA, the company will be notified that the unsanitized copy of the application will be placed in the public file.

EPA is committed to the public disclosure of as much nonconfidential information submitted in exemption applications as possible. Requiring up-front substantiation of confidentiality claims and continued close scrutiny of such claims through the established claim review process will ensure that as much information as possible is released. Public interest in the information in exemption applications and the need for public participation in the review of applications justifies this approach. Up-front substantiation obviates the need for follow-up substantiation by submitters resulting from EPA review or Freedom of Information Act requests and thereby facilitates public participation in the process of reviewing exemption applications.

X. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS-62036). A public version of the record, without any confidential business information, is available in the TSCA Public Docket Office, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Room NE-G004, 401 M Street, SW, Washington, DC.

This record contains information considered by EPA in developing this rule. The record includes: (1) All Federal Register notices, (2) relevant support documents, (3) reports, (4) memoranda and letters, and (5) hearing transcripts, responses to comments, and other documents related to this rulemaking.

XI. References


A. Regulatory Flexibility Act

The RIA also estimates that the rule will, over the 15-year period analyzed, avoid at least 200 cancer cases, if benefits are not discounted, and 148 cancer cases, if benefits are discounted at 3 percent. If analogous exposures are not assumed, the estimates of cancer cases-avoided are 104 cases, if benefits are not discounted, and 120 cases, if benefits are discounted at 3 percent. As is stated in Unit V.D of this preamble, EPA believes that these costs are reasonable and that the rule is the least burdensome way of reducing the unreasonable risk posed by exposure to asbestos from the manufacture, importation, processing, use, and disposal of asbestos-containing products.

This rule was submitted to the Office of Management and Budget (OMB) for review, as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator may certify that a rule will not, if promulgated, have a significant impact on a substantial number of small entities and, therefore, does not require a regulatory flexibility analysis.

EPA has analyzed the economic impact of this final rule on small businesses. A summary of this analysis appears in the RIA and Unit V.D of this preamble. Based on the discussion in that Unit, EPA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The reporting and recordkeeping provisions of this final rule have been submitted to OMB for approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the Federal Register.

Public reporting burden for this collection of information is estimated to average less than 2 hours annually per firm over the 3-year period reviewed for the analysis of regulatory burden. This burden estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This estimate of annual burden is a relatively low figure because of the small number of firms affected by the regulatory actions taken during the period reviewed for the analysis of regulatory burden.

Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Desk Officer for EPA.

List of Subjects in 40 CFR Part 763
Asbestos, Environmental protection, Hazardous substances.

Dated July 6, 1989.
William K. Reilly,
Administrator.

Therefore, 40 CFR Part 763 is amended as follows.

PART 763—AMENDED

1. The authority citation for Part 763 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2607(c).

2. By reserving Subpart H and adding new Subpart I to read as follows:

Subpart I—Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements

§ 763.160 Scope.

This subpart prohibits the manufacture, importation, processing, and distribution in commerce of the asbestos-containing products identified and at the dates indicated in §§ 763.165, 763.167 and 763.169. This subpart requires that products subject to this rule’s bans, but not yet subject to a ban on distribution in commerce, be labeled. This subpart also includes general exemptions and procedures for
requesting exemptions from the provisions of this subpart.

§ 763.163 Definitions.

For purposes of this subpart:

Asbestos. means any asbestos-containing product which is intended for use as a filler for acetylene cylinders.

Acetylene-cylinder filler means an asbestos-containing product which is intended for use as a filler for acetylene cylinders.


Aftermarket part means any part offered for sale for installation in or on a motor vehicle after such vehicle has left the manufacturer's production line.

Agency means the United States Environmental Protection Agency.

Arc chute means an asbestos-containing product that acts as a chute or guidance device and is intended to guide electric arcs in applications such as motor starter units in electric generating plants.

Asbestos" means the asbestiform varieties of: chrysotile (serpentine); crocidolite (riebeckite; amosite; anthophyllite; and actinolite.

Asbestos-containing product means a product containing asbestos as a matrix component or which contains more than 1 percent asbestos by weight or area.

Asbestos cement means the use of asbestos in the form of a corrugated sheet used as a non-flat surfaced reinforcing or insulating material. Major applications of this product include: building siding or roofing; linings for waterways; and components in cooling towers.

Asbestos cement (A/C) corrugated sheet means an asbestos-containing product made of cement and in the form of a corrugated sheet used as a non-flat surfaced reinforcing or insulating material. Major applications of this product include: wall linings; partitions; soft felt; electrical barrier boards; bus bar run separators; reactance coil partitions; laboratory work surfaces; and components of vaults, ovens, safes, and broilers.

Asbestos cement (A/C) pipe and fittings means an asbestos-containing product made of cement and intended for use as pipe or fittings for joining pipe. Major applications of this product include: pipe used for transmitting water or sewage; conduit pipe for protection of utility or telephone cable; and pipes used for air ducts.

Asbestos cement (A/C) shingle means an asbestos-containing product made of cement and intended for use as a siding, roofing, or construction shingle serving the purpose of covering and insulating the surface of building walls and roofs.

Asbestos clothing means an asbestos-containing product designed to be worn by persons.

Asbestos-containing product means any product to which asbestos is deliberately added in any concentration or which contains more than 1 percent asbestos by weight or area.

Asbestos diaphragm means an asbestos-containing product that is made of paper and intended for use as a filter in the production of chlorine and other chemicals, and which acts as a mechanical barrier between the cathodic and anodic chambers of an electrolytic cell.

Automated transmission component means an asbestos-containing product used as a friction material in vehicular automatic transmissions.

Battery separator means an asbestos-containing product used as an insulator or separator between the negative and positive terminals in batteries and fuel cells.

Beater-aid gasket means an asbestos-containing product that is made of paper intended for use as a gasket, and designed to prevent leakage of liquids, solids, or gases and to seal the space between two sections of a component in circumstances not involving rotary, reciprocating, and helical motions. Major applications of beater-aid gaskets include: gaskets for internal combustion engines; carburetors; exhaust manifolds; compressors; reactors; distillation columns; and other apparatus.

Brake block means an asbestos-containing product intended for use as a friction material in drum brake systems for vehicles rated at 26,001 pounds gross vehicle weight rating (GVWR) or more.

Brake lining means any asbestos-containing product that is made of paper intended for use as a friction material in drum brake systems for vehicles rated at 26,001 pounds gross vehicle weight rating (GVWR) or more.

Commerce has the same meaning as in section 3 of the Act. But the term does not include actions taken with respect to an asbestos-containing product (to sell, resell, deliver, or hold) in connection with the end use of the product by persons who are users (persons who use the product for its intended purpose after it is manufactured or processed). The term also does not include distribution by manufacturers, importers, and processors, and other persons solely for purposes of disposal of an asbestos-containing product.

Commercial paper means an asbestos-containing product which is made of paper intended for use as general insulation paper or muffler paper. Major applications of commercial papers are insulation against fire, heat transfer, and corrosion in circumstances that require a thin, but durable, barrier.

Commercial and industrial friction product means an asbestos-containing product, which is either molded or woven, intended for use as a friction material in braking and gear changing components in industrial and commercial machinery and consumer appliances. Major applications of this product include: hand brakes; segments; blocks; and other components used as brake linings, rings and clutches in industrial and commercial machinery and consumer appliances.

Commercial paper means an asbestos-containing product which is made of paper intended for use as general insulation paper or muffler paper. Major applications of commercial papers are insulation against fire, heat transfer, and corrosion in circumstances that require a thin, but durable, barrier.

Corrugated paper means an asbestos-containing product made of corrugated paper, which is often cemented to a flat backing, may be laminated with foils or other materials, and has a corrugated surface. Major applications of asbestos corrugated paper include: thermal insulation for pipe coverings; block insulation; panel insulation in elevators; insulation in appliances; and insulation in low-pressure steam, hot water, and process lines.

Asbestos-containing product means an asbestos-containing product which is made of paper intended for use as a friction material in drum brake systems for vehicles rated at 26,001 pounds gross vehicle weight rating (GVWR) or more.

Disc brake pad for heavy-weight vehicles means an asbestos-containing product intended for use as a friction material in disc brake systems for vehicles rated at 26,001 pounds gross vehicle weight rating (GVWR) or more.

Disc brake pad for heavy-weight vehicles means an asbestos-containing product intended for use as a friction material in disc brake systems for vehicles rated at 26,001 pounds gross vehicle weight rating (GVWR) or more.

Flooring felt means an asbestos-containing product which is made of paper and consisting of asbestos fibers and high-temperature resistant organic binders and used in or with electrical devices for purposes of...
period, the term “model year” shall
apply to the calendar year, provided that if the
manufacturer of such a product has not published a
specific model name, the term “model year” shall
apply to the calendar year for which the product
was manufactured.

“Import” means to bring into the
customs territory of the United States except for:
(1) Shipment through the
customs territory of the United States
for export without any use, processing,
or disposal within the customs territory
of the United States; or (2) entering the
customs territory of the United States as
a component of a product during normal
personal or business activities involving
use of the product.

“Importer” means anyone who
imports a chemical substance, including
a chemical substance as part of a
mixture or article, into the customs
territory of the United States.

“Person” means any natural person,
firm, company, corporation, joint
venture, partnership, sole proprietorship,
association, or any other business
entity; any State or political subdivision
of any State; any agency, or instrumentality
of the Federal Government.

“Manufacturer” means to produce or
manufacture in the United States.

“Model year” means the
manufacturer’s annual production
period which includes January
1 of such calendar year, provided that if the
manufacturer has no annual production
period, the term “model year” shall
mean the calendar year.

“New uses of-asbestos” means
commercial uses of asbestos not
identified in Subpart C of 19 CFR
Part 144.

“Reinforced plastic” means an
asbestos-containing product made from
asbestos, but which solidifies when
exposed to air, and which is intended
for use as a gasket. Major applications of this
product include: seals in pumps; seals in
valves; seals in compressors; seals in
mixers; seals in swing joints; and seals in
hydraulic cylinders.

“Roof coating” means an
asbestos-containing product which is
initially a semi-liquid mixture of butyl rubber
and asbestos, but which solidifies when
exposed to air, and which is intended
for use as a sealing agent. Major
applications of this product include:
seals for building and automotive
windows, seals for aerospace
equipment components, and sealants for
insulated glass.

“Sheet gasket” means either (1) an
asbestos-containing product consisting
of asbestos and elastomeric or other
binders rolled in homogenous sheets at
some point in its manufacture and
intended for use as a gasket, or (2) any
asbestos-containing product made from
branded or twisted rope, slit or woven
tape, yarn, or other textile products
intended for use as a gasket. Sheet
gaskets are used to seal the space
between two sections of a component
and thereby prevent leakage in such
applications as: exhaust, cylinder head,
and intake manifolds; pipe flanges;
auto-clavés; vulcanizers; pressure
vessels; cooling towers; turbochargers;
and gear cases. This category includes
flange, spiralwound, tadpole, manhole,
handhole, door, and other gaskets or
seals.

“Specialty industrial gaskets” means
sheet or paper add gaskets designed for
industrial uses in either (1)
non-corrosive environments where temperatures are
750 degrees Fahrenheit or greater, or (2)
corrosive environments. An industrial
gasket is one designed for use in an
environment which is a “consumer
product” within the meaning of the
Consumer Product Safety Act (CPSA),
15 U.S.C. 1262, or for use in a “motor
vehicle” or “motor vehicle equipment”
within the meaning of the National
Traffic and Motor Vehicle Safety Act
A corrosive environment is one in which
the gasket is exposed to concentrated

importation or processing of which
would be initiated for the first time after
August 25, 1969. The following products
are also not new uses of asbestos:
acetylene cylinders, arc chutes, asbestos
diaphragms, battery separators, high
density electrical paper, missile liner,
reinforced plastic, sealant tape, and
textiles.

“Non-roof coating” means an
asbestos-containing product intended
for use as a coating, cement, adhesive,
or sealant and not intended for use on
roofs. Major applications of this product
include: liquid sealants; semi-liquid
glazing, caulking and patching
compounds; asphalt-based compounds;
epoxy adhesives; butyl rubber sealants;
vehicle undercoatings; vinyl sealants;
and compounds containing asbestos
fibers that are used for bonding, weather
proofing, sound deadening, sealing,
coating; and other such applications.

“Oven” means a chemical substance
which is not a “consumer
article” within the meaning of the
Consumer Product Safety Act (CPSA),
15 U.S.C. 1262, composed of an
asbestos-containing product
laminated together. Major applications of this
product include: office
partitioning; garage paneling; linings for
stoves and electric switch boxes; and
fire-proofing agent for security boxes,
 safes, and files.

“Roof coating” means an
asbestos-containing product intended for use as a
coating, cement, adhesive, or sealant on
roofs. Major applications of this product
include: waterproofing; weather
resistance; sealing; repair; and surface
rejuvenation.

“Roofing felt” means an asbesto-
containing product that is made of paper
felt intended for use on building roofs as
a covering or underlayer for other roof
coverings.

“Sealant tape” means an
asbestos-containing product which is
initially a semi-liquid mixture of butyl rubber
and asbestos, but which solidifies when
exposed to air, and which is intended
for use as a sealing agent. Major
applications of this product include:
sealants for building and automotive
windows, seals for aerospace
equipment components, and sealants for
insulated glass.

“Sheet gasket” means either (1) an
asbestos-containing product consisting
of asbestos and elastomeric or other
binders rolled in homogenous sheets at
some point in its manufacture and
intended for use as a gasket, or (2) any
asbestos-containing product made from
branded or twisted rope, slit or woven
tape, yarn, or other textile products
intended for use as a gasket. Sheet
gaskets are used to seal the space
between two sections of a component
and thereby prevent leakage in such
applications as: exhaust, cylinder head,
and intake manifolds; pipe flanges;
auto-clavés; vulcanizers; pressure
vessels; cooling towers; turbochargers;
and gear cases. This category includes
flange, spiralwound, tadpole, manhole,
handhole, door, and other gaskets or
seals.

“Specialty industrial gaskets” means
sheet or paper add gaskets designed for
industrial uses in either (1)
non-corrosive environments where temperatures are
750 degrees Fahrenheit or greater, or (2)
corrosive environments. An industrial
gasket is one designed for use in an
environment which is a “consumer
product” within the meaning of the
Consumer Product Safety Act (CPSA),
15 U.S.C. 1262, or for use in a “motor
vehicle” or “motor vehicle equipment”
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or sealant and not intended for use on
roofs. Major applications of this product
include: liquid sealants; semi-liquid
glazing, caulking and patching
compounds; asphalt-based compounds;
epoxy adhesives; butyl rubber sealants;
vehicle undercoatings; vinyl sealants;
and compounds containing asbestos
fibers that are used for bonding, weather
proofing, sound deadening, sealing,
coating; and other such applications.

“Oven” means a chemical substance
which is not a “consumer
article” within the meaning of the
Consumer Product Safety Act (CPSA),
15 U.S.C. 1262, composed of an
asbestos-containing product
laminated together. Major applications of this
product include: office
partitioning; garage paneling; linings for
stoves and electric switch boxes; and
fire-proofing agent for security boxes,
 safes, and files.

“Roof coating” means an
asbestos-containing product intended for use as a
coating, cement, adhesive, or sealant on
roofs. Major applications of this product
include: waterproofing; weather
resistance; sealing; repair; and surface
rejuvenation.

“Roofing felt” means an asbesto-
containing product that is made of paper
felt intended for use on building roofs as
a covering or underlayer for other roof
coverings.

“Sealant tape” means an
asbestos-containing product which is
initially a semi-liquid mixture of butyl rubber
and asbestos, but which solidifies when
exposed to air, and which is intended
for use as a sealing agent. Major
applications of this product include:
sealants for building and automotive
windows, seals for aerospace
equipment components, and sealants for
insulated glass.

“Sheet gasket” means either (1) an
asbestos-containing product consisting
of asbestos and elastomeric or other
binders rolled in homogenous sheets at
some point in its manufacture and
intended for use as a gasket, or (2) any
asbestos-containing product made from
branded or twisted rope, slit or woven
tape, yarn, or other textile products
intended for use as a gasket. Sheet
gaskets are used to seal the space
between two sections of a component
and thereby prevent leakage in such
applications as: exhaust, cylinder head,
and intake manifolds; pipe flanges;
auto-clavés; vulcanizers; pressure
vessels; cooling towers; turbochargers;
and gear cases. This category includes
flange, spiralwound, tadpole, manhole,
handhole, door, and other gaskets or
seals.

“Specialty industrial gaskets” means
sheet or paper add gaskets designed for
industrial uses in either (1)
non-corrosive environments where temperatures are
750 degrees Fahrenheit or greater, or (2)
corrosive environments. An industrial
gasket is one designed for use in an
environment which is a “consumer
product” within the meaning of the
Consumer Product Safety Act (CPSA),
15 U.S.C. 1262, or for use in a “motor
vehicle” or “motor vehicle equipment”
within the meaning of the National
Traffic and Motor Vehicle Safety Act
(pH less than 2), highly oxidizing mineral acids (e.g., sulfuric, nitric, or chromic acid) at temperatures above ambient.

“Specialty paper” means an asbestos-containing product that is made of paper intended for use as filters for beverages or other fluids or as paper for filter or cooling towers. Cooling tower fill consists of asbestos paper that is used as a cooling agent for liquids from industrial processes and air conditioning systems.

“State” has the same meaning as in section 3 of the Act.

“Stock-on-hand” means the products which are in the possession, direction, or control of a person and are intended for distribution in commerce.

“Textiles” means an asbestos-containing product such as: yarn; thread; wick; cord; branded and twisted rope; braded and woven tubing; mat; roving; cloth; slit and woven tape; lap; felt; and other bonded or non-woven fabrics.

“United States” has the same meaning as in section 3 of the Act.

“Vinyl-asbestos floor tile” means an asbestos-containing product composed of vinyl resins and used as floor tile.

§ 763.165 Manufacture and importation prohibitions.

(a) After August 27, 1990, no person shall manufacture or import the following asbestos-containing products, either for use in the United States or for export: A/C corrugated sheet, A/C flat sheet, asbestos clothing, flooring felt, pipeline wrap, roofing felt, vinyl/asbestos floor tile, and new uses of asbestos.

(b) After August 25, 1993, no person shall manufacture or import the following asbestos-containing products, either for use in the United States or for export: automatic transmission components, clutch facings, commercial and industrial asbestos friction products, and sheet and beater-add gaskets (except specialty industrial gaskets).

(c) After August 25, 1993, no person shall manufacture or import, including as part of a motor vehicle, asbestos-containing disc brake pads for light-medium- and heavy-weight vehicles, and drum brake linings for the following uses in the United States or for export:

1. As original equipment in 1994 or later model year motor vehicles, or
2. As aftermarket replacement parts in brake systems designed for use with non-asbestos replacement parts.

(d) After August 26, 1995, no person shall manufacture or import the following asbestos-containing products, either for use in the United States or for export: disc brake pads for use in light-medium- and heavy-weight vehicles and drum brake linings manufactured, imported, or marketed for use as aftermarket replacement parts in brake systems designed for use with asbestos-containing friction products; A/C pipe, A/C shingle, brake blocks, commercial paper, corrugated paper, millboard, non- roofing coatings, cardboard, roof coatings, and specialty paper.

(e) The import prohibitions of this subpart do not prohibit:

1. The import into the customs territory of the United States of products imported solely for shipment outside the customs territory of the United States, unless further repackaging or processing of the product is performed in the United States; or
2. Activities involving purchases or acquisitions of small quantities of products made outside the customs territory of the United States for personal use in the United States.

§ 763.167 Processing prohibitions.

(a) After August 27, 1990, no person shall process for any use, either in the United States or for export, any of the asbestos-containing products listed at § 763.165(a).

(b) After August 25, 1993, no person shall process for any use, either in the United States or for export, any of the asbestos-containing products listed at § 763.165(b) and (c).

(c) After August 26, 1996, no person shall process for any use, either in the United States or for export, any of the asbestos-containing products listed at § 763.165(d).

§ 763.169 Distribution in commerce prohibitions.

(a) After August 27, 1992, no person shall distribute in commerce, either for use in the United States or for export, any of the asbestos-containing products listed at § 763.165(a).

(b) After August 25, 1994, no person shall distribute in commerce, either for use in the United States or for export, any of the asbestos-containing products listed at § 763.165(b) and (c).

(c) After August 25, 1997, no person shall distribute in commerce, either for use in the United States or for export, any of the asbestos-containing products listed at § 763.165(d).

(d) A manufacturer, importer, processor, or any other person who is subject to a ban on distribution in commerce in paragraph (a), (b), or (c) of this section must, within 6 months of the effective date of the ban, distribute in commerce, dispose of all remaining stock-on-hand of that product, by means that are in compliance with applicable local, State, and Federal restrictions which are current at that time.

§ 763.171 Labeling requirements.

(a) After August 27, 1990, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(a) shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers’ importers’ and processors stock-on-hand as of August 27, 1990.

(b) After August 25, 1992, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(b) and (c), and disc brake pads for use in light-medium- and heavy-weight vehicles and drum brake linings manufactured, imported, or marketed for use as aftermarket replacement parts in brake systems designed for use with asbestos-containing friction products shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers’ importers’ and processors’ stock-on-hand as of August 25, 1992.

(c) After August 25, 1995, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(d), except disc brake pads for use in light-medium- and heavy-weight vehicles and drum brake linings manufactured, imported, or marketed for use as aftermarket replacement parts in brake systems designed for use with asbestos-containing friction products, shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers’ importers’ and processors’ stock-on-hand as of August 25, 1995.

(d) The label shall be placed directly on the visible exterior of the wrappings and packaging in which the product is placed for sale, shipment, or storage. If the product has more than one layer of external wrapping or packaging, the label must be attached to the innermost layer adjacent to the product. If the innermost layer of product wrapping or packaging does not have a visible exterior surface larger than 5 square inches, either a tag meeting the requirements of paragraph (e) of this section must be securely attached to the product’s innermost layer of product wrapping or packaging, or a label must be attached to the next outer layer of product packaging or wrapping. Any products that are distributed in

Labeling requirements.

(a) After August 27, 1990, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(a) shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers’ importers’ and processors stock-on-hand as of August 27, 1990.

(b) After August 25, 1992, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(b) and (c), and disc brake pads for use in light-medium- and heavy-weight vehicles and drum brake linings manufactured, imported, or marketed for use as aftermarket replacement parts in brake systems designed for use with asbestos-containing friction products shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers’ importers’ and processors stock-on-hand as of August 25, 1992.

(c) After August 25, 1995, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(d), except disc brake pads for use in light-medium- and heavy-weight vehicles and drum brake linings manufactured, imported, or marketed for use as aftermarket replacement parts in brake systems designed for use with asbestos-containing friction products, shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers’ importers’ and processors’ stock-on-hand as of August 25, 1995.

(d) The label shall be placed directly on the visible exterior of the wrappings and packaging in which the product is placed for sale, shipment, or storage. If the product has more than one layer of external wrapping or packaging, the label must be attached to the innermost layer adjacent to the product. If the innermost layer of product wrapping or packaging does not have a visible exterior surface larger than 5 square inches, either a tag meeting the requirements of paragraph (e) of this section must be securely attached to the product’s innermost layer of product wrapping or packaging, or a label must be attached to the next outer layer of product packaging or wrapping. Any products that are distributed in
commerce to someone other than the end user, shipped, or stored without packaging or wrapping must be labeled or tagged directly on a visible exterior surface of the product as described in paragraph (e) of this section. 

Labels must be either printed directly on product packaging or in the form of a sticker or tag made of plastic, paper, metal, or other durable substances. Labels must be attached in such a manner that they cannot be removed without defacing or destroying them. Product labels shall appear as in paragraph (e)(2) of this section and consist of block letters and numerals of color that contrasts with the background of the label or tag. Labels shall be sufficiently durable to equal or exceed the life, including storage and disposal, of the product packaging or wrapping. The size of the label or tag must be at least 15.25 cm (6 inches) on each side. If the product packaging is too small to accommodate a label of this size, the label may be reduced in size proportionately to the size of the product packaging or wrapping down to a minimum 2.5 cm (1 inch) on each side if the product wrapping or packaging has a visible exterior surface larger than 5 square inches. 

(2) Products subject to this subpart shall be labeled in English as follows:

NOTICE

This product contains ASBESTOS. The U.S. Environmental Protection Agency has banned the distribution in U.S. commerce of this product under section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) as of (insert effective date of ban on distribution in commerce). Distribution of this product in commerce after this date and intentionally removing or tampering with this label are violations of Federal law.

(f) No one may intentionally remove, deface, cover, or otherwise obscure or tamper with a label or sticker that has been applied in compliance with this section, except when the product is used or disposed of.

§ 763.173 General exemptions.

(a) Persons who are subject to the prohibitions imposed by § 763.165, 763.167 or 763.169 may file an application for an exemption. Persons whose exemption applications are approved by the Agency may manufacture, import, process, or distribute in commerce the banned product as specified in the Agency's approval of the application. No applicant for an exemption may continue the banned activity that is the subject of an exemption application after the effective date of the ban unless the Agency has granted the exemption or the applicant receives an extension under paragraph (b)(6) or (9) of this section.

(b) Application filing dates. (1) Applications for products affected by the prohibitions under §§763.165(a) and 763.167(a) may be submitted after August 25, 1989. Complete applications received after that date, but before November 27, 1989, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after November 27, 1989, will be either granted or denied by EPA as soon as is feasible.

(2) Applications for products affected by the ban under §763.169(c) may not be submitted prior to February 26, 1990. Complete applications received after that date, but before August 26, 1991, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 26, 1991, will be either granted or denied by EPA as soon as is feasible.

(3) Applications for products affected by the ban under §§763.165(b) or (c) and 763.167(b) or (c) may not be submitted prior to February 26, 1992. Complete applications received after that date, but before August 25, 1992, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 25, 1992, will be either granted or denied by EPA as soon as is feasible.

(4) Applications for products affected by the ban under §763.169(b) or (c) may not be submitted prior to February 26, 1993. Complete applications received after that date, but before August 25, 1993, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 25, 1993, will be either granted or denied by EPA as soon as is feasible.

(5) Applications for products affected by the ban under §§763.165(d) and 763.167(d) may not be submitted prior to February 27, 1995. Complete applications received after that date, but before August 25, 1995, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 25, 1995, will be either granted or denied by EPA as soon as is feasible.

(6) Applications for products affected by the ban under §763.169(d) may not be submitted prior to February 26, 1996. Complete applications received after that date, but before August 26, 1996, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 26, 1996, will be either granted or denied by EPA as soon as is feasible.

(7) The agency will consider an application for an exemption from a ban under §763.169 for a product at the same time the applicant submits an application for an exemption from a ban under §763.165 or §763.167 for that product. EPA will grant an exemption at that time from a ban under §763.169 if the Agency determines it appropriate to do so.

(8) If the Agency denies an application less than 30 days before the effective date of a ban for a product, the applicant may continue the activity for 30 days after receipt of the denial from the Agency.

(9) If the Agency fails to meet the deadlines stated in paragraphs (b)(1) through (6) of this section for granting or denying a complete application in instances in which the deadline is before the effective date of the ban to which the application applies, the applicant will be granted an extension of 1 year from the Agency's deadline date. During this extension period the applicant may continue the activity that is the subject of the exemption application. The Agency will either grant or deny the application during the extension period. The extension period will terminate either on the date the Agency grants the application or 30 days after the applicant receives the Agency's denial of the application. However, no extension will be granted if the Agency is scheduled to grant or deny an application at some date after the effective date of the ban, pursuant to the deadlines stated in paragraphs (b)(1) through (6) of this section.

(c) Where to file. All applications must be submitted to the following location: TSCA Document Processing Center (TS-790), Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M St., SW Washington, D.C. 20460, ATTENTION: Asbestos Exemption.

(d) Content of application and criteria for decisionmaking.

(1) Content of application. Each application must contain the following:

(i) Name, address, and telephone number of the applicant.

(ii) Description of the manufacturing, import, processing, and/or distribution in commerce activity for which an exemption is requested, including a description of the asbestos-containing product to be manufactured, imported, processed, or distributed in commerce.

(iii) Identification of locations at which the exempted activity would take place.
(iv) Length of time requested for exemption (maximum length of an exemption is 4 years).

(v) Estimated amount of asbestos to be used in the activity that is the subject of the exemption application.

(vi) Data demonstrating the exposure level over the life cycle of the product that is the subject of the application.

(vii) Data concerning:
(A) The extent to which non-asbestos substitutes for the product that is the subject of the application fail significantly short in performance under necessary product standards or requirements, including laws or ordinances mandating product safety standards.

(B) The costs of non-asbestos substitutes relative to the costs of the asbestos-containing product and, in the case in which the product is a component of another product, the effect on the cost of the end-use product of using the substitute component.

(C) The extent to which the product or use serves a high-valued use.

(viii) Evidence of demonstrable good faith attempts by the applicant to develop and use a non-asbestos substance or product which may be substituted for the asbestos-containing product or the asbestos in the product or use that is the subject to the application.

(ix) Evidence, in addition to that provided in the other information required with the application, showing that the continued manufacture, importation, processing, distribution in commerce, and use, as applicable, of the product will not present an unreasonable risk of injury to human health.

(2) Criteria for decision (existing products). After considering all the information provided by an applicant under paragraphs (d)(1) through (e) of this section, and any other information available to EPA, EPA will grant an exemption from the prohibitions in §§ 763.165, 763.167 or 763.169 for an applicant's asbestos-containing product only if EPA determines both of the following:

(i) The applicant has made good faith attempts to develop and use a non-asbestos substance or product which may be substituted for the asbestos-containing product or the asbestos in the product or use, and those attempts have failed to produce a substitute or a substitute that results in a product that can be economically produced.

(ii) Continued manufacturing, processing, distribution in commerce, and use, as applicable, of the product will not present an unreasonable risk of injury to human health.

(3) Criteria for decision (new products). Requests to develop and use an asbestos substance or product will be treated as a petition pursuant to Section 21 of TSCA.

(e) The Agency reserves the right to request further information from an exemption applicant if necessary to complete the Agency’s evaluation of an application.

(f) Upon receipt of a complete application, the Agency will issue a notice in the Federal Register announcing its receipt and invite public comments on the merits of the application.

(g) If the application does not include all of the information required in paragraph (d)(1) of this section, the Agency will return it to the applicant as incomplete and any resubmission of the application will be considered a new application for purposes of the availability of any extension period. If the application is substantially inadequate to allow the Agency to make a reasoned judgment on any of the information required in paragraph (d) of this section and the Agency chooses to request additional information from the applicant, the Agency may also determine that an extension period provided for in paragraph (b)(7) of this section is unavailable to the applicant.

(b) When denying an application, the Agency may seek to enjoin the manufacture, import, processing, or distribution in commerce of asbestos-containing products in violation of this subpart, or act to seize any asbestos-containing products manufactured, imported, processed, or distributed in commerce in violation of this subpart, or take any other actions under the authority of section 7 or 17 of the act (15 U.S.C. 2606 or 2616) that are appropriate.

§ 763.175 Enforcement.

(a) Failure to comply with any provision of this subpart is a violation of section 15 of the Act (15 U.S.C. 2614).

(b) Failure or refusal to establish and maintain records, or to permit access to or copying of records as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(c) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(e) The Agency may seek to enjoin the manufacture, import, processing, or distribution in commerce of asbestos-containing products in violation of this subpart, or act to seize any asbestos-containing products manufactured, imported, processed, or distributed in commerce in violation of this subpart, or take any other actions under the authority of section 7 or 17 of the act (15 U.S.C. 2606 or 2616) that are appropriate.

§ 763.176 Inspections.

The Agency will conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this subpart.

§ 763.178 Recordkeeping.

(a) Inventory. (1) Each person who is subject to the prohibitions imposed by §§ 763.165 and 763.167 must perform an inventory of the stock-on-hand of each banned product as of the effective date of the ban for that product for the applicable activity.

(2) The inventory shall be in writing and shall include the type of product, the number of product units currently in the stock-on-hand of the person performing the inventory, and the location of the stock.

(3) Results of the inventory for a banned product must be maintained by the person for 3 years after the effective date of the § 763.165 or § 763.167 ban on the product.
[b] Records. (1) Each person whose activities are subject to the bans imposed by §§ 763.165, 763.167 and § 763.169 for a product must, between the effective date of the § 763.165 or § 763.167 ban on the product and the § 763.169 ban on the product, keep records of all commercial transactions regarding the product, including the dates of purchases and sales and the quantities purchased or sold. These records must be maintained for 3 years after the effective date of the § 763.169 ban for the product.

(2) Each person who is subject to the requirements of § 763.171 must, for each product required to be labeled, maintain a copy of the label used in compliance with § 763.171. These records must be maintained for 3 years after the effective date of the ban on distribution in commerce for the product for which the § 763.171 requirements apply.

§ 763.179 Confidential business information claims.

(a) Applicants for exemptions under § 763.173 may assert a Confidential Business Information ([CBI]) claim for information in an exemption application or supplement submitted to the Agency under this subpart only if the claim is asserted in accordance with this section, and release of the information would reveal trade secrets or confidential commercial or financial information, as provided in section 14(a) of the Act. Information covered by a CBI claim will be treated in accordance with the procedures set forth in 40 CFR Part 2, Subpart B. The Agency will place all information not claimed as CBI in the manner described in this section in a public file without further notice to the applicant.

(b) Applicants may assert CBI claims only at the time they submit a completed exemption application and only in the specified manner. If no such claim accompanies the information when it is received by the Agency, the information may be made available to the public without further notice to the applicant. Submitting that information as business confidential must do so by writing the word "Confidential" at the top of the page on which the information appears and by underlining, circling, or placing brackets ([ ]]) around the information claimed CBI.

(c) Applicants who assert a CBI claim for submitted information must provide the Agency with two copies of their exemption application. The first copy must be complete and contain all information being claimed as CBI. The second copy must contain only information not claimed as CBI. The Agency will place the second copy of the submission in a public file. Failure to furnish a second copy of the submission when information is claimed as CBI in the first copy will be considered a presumptive waiver of the claim of confidentiality. The Agency will notify the applicant by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The applicant has 30 days from the date of receipt of notification to submit the required second copy. Failure to submit the second copy will cause the Agency to place the first copy in a public file.

(d) Applicants must substantiate all claims of CBI at the time the applicant asserts the claim, i.e., when the exemption application or supplement is submitted, by responding to the questions in paragraph (e) of this section. Failure to provide substantiation of a claim at the time the applicant submits the application will result in a waiver of the CBI claim, and the information may be disclosed to the public without further notice to the applicant.

(e) Applicants who assert any CBI claims must substantiate all claims by providing detailed responses to the following:

1) Is this information subject to a patent or patent application in the United States or elsewhere? If so, why is confidentiality necessary?

2) For what period do you assert a claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

3) Has the information that you are claiming as confidential been disclosed to persons outside of your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

4) Briefly describe measures taken by your company to guard against undesired disclosure of the information you are claiming as confidential to others.

5) Does the information claimed as confidential appear in any advertising or promotional materials for the product or the resulting end product, safety data sheets or other similar materials for the product or the resulting end product, professional or trade publications, or any other media available to the public or to your competitors? If you answered yes, indicate where the information appears.

6) If the Agency disclosed the information you are claiming as confidential to the public, how difficult would it be for the competitor to enter the market for your product? Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

7) Has the Agency, another Federal agency, or a Federal court made any confidentiality determination regarding this information? If so, provide copies of such determinations.

8) How would your company's competitive position be harmed if the Agency disclosed this information? Why should such harm be considered substantial? Describe the causal relationship between the disclosure and harm.

9) In light of section 14(b) of TSCA, if you have claimed information from a health and safety study as confidential, do you assert that disclosure of this information would disclose a process used in the manufacturing or processing of a product or information unrelated to the effects of asbestos on human health and the environment? If your answer is yes, explain.

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Part IV

Environmental Protection Agency

40 CFR Parts 22 and 142
Safe Drinking Water Act Administrative Enforcement Regulations; Proposed Rule
ENVIROMENTAL PROTECTION AGENCY

40 CFR Parts 22 and 142
[FR-3494-8]

Safe Drinking Water Act
Administrative Enforcement Regulations

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth the procedures the Environmental Protection Agency will follow to implement section 1414(g) of the Safe Drinking Water Act (SDWA), 42 U.S.C. 300g-3(g). This section, among other things, provides the Administrator with authority to issue compliance orders to violators of Part B (applicable to public water suppliers) or section 1445 of the SDWA (applicable to public water suppliers and underground injectors), 42 U.S.C. 300g and 300-4, and to administratively enforce such orders. Section 1414(g) compliance orders may not take effect until after "notice and opportunity for public hearing and, in the case of a State having primary enforcement responsibility for public water systems in that State, until after the Administrator has provided the State with an opportunity to confer with the Administrator regarding the proposed order." 42 U.S.C. 300g-3(g)(2).

DATES: EPA will accept public comments on the proposed regulations until September 11, 1989, either in writing or at an informal public hearing to be held in Washington, DC on August 15, 1989. Requests to present oral testimony at the public hearing must be received on or before August 11, 1989.

ADDRESSES: Interested persons may participate in this proposed rulemaking by submitting written comments to the Comment Clerk, State Programs Division (WH-550E), Office of Drinking Water, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. All comments should be typed or printed. The public hearing will be held on August 15, 1989 beginning at 9 a.m. in Conference Room No. 13 of the Washington Information Center, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Donald M. Olson, State Programs Division, Underground Injection Control Branch (WH-550E), Office of Drinking Water, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 382-5558.

SUPPLEMENTARY INFORMATION: A copy of all public comments will be available for inspection and copying at Room 1143 East Tower, 401 M Street SW Washington, DC 20460. The EPA public information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

I. Background

The Safe Drinking Water Act was enacted in 1974. At that time, with one exception, it contained no provisions for EPA to enforce its terms administratively. Later amendments to the SDWA did not provide such authority until June 19, 1986, when Congress added a new provision, section 1414(g).1

On January 20, 1987 EPA issued "FWS [Public Water Supply] and UIC Administrative Enforcement, Orders Issued under Guidance." This material included administrative procedures governing penalty procedures and model formats for the benefit of EPA regional personnel charged with implementing the 1986 SDWA Amendments. Specifically, the material included the following

1. Administrative Order Issuance Procedure Guidance,
2. governing notice and hearing procedures for compliance order issuance under sections 1414(g) (1) and (2) of the SDWA, 42 U.S.C. 300g-3(g)(1) and (2), and procedures governing penalty orders issued under section 1414(g)(3) of the SDWA, 42 U.S.C. 300g-3(g)(3), which were "set out in the form of a regulation with the expectation that in the near future EPA will notice [these procedures] in a proposed rulemaking." EPA issued this procedural guidance as "binding" and "to be used by all Regions without change. The section 1414(g)(3) guidance required use of the Agency's Consolidated Rules of Practice found at 40 CFR Part 22. EPA has used this guidance since January 20, 1987. Today, with only minor or technical changes, the Agency is proposing this guidance as a rule as authorized by section 1450 of the SDWA, 42 U.S.C. 300j-9.

II. Section-by-Section Analysis

A. Overview of Proposed Regulations

Section 1414(g)(1) of the SDWA, 42 U.S.C. 300g-3(g)(1), authorizes the EPA Administrator to issue a compliance order in any case in which the Administrator may bring a civil action under section 1414 or section 1445 of the SDWA, 42 U.S.C. 300g-3(g) or 300j-1. Section 1414(g)(2), 42 U.S.C. 300g-3(g)(2), further provides:

An order issued under this subsection shall not take effect until after notice and opportunity for public hearing and, in the case of a State having primary enforcement responsibility for public water systems in that State, until after the Administrator has provided the State with an opportunity to confer with the Administrator regarding the proposed order. A copy of any order proposed to be issued under this subsection shall be sent to the appropriate State agency of the State involved if the State has primary enforcement responsibility for public water systems in that State. Any order issued under this subsection shall state with reasonable specificity the nature of the violation. In any case in which an order under this subsection is issued to a corporation, a copy of such order shall be issued to appropriate corporate officers.

EPA today proposes rules establishing procedures under which it will exercise the authority conferred by section 1414(g). EPA also is proposing conforming amendments to 40 CFR Part 22 (Consolidated Rules of Practice) to implement section 1414(g)(3) of the SDWA, 42 U.S.C. 300g-3(g)(3). That provision of the law, referring to administrative penalties for violation of an administrative compliance order issued under section 1414(g), states that:

Whenever any civil penalty sought by the Administrator under this paragraph does not exceed a total of $5,000, the penalty shall be assessed by the Administrator after notice and opportunity for a hearing on the record in accordance with section 554 of title 5 of the United States Code.

EPA's Consolidated Rules of Practice, 40 CFR Part 22, establish procedures for the administrative assessment of civil penalties that conform to the requirements of section 554 of title 5 of the United States Code, the Administrative Procedure Act.

In interpreting the SDWA, the Agency has taken note of the legislative history of section 1414(g), which states:

The Administrative order authority provides for more efficient enforcement against less significant violations and is expected to enable EPA to develop a more aggressive enforcement program. The purpose of adding administrative order authority is not to replace judicial enforcement, but to add a complementary enforcement mechanism.

S. Rep. No. 99-56, 99th Cong., 1st Sess. (1985) [Accompanying S. 124]. The proposed rule is intended to implement the legislative intent favoring efficient and aggressive enforcement through use of section 1414(g) orders. The proposed procedures are not intended to confer
any rights to persons affected by an order beyond those required by statute.

The procedures proposed for section 1414(g)(2) compliance orders provide an an opportunity for informal, information-gathering, nonadjudicatory hearings prior to issuance of the orders. The orders will state the nature of the violation under section 1414(g)(1) and may specify a reasonable time for compliance. They will require compliance with existing duties under the SDWA, but will not alter those existing duties or obligations or create new obligations. The hearing and resulting compliance order will not be determinative of the underlying statutory rights and responsibilities, and therefore are not subject to pre-enforcement judicial review. Moreover, as explained in more detail below, penalties for violation of the order and of the SDWA may be assessed only after a duly noticed adjudicatory hearing. The existence of administrative order violations and imposition of penalties will be issues to be adjudicated at the penalty hearing, which will be conducted in accordance with section 554 of the Administrative Procedure Act. EPA believes that these proposed rules are fully consistent with applicable due process requirements. See Asbestec Construction Services Inc. v. EPA, No. 87-4120 (2d Cir. June 15, 1988); 18 ELR 21029.

EPA's use of information-gathering, informal hearings for administrative compliance orders under section 1414(g)(2) is consistent with both the language and intent of the 1986 SDWA amendments. The Senate Report's explanation, later adopted by the Conference Committee, provides a strong indication that EPA should adopt informal, efficient administrative proceedings to implement its compliance order authority. The interpretation also is consistent with the opportunities for public participation and State consultation created by the statute; both requirements serve to inform the Administrator of relevant information before a compliance order becomes effective.

In contrast, section 1414(g)(3) expressly requires the Administrator to use procedures in accordance with 5 U.S.C. 554 (the section of the Administrative Procedure Act labelled "Adjudications") in assessing an administrative penalty of up to $5,000 for persons violating a section 1414(g) compliance order. Penalties in excess of $5,000 must be assessed by a civil action brought in U.S. District Court. By statute, hearings conducted by the Agency under section 1414(g)(3) will be adjudicatory in nature and afford the more formal procedures prescribed by the APA. As noted above, by this rulemaking the Agency proposes that EPA will use its already-promulgated Consolidated Rules of Practice (with some supplemental rules specific to penalty orders issued under section 1414(g)(3) of the SDWA) in pursuing administrative penalties under section 1414(g)(3).

B. Procedures for PWS Administrative Compliance Orders

1. Section 142.201: Purpose

This subsection explains the purpose of the procedures set forth in Subpart K.

2. Section 142.202: Definitions

This subsection provides only two definitions. Other terms used throughout this proposed subpart are used according to the statute or as part of common usage.

3. Section 142.203: Proposed Administrative Compliance Orders

Section 1414(g)(2) of the SDWA requires EPA to propose compliance orders and further provides that an order shall not take effect until an opportunity for a hearing and, in primary States, opportunity for the State to confer with EPA. Under these proposed regulations the Administrator, upon finding a person or supplier of water in violation of relevant parts of Part B of the SDWA or of section 1445 of the SDWA, has the discretion to propose an administrative compliance order. The proposed rule tracks the statutory requirement that the order "state with reasonable specificity the nature of the violation, and also makes explicit the implicit authority of the Administrator to establish a reasonable compliance schedule in the order. In some cases, such as overdue reporting or failure to monitor, no schedule may be necessary. In those cases, compliance should be required at once. In a number of circumstances, however, immediate compliance will not be physically possible. In such cases, the Administrator will have the discretion to establish a reasonable time for compliance, and necessary interim steps, such as periodic reports to EPA, to allow the Agency to oversee the respondent's efforts to achieve it.

4. Section 142.204: Notice of Proposed Administrative Compliance Order

This subsection implements the SDWA's requirement to provide notice of a proposed order. The subsection requires EPA to provide notice to the alleged violator, the public and, if applicable, the PWS primacy State. The notices are necessary to inform the public water supply and the public of their opportunity for a hearing and the primacy State of its right to a conference with EPA and opportunity to request a hearing.

(a) Section 142.204(a): The Party. This subsection requires a notice to the party by certified mail, return receipt requested. The additional procedure for corporate parties follows the statutory requirements of Section 1414(g)(2). If a party refuses service or does not claim the certified mail notice, the Agency shall provide notice by another appropriate means.

(b) Section 142.204(b): The Public. This subsection requires notice to the public. Because the size and type (e.g., urban or rural) of the potentially affected public vary widely, the appropriate means of providing this notice is left to the discretion of EPA. In the circumstances of each case, however, the public notification shall be reasonably calculated to provide notice to the affected public.

(c) Section 142.204(c): The State (where applicable). If a party is located within a PWS primacy State, the proposed regulations require EPA to provide notice to the appropriate State agency by certified mail, return receipt requested.

5. Section 142.205: Opportunity for Public Hearings; Opportunity for State Conferences

The SDWA requires "opportunity for public hearing and, in the case of a State having primary enforcement responsibility for public water systems in that State, an opportunity to confer with the Administrator regarding the proposed order. section 1414(g)(2). The PWS primacy State's opportunity to confer with EPA extends only to proposed orders against public water suppliers, not UIC violators of Section 1445 of the Act.

(a) Section 142.205(a). This subsection provides that a public hearing shall be held upon a timely request by the party or a primacy State. The provision of these proposed rules that affords parties and primacy States a public hearing upon request reflects their direct interest in the order. All requests for hearings will be honored if they are related to the purposes specified in § 142.206(a).

In addition, the Administrator must hold a public hearing if he determines that the public has expressed "a significant interest in the convening of a public hearing within fourteen days of the date of the notice. This provision is patterned after 40 CFR 124.12, regarding
Proposed Regulations, these proposed rules provide for informal, fact-finding hearings which are by their nature nonjudicative. The Agency is proposing streamlined procedures that focus the hearings on those elements of the findings and proposed order that materially affect the public water supplier.

(a) Section 142.206(a). The Administrator, or his delegatee, shall convene a public hearing pursuant to § 141.205(a), or may convene a public hearing upon his own initiative. The subjects of the hearing will be limited to the accuracy of the findings of fact in the proposed order and, if applicable, the reasonableness of the time for a party to comply with the order.

(b) Section 142.206(b). This section sets forth the role of the Hearing Officer, who presides over any public hearing held under section 141.205(c) of the Act. The Administrator or his delegatee shall appoint a Hearing Officer prior to convening a public hearing. See § 142.202(a). Because of the informal, information-gathering nature of a public hearing held under this subpart, see Overview discussion above, the Hearing Officer has broad discretion in establishing the “forms and procedures” of the hearing. Because the primary purpose of the hearing is to improve the administrator’s informational basis for decision, the Hearing Officer must also “maintain a complete and accurate record of the proceedings” and maintain the record in a permanent form. Any information received by the Hearing Officer becomes part of the administrative record, which provides the factual basis for the order and the time provided for compliance. Because of this use of information gathered in the hearing, the Hearing Officer must provide the record of the hearing to the Administrator or his delegatee to serve as the basis for a compliance order.

(c) Section 142.206(c). This section describes what matters are relevant at a hearing under this subpart and in what manner and by whom the information may be conveyed to the Agency. There are no restrictions on who may present information at or before a hearing. Because of the potential expense and inconvenience to the public of attending a hearing, as well as for purposes of administrative convenience, the Agency is proposing that relevant written testimony submitted before the date set for a public hearing will be considered by EPA as part of the administrative record. Written testimony may substitute for or supplement oral testimony. Relevant matters at a public hearing or in written testimony under this subpart are limited to the facts of the party’s alleged violations of those parts of the SDWA referenced in proposed § 141.202(b) and, where applicable, the reasonableness of the time provided for compliance in a proposed section 1414(g)(2) order.

7 Section 142.207 Issuance, Amendment or Withdrawal of Administrative Compliance Order

This section provides that the Administrator, based on the administrative record, shall issue, amend or withdraw the proposed order.

(a) Section 142.207(a). The Administrator or his delegatee shall make his decision on the order based on relevant information in the administrative record. The administrative record includes the relevant information initially considered by EPA in preparing the proposed order and also includes all relevant information that EPA received under proposed §§ 141.205(b) and 141.206(c), or that is otherwise received by EPA. In addition, EPA retains discretion to withdraw a proposed compliance order without the necessity for a State conference or a public hearing if there are sufficient independent grounds for withdrawal, such as new information that clearly demonstrates a lack of violation or lack of jurisdiction.

(b) Section 142.207(b). This section requires the Agency official issuing the compliance order to establish a date for compliance that is reasonable and is premised on the administrative record.

(c) Section 142.207(c). The Administrator is to withdraw, amend and issue as an order or issue as an order without material change, each proposed order “in writing and within a reasonable time. After issuance, each compliance order is to be provided to the party, the primacy State (if in a primacy State), and members of the public who participated under proposed § 141.206(c). Notification of appropriate persons under this section should occur simultaneously and immediately upon issuance of the compliance order.

6 Section 142.208 Administrative Assessment of Civil Penalty for Violation of Administrative Compliance Order

This section references 40 CFR Part 22, the Consolidated Rules of Practice, for procedures to impose an administrative penalty assessed pursuant to section 1414(g)(3)(B) of the Act for violation of a compliance order issued under section 1414(g) (1) and (2) of the Act.
C. Section 1414(g)(3) Regulations: 40 CFR 22.01 and 22.42

1. Section 22.01(a)(9). This provision expands the scope of the generally applicable Part 22 rules to include administrative penalty assessments conducted under section 1414(g)(3)(B) of the SDWA.

2. Section 22.42: Supplemental Rule of Practice Governing the Administrative Assessment of Civil Penalties for Violation of Compliance Orders Issued Under Section 1414(g)(3)(B) of the Safe Drinking Water Act. This section adds rules of practice of Part 22 that specifically govern procedures to assess civil penalties under section 1414(g)(3)(B) of the SDWA.

(a) Section 22.42(b): Person. The term "person" is to include "any officer, employee or agent of any corporation, company or association, in accordance with section 1401 of the SDWA, 42 U.S.C. 300f.

(b) Section 22.42(c): Complaint Issuance. This section enables the appropriate Agency official to issue a Complaint under the SDWA and the Consolidated Rules of Practice.

(c) Section 22.42(d): Content of Complaint. The content of the complaint under section 1414(g)(3) requires the recitation of the violation of the section 1414(g)(1) administrative compliance order and the recitation of the underlying violations of the SDWA.

(d) Section 22.42(e): Scope of Hearing. The scope of hearing clarifies that Agency actions which could have been subject to review under section 1448 of the Act, 42 U.S.C. 300j–7 may not be challenged in a section 1414(g)(3)(B) administrative forum.

III. Economic and Regulatory Impact

A. Regulatory Flexibility Analysis

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., an agency is required to prepare an initial regulatory flexibility analysis whenever it is required to publish a general notice of any proposed rule, unless the head of the agency certifies that the rule, if promulgated, will not have a significant impact on a substantial number of small entities. These proposed regulations require no additional reporting or other burdens by the regulated community. Therefore, the Administrator certifies that this regulation will not have a significant impact on a substantial number of small entities.

B. Executive Order 12891

Under Executive Order 12891, EPA must judge whether the proposed regulations are major and therefore subject to the requirement of a Regulatory Impact Analysis. As described above, these proposed rules do not impose additional burdens beyond those already prescribed by the SDWA Amendments of 1986. They do not have an annual effect on the economy of $100 million or more, nor do they satisfy any of the other criteria listed in section 1(b) of the Executive Order. Therefore, these proposed regulations do not constitute a major rulemaking. This proposal has been submitted to OMB for review as required by Executive Order 12291.

List of Subjects

40 CFR Part 22

Administrative practices and procedures, Appeals and administrative review.

40 CFR Part 142

Administrative practice and procedures, Monitoring, reporting and recordkeeping requirements. Water supply.


William K. Reilly.

Administrator.

For the reasons set out in the preamble, Title 40, Chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for Part 142 continues to read as follows:

Authority: Safe Drinking Water Act (42 U.S.C. 300f et seq., as amended, unless otherwise noted).

2. Subpart J is reserved and a new Subpart K is added to Part 142 to read as follows:

Subpart K—Procedures for PWS Administrative Compliance Orders

Sec.

142.201 Purpose.
142.202 Definitions.
142.203 Proposed administrative compliance orders.
142.204 Notice of proposed administrative compliance orders.
142.205 Opportunity for public hearings; opportunity for State conferences.
142.206 Conduct of public hearings.
142.207 Issuance, amendment or withdrawal of administrative compliance order.
142.208 Administrative assessment of civil penalty for violation of administrative compliance order.

Subpart J—(Reserved)

Subpart K—Procedures for PWS Administrative Compliance Orders

§142.201 Purpose.

This part prescribes procedures for notice and opportunity for public hearings, conferences with primary States and issuance of administrative compliance orders under section 1414(g) of the Safe Drinking Water Act, 42 U.S.C. 300g–3(g).

§142.202 Definitions.

(a) The term "Hearing Officer" means an Environmental Protection Agency employee who has been delegated by the Administrator the authority to preside over a public hearing held pursuant to section 1414(g)(2) of the Safe Drinking Water Act, 42 U.S.C. 300g–3(g)(2).

(b) The term "party" means any "person" or "supplier of water" as defined in section 1401 of the SDWA, 42 U.S.C. 300f, alleged to have violated any regulation implementing section 1412 of the SDWA, 42 U.S.C. 300q–1, any schedule or other requirement imposed pursuant to section 1415 or section 1416 of the SDWA, 42 U.S.C. 300q–4 and 300q–5, or section 1445 of the SDWA, 42 U.S.C. 300q–4, or any regulation implementing section 1445.

§142.203 Proposed administrative compliance orders.

If the Administrator finds that a party has violated a regulation, schedule, or other requirement of the SDWA referenced in §142.202(b), the Administrator may prepare a proposed administrative compliance order that would require the party to comply with the regulation, schedule, or other requirement that is alleged to have been violated. Any such proposed administrative order shall state with reasonable specificity the nature of the violation, and may specify a reasonable time for compliance.

§142.204 Notice of proposed administrative compliance orders.

The Administrator simultaneously shall provide a copy of any proposed administrative compliance order to:

(a) The party. In any case in which the party is a corporation, the Administrator shall provide a copy of a proposed administrative compliance order to an appropriate corporate officer. The Administrator shall provide notice under this subsection by sending such a copy, by certifies mail, return receipt requested. If certified mail is refused or unclaimed, the Administrator shall
provide notice by another appropriate means.

(b) The public. The Administrator shall make publicly available each proposed administrative compliance order at the time of its proposal; and

(c) The State. In the case of a State with primary enforcement responsibility for public water systems pursuant to section 1413(a) of the SDWA, 42 U.S.C. 300g-3(a), the Administrator shall provide notice under this subsection by sending a copy of each proposed administrative compliance order by certified mail, return receipt requested to the appropriate State agency of the State involved.

§ 142.205 Opportunity for public hearings; opportunity for State conferences.

(a) The Administrator shall provide the party, the public and the State an opportunity for a public hearing on any proposed administrative compliance order by stating in a letter accompanying each proposed administrative compliance order (or its copy) that a public hearing shall be convened if the party or the State sends written notice of such request to the Administrator within fourteen days of the date the proposed administrative compliance order is noticed under § 142.204, or if the Administrator determines that within fourteen days of the date of notice the public has expressed a significant interest in the convening of a public hearing. Hearings will be held only for the purposes specified in § 142.206(a). All requests for hearings shall specify which of the purposes specified in § 142.206(a) is the basis for the request. The Administrator may extend the time allowed for submitting requests for good cause.

(b) In the case of a State with primary enforcement responsibility under section 1413(a) of the SDWA, the Administrator shall provide the State with an opportunity to confer regarding any proposed administrative compliance order to a public water supplier by stating in a letter accompanying each mailing of the proposed administrative compliance order sent to the State that such a conference shall be held between the State and the Administrator, if the State requests such a conference within ten days of the date the proposed administrative compliance order is noticed under § 142.204.

(c) For purposes of this subsection, notice occurs three days after the date of mailing or other means of notification, excluding Saturdays, Sundays and federal holidays.

§ 142.206 Conduct of public hearings.

(a) The purpose of the public hearing shall be to determine whether a proposed administrative order:

(1) Has correctly determined the extent and nature of a party's violation of any regulation, schedule, or other requirement of the SDWA referenced in § 142.202(b) and

(2) has provided, where appropriate, a reasonable time for the party to comply with applicable requirements of the SDWA and its implementing regulations.

(b) Prior to convening a public hearing under this subsection, the Administrator shall appoint a Hearing Officer. The Hearing Officer shall preside over any public hearing convened under this section. The Hearing Officer shall determine the form and procedures of the public hearing, and shall maintain a complete and accurate record of the proceedings in written or other permanent form. The Hearing Officer shall provide the Administrator with the record of any public hearing conducted under this subsection.

(c) The party, any member of the public, or the State may present information to the Hearing Officer at the public hearing (or to the Administrator in writing before the date set for the public hearing) relevant to whether:

(1) The party has violated the applicable regulation, schedule, or other requirement referenced in the proposed administrative compliance order;

(2) The party has violated any other applicable regulation, schedule, or other requirement of the SDWA referenced in § 142.202(b); and

(3) The proposed order, where appropriate, provides a reasonable time for the party to comply with applicable requirements of the SWDA and its implementing regulations.

§ 142.207 Issuance, amendment or withdrawal of administrative compliance order.

(a) Based on the administrative record, the Administrator shall either issue the order as proposed, amend the proposed order or withdraw the proposed order.

(b) Any order issued shall require the party to comply with any applicable regulation, schedule, or other requirement of the SDWA referenced in § 142.202 and may establish a time or date for compliance which the Administrator determines is reasonable, based on the administrative record.

(c) The Administrator shall determine within a reasonable time whether to issue, amend or withdraw the proposed order and shall promptly notify in writing the party, all members of the public participating under § 142.206(c) and the State, in the case of a State with primary enforcement authority over public water systems pursuant to section 1413(a) of the SDWA, or in the case of a State participating under § 142.206(c).

§ 142.208 Administrative assessment of civil penalty for violation of administrative compliance order.

In the event the Administrator decides to seek a penalty under the authority provided in section 1414(g)(3)(B) of the SDWA, 42 U.S.C. 300g-3(g)(3)(B), for violation of, or failure or refusal to comply with, an order, the procedures provided in 40 CFR Part 22 shall govern the assessment of such a penalty.

PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION OR SUSPENSION OF PERMITS

3. The authority citation for Part 22 is revised to read as follows:


4. The introductory text of § 22.01(a) is republished without change for the convenience of the reader and § 22.01(a)(9) and 22.42 are added to read as follows:

§ 22.01 Scope of these rules.

(a) These rules of practice govern all adjudicatory proceedings for:

(9) The assessment of any civil penalty conducted under Section 1414(g)(3)(B) of the Safe Drinking Water Act as amended (42 U.S.C. 300g-3(g)(3)(B)).


(a) Scope of these supplemental rules. These supplemental rules of practice shall govern, in conjunction with the preceding Consolidated Rules of Practice (40 CFR Part 22), all proceedings to assess a civil penalty
under section 1414(g)(3)(B) of the Safe Drinking Water Act, 42 U.S.C. 300g-3 (g)(3)(B). Where inconsistencies exist between these supplemental rules and the Consolidated Rules, these supplemental rules shall apply.

(b) Definition of “person.” In addition to the terms set forth in 40 CFR 22.03(a) that define “person,” for purposes of this section and proceedings under section 1414(g)(3)(B) of the Safe Drinking Water Act, the term “person” shall also include any officer, employee, or agent of any corporation, company or association.

c) Issuance of complaint. If the Administrator determines that a person has violated any provision of a compliance order issued under section 1414(g)(1) of the Safe Drinking Water Act, 42 U.S.C. 300g-3(g)(1), he may institute a proceeding for the assessment of a civil penalty by issuing a complaint under the Act and this Part.

d) Content of the complaint. A complaint for the assessment of civil penalties under this Part shall include specific reference to:

1. Each provision of the compliance order issued under section 1414(g)(1) of the Act, 42 U.S.C. 300g-3(g)(1), which is alleged to have been violated; and

2. Each violation of a Safe Drinking Water Act regulation, schedule, or other requirement which served as the basis for the compliance order which is alleged to have been violated.

e) Scope of hearing. Action of the Administrator with respect to which judicial review could have been obtained under Section 1448 of the Safe Drinking Water Act, 42 U.S.C. 300j-7 shall not be subject to review in an administrative proceeding for the assessment of a civil penalty under section 1414(g)(3)(B) of the SDWA and this Part.
Part V

Environmental Protection Agency

40 CFR Part 707
Export Notification Requirement; Proposed Change to Reporting Requirements; Proposed Rule
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 707

[OPTS-120004; FRL-3614-6]

Export Notification Requirement; Proposed Change to Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing amendments to the export notification rules at Subpart D of 40 CFR Part 707 that would change the current annual notification requirement for exporters of chemical substances and mixtures (chemicals) subject to test rules or consent orders (test rules) under section 4 of the Toxic Substances Control Act (TSCA) to a one-time export notification requirement for each exporter of such a chemical per each country of destination. EPA believes the proposed amendments would facilitate foreign governments’ monitoring of chemicals by relieving the administrative burden imposed by the present annual notices received on chemicals subject to TSCA section 4 test rules and through encouraging the thoughtful review of notices regarding chemicals subject to more restrictive regulatory action. Additionally, the proposed amendments are necessary to reduce the notification burden on EPA and industry, and because under the current annual notice requirement the large volume of notices received has hampered EPA’s ability to respond to requests from foreign governments for additional information on a particular chemical or export notice.

DATE: Written comments on this proposed rule must be submitted by September 11, 1989.

ADDRESS: Comments should be bear the docket control number OPTS-120004 and should be submitted, in triplicate, to: TSCA Public Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Room NE-C004, 401 M Street, SW., Washington, DC 20460.

All written comments on this proposed rule will be available for public inspection at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.


Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is proposing amendments to the export notification rules which would change the current recurring annual requirement of export notification to EPA for section 4 test rule chemicals to a one-time export notification requirement for each exporter of such a chemical to each country. EPA is also proposing to provide a one-time notice to each importing country for a particular section 4 test rule chemical.

I. Authority

EPA is proposing this amendment pursuant to section 12(b) of TSCA, 15 U.S.C. 2611(b).

Section 12(b) of TSCA requires that any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under TSCA section 4 or 5(b), an order has been issued under section 5, a rule has been proposed or promulgated under section 5 or 6, or relief has been granted under section 5 or 7 to notify the Administrator of EPA of such exportation or intent to export. Upon receipt of such notification, section 12(b) of TSCA requires EPA to furnish the government of the importing country with:

1. Notice of the availability of data received pursuant to action under section 4 or 5(b), or
2. Notice of such rule, order, action, or relief under section 5, 6, or 7

EPA maintains a public record of all notices received and sent under section 12(b), except for information that has been claimed as confidential business information under TSCA section 14.

II. Summary of This Proposed Rule

EPA is proposing to require persons who export or who intend to export to a specific country a chemical for which notification is required under section 12(b) of TSCA by virtue of section 4 test rules to submit a one-time notice to EPA of that export for each such chemical and country. EPA is not proposing a change in the current recurring annual export notification requirements triggered by a rule, order, action, or relief under sections 5, 6, and 7 of TSCA. EPA is neither proposing any change in the required contents of the notice (40 CFR 707.67) nor any revision with regard to the time deadline for submission of an export notice to EPA, that is, within 7 days of forming an intent to export or the date of export, whichever is earlier, 40 CFR 707.65(e)(5). However, EPA is proposing to require that each exporter provide only one notification, per chemical, for each country of export after the issuance of a section 4 test rule. Currently, exporters are required to notify EPA annually of exports of chemicals subject to section 4 test rules.

EPA is also proposing to modify the process for notifying foreign governments of export of section 4 test rule chemicals by providing only one notice per section 4 test rule chemical to each importing country. The content of the information sent in the proposed one-time notification for section 4 test rule chemicals would be identical to that provided under the current annual notification scheme. Importing countries would get the same information on section 4 test rule chemicals, but only once.

EPA requests comments on this proposed amendment, particularly with regard to whether the proposed changes would provide adequate information to foreign governments about chemicals imported from the United States which are subject to test rules, as well as whether the proposed changes would offer a burden reduction for the regulated industry. The role of Non-Governmental Organizations (NGOs) in implementing the proposed amendments is not addressed because the export notification information that such NGOs can obtain is limited by the provisions of section 14 of TSCA.

III. Reasons for Proposing This Rule

A. Background

In the Federal Register of December 16, 1986 (45 FR 62844), EPA promulgated rules implementing section 12(b) of TSCA. Persons subject to the implementing rules are currently required to submit a written notice to EPA for the first export or intended export to a particular country in a calendar year for chemicals subject to a rule, order, action, or relief under sections 4, 5, 6, and 7 of TSCA. Upon receipt of such notification from an exporter, the implementing rules require that EPA provide the importing country with a summary of the regulatory action taken or indicate the availability of data received pursuant to action under section 4 or 5(b), or notice of a rule, order, action, or relief under section 5, 6, or 7 of TSCA.

At the time EPA promulgated the section 12(b) rule at 40 CFR Part 707 EPA did not have the practical experience it now has in estimating the impact of certain regulatory actions. At that time EPA did not believe that the rule would impose an excessive burden upon foreign governments, industry, or...
EPA resources. However, recent experience has demonstrated to EPA that an increasing number of section 12(b) notices are received by EPA each year.

In 1983, EPA received 438 section 12(b) notices on 15 chemical substances; of this number, none were in response to section 4 test rules. That number increased to 524 notices on 37 substances in 1984 (31 in response to section 4 actions), 819 notices on 115 substances in 1985 (283 in response to section 4 actions), and 2,058 notices on 186 substances in 1986 (1,506 in response to section 4 actions). Approximately 4,300 notices were received in 1988 on substances (3,350 in response to section 4 actions). EPA projected totals for 1989 are for approximately 4,700 notices (3,752 in response to section 4 actions); for 1993, the number is expected to be greater than 8,200 (6,950 in section 4 actions).

The increase in section 12(b) notices received by EPA has led to a corresponding increase in the number of notices EPA has sent to foreign governments. In 1984, EPA sent 406 notices to foreign governments. This number increased to 533 in 1985, 809 in 1986, and 1,035 in 1987. Approximately 2,100 notices were sent in 1988. EPA projections for 1989 are for over 2,300 notices to be sent to foreign governments (770 to 1,074 in response to section 4 actions). This continually increasing volume of notification has created a situation in which the effectiveness of many foreign governments’ import monitoring programs may be hampered by the processing of more and more notices.

At the present time, a fourth of a half of the section 12(b) notices received by EPA from a particular company are other than first-time notices (i.e., repeat notices for subsequent annual exports to the same country). EPA anticipates that the proportion of repeat notices will grow in relation to the total number of notices received because the regulatory actions that trigger section 12(b) reporting requirements either do not sunset (e.g., section 5 or 8 rules) or remain in place for relatively long periods of time (e.g., section 4 rules). The continuous increase in section 12(b) reporting is making import monitoring more difficult for many foreign countries, is placing an increasing burden on industry, and is placing an increasing administrative burden on EPA.

EPA believes that part of this difficulty is based on the fact that a large number of notices sent to foreign governments pertain to section 12(b) reporting for TSCA section 4 test rule chemicals. In most cases, test rules are issued because EPA does not have sufficient health and safety or environmental data on a particular chemical to make a fully informed decision regarding the appropriateness of regulatory control for that chemical. These test rules may be in effect for as long as 10 years before the end of the data reimbursement period when they cease to be in effect. EPA believes that continued annual reporting under section 12(b) for these chemicals would be of only limited value to foreign governments. In most cases, there exists insufficient health or environmental data on these chemicals, such that EPA has not proposed or taken action to ban or restrict their production or use, and foreign governments are likely to take no regulatory action either in the absence of data.

Because the regulatory actions which trigger section 12(b) reporting requirements are mandated by TSCA, it is not possible for EPA to change the triggering actions. EPA believes that the most practical means of maintaining the quality of notification, of improving the scrutiny importing countries give to notices, and of reducing burden on both industry and EPA is to amend the section 12(b) reporting rules under 40 CFR Part 707 to reduce the volume of notices. The amendment that EPA believes will retain the greatest utility to foreign governments while simultaneously resulting in a decreased burden on industry and EPA, would be rescinding the current annual notice requirement for section 4 test rule chemicals and allowing persons to submit a one-time notice to EPA for a particular country for each section 4 test rule chemical.

EPA believes these amendments would maintain, if not increase, the degree of protection to human health and the environment afforded by the current notification system while reducing the reporting burden on exporters and the administrative burden on EPA. Under the current annual notice requirement, a large increase in the volume of annual notices, due primarily to a significant increase in the number of section 4 test rules promulgated by EPA, has reduced EPA’s ability to respond to requests for additional information on a particular chemical or export notice. At the same time, the increasing volume of notices makes it difficult for countries which receive a large number of notices to distinguish between chemicals for which EPA has taken action to restrict based on a determination of unreasonable risk to human health or the environment, and those chemicals for which EPA has requested data but not yet made a definitive risk determination. Although EPA provides a copy of the applicable rule, including a summary of the action taken by EPA, many importing country representatives have commented anecdotally that all section 12(b) notices are considered by importing countries, particularly developing countries, to be of equal concern.

EPA believes that the purpose of the export notification requirements of section 12(b) of TSCA is to ensure that foreign governments are alerted when EPA knows that such governments are importing chemicals about which EPA has expressed some degree of concern. EPA’s responsibility is both to alert the importing country, and to make information and data available to the importing government so that government can assess the risks and benefits of importing and using that chemical. While some countries may use the notices to monitor trends in imports from the United States of chemicals subject to section 12(b), EPA believes the supply of data necessary to control chemicals within the importing country would be substantially unchanged by this proposed rule as there would be little, if any, net loss or supportive data potentially useful in carrying out this function.

By decreasing the volume of notices importing countries receive on section 4 test rule chemicals for which additional data are being gathered, the proposed rule may actually increase the relative effectiveness of the notification by allowing foreign governments to focus their efforts on notices for section 5, 6, or 7 chemicals for which restrictive regulatory action has been proposed or promulgated. Internationally, the movement is toward differentiation between banned or severely restricted chemicals and chemicals for which additional data gathering is still ongoing. This proposed rule is a step in that direction.

The differentiation is commonly referred to as a system of Prior Informed Consent (PIC). The United States Government is participating in negotiations with international organizations such as the United Nations Environment Programme (UNEP) on the development of a PIC scheme. This proposed rule is consistent with the international interest in developing a system of PIC. EPA believes that by reducing the ever increasing volume of notices received on section 4 test rule chemicals, importing countries can better differentiate...
between chemicals for which EPA has taken restrictive action and chemicals for which additional toxicological testing has been required.

B. Alternatives

Before proposing this rule, EPA considered a variety of other alternative regulatory approaches to reducing the burden of section 12(b) export notification and increasing its effectiveness.

1. One alternative would be to establish a new "sunset" date for reporting under section 12(b) triggered by a final TSCA section 4 test rule. One possible sunset date considered by EPA would be the date on which the first test data are required to be submitted under the test rule. In this event, EPA would have actual test data available when foreign governments were notified. Persons subject to the rule would still be required to submit export notices to EPA annually thereafter, the EPA would notify such foreign governments on an annual basis. Thus, importing countries would still receive a large number of notifications resulting from section 4 test rules. This new sunset date would provide some decrease in burden on industry and EPA, but the decrease in burden in this instance would not be significant because in many cases initial section 4 test data are required to be submitted to EPA within a 1-year time frame.

EPA also considered another possible sunset date which would require submission of a TSCA section 12(b) notice upon the receipt of adverse test data under a section 4 test rule. In this instance, notices to foreign governments would be of maximum utility, because EPA would possess actual data regarding the adverse health or environmental effects of a substance. This new sunset date would provide a modest decrease in reporting burden to industry. However, EPA would be required to make rapid, and potentially controversial case-by-case hazard determinations on test data. These determinations would then likely need to be made formal by Federal Register notices announcing EPA's conclusions. This approach would provide a modest reduction in burden on industry but result in a many-fold increase in burden on EPA. This approach also contradicts the statutory language of TSCA section 12(b) because export notification is triggered by a requirement for the submission of data under section 4, not just adverse data. Foreign countries may find knowledge of non-adverse data as useful as adverse data.

2. Another alternative would be to establish a new "sunrise" date for reporting under section 12(b) triggered by a final TSCA section 4 test rule. One possible sunrise date considered by EPA would be the date on which the final test data submission is required under the test rule. At the present time, persons are subject to test rules from the time of the effective date to the end of the data reimbursement period, which may be up to five years after the final test data are required. This approach could cut as many as 6 years of reporting by industry. This approach remains attractive to EPA because it does offer a decrease in burden. However, persons subject to section 12(b) would still be required to submit annual reports until the time of the last data submission, and the value of those additional reports may not be significant over and above the one-time report that would be required by the proposed approach.

3. EPA also considered establishing a "percentage" cutoff from section 12(b) reporting triggered by section 4 test rules. In this case, if the section 4 test rule chemical was present in an exported product at a low level (e.g., 1.0 percent or 0.1 percent), export notification would not be required. While this alternative may provide exporters of mixtures containing section 4 chemicals with a modest reduction in reporting burden, EPA believes that the one-time notification for section 4 chemicals will result in a far greater reduction in reporting burden to industry and in administration to EPA.

4. A final alternative considered by EPA would be to establish a one-time notification requirement for all actions which trigger section 12(b) notification. Thus, exporters would be required to submit one notice per country for each chemical subject to a rule, order, action, or relief under section 4, 5, 6, or 7 of TSCA. Under this alternative, EPA would provide each importing country with one notice per chemical subject to section 12(b) notification. This approach would alleviate burden associated with all activities that trigger section 12(b) export notification, and would also provide a reduction in reporting burden on industry and a reduction in the administrative burden on EPA. However, this approach would reduce for all section 12(b) triggering activities the total number of notices received by foreign governments. Such a reduction could potentially hamper the ability of foreign governments to monitor imports of chemicals for which EPA has proposed or taken regulatory action on the basis that they present unreasonable risks.

EPA requests comments on the alternatives discussed above. EPA also requests that commenters alert EPA to any reasonable alternatives not considered here. Before developing the final rule, EPA will consider all comments and alternatives received with regard to this proposed rule.

IV Economic Impact

EPA has evaluated the potential costs of the proposed amendments to persons subject to section 12(b) reporting requirements. The amendment would reduce the number of submissions sent to EPA from companies exporting chemicals subject to test rules under TSCA section 4, and would also reduce the number of notifications sent by EPA to foreign governments. These reductions would save both industry and EPA resources and will be referred to collectively as the "reduction in reporting burden.

The procedure used to estimate the reduction in 1989 reporting burden for industry is a several step process. First, an estimate of the reduction in industry submissions requires taking the estimated submissions which would still be required after promulgation of this proposed rule (2,319 to 2,908) and subtracting those values from the base line estimate of submissions under the current reporting scheme (4,667). This decrease is estimated at 1,761 to 2,348 submissions and based upon an estimated industry cost of $10 to $50 per submission, yields a 1989 industry savings of $18,000 to $117,000. The net present value of this industry savings from 1980 to 1993 is estimated at $114,000 to $759,000 using a 3 percent discount rate, and at $99,000 to $657,000 using a discount rate of 10 percent.

EPA resource savings from this proposed rule would occur because the EPA Office of Toxic Substances (OTS) would handle fewer submissions from industry and would send out fewer notifications to foreign governments. The estimated 1989 EPA savings in handling submissions would be the cost of handling a submission ($5) times the decrease in submissions (1,761 to 2,348), or $9,000 to $12,000. The estimated 1989 EPA savings for sending out fewer notices is the EPA cost per section 12(b) notification sent ($40) times the estimated decrease in notifications (770 to 1,014) or $31,000 to $41,000. Thus, by combining these estimates, the overall 1989 EPA savings that would be generated by this proposed rule are estimated at $40,000 ($9,000 + $31,000) to $53,000 ($12,000 + $41,000). The net present value of this overall EPA savings from 1980 to 1993 is estimated at $256,000 to $331,000 using a 3 percent
discount rate, and at $222,000 to $287,000 using a 10 percent discount rate.

By combining the 1989 resource savings to industry ($18,000 to $117,000) with the 1989 resource savings to EPA ($40,000 to $55,000), the total 1989 reduction in reporting burden generated by this proposed rule is estimated at $58,000 to $170,000. The net present value of this total reduction in reporting burden from 1989 to 1993 is estimated at $370,000 to $1,090,000 using a 3 percent discount rate, and at $321,000 to $944,000 using a 10 percent discount rate.

Persons are directed to the record for the rulemaking at the address listed in Unit V below for the assumptions and detailed calculations used in the economic analysis for this proposed rule. The analysis contained in the record also analyzes the economic impacts of alternatives 2 and 4 discussed in Unit III.B. of this preamble. The 1989 industry savings is estimated at $17,000 to $85,000 for alternative 2, and $25,000 to $147,000 for alternative 4. The net present value of this industry savings from 1989 to 1993 is estimated at $174,000 to $870,000 (3 percent discount rate) and at $149,000 to $746,000 (10 percent discount rate) for alternative 2, and at $139,000 to $823,000 (3 percent discount rate) and at $121,000 to $801,000 (10 percent discount rate) for alternative 4. The 1989 EPA savings is estimated at $30,000 for alternative 2, and at $49,000 to $86,000 for alternative 4. The net present value of EPA savings from 1989 to 1993 is estimated at $384,000 (3 percent discount rate) and $326,000 (10 percent discount rate) for alternative 2, and at $309,000 to $407,000 (3 percent discount rate) and $268,000 to $354,000 (10 percent discount rate) for alternative 4.

By combining the 1989 resources savings to industry with the 1989 resource savings to EPA, the total 1989 reduction in reporting burden generated by alternative 2 is estimated at $55,000 to $123,000, and at $71,000 to $213,000 for alternative 4. The net present value of this total reduction in reporting burden from 1989 to 1993 is estimated at $558,000 to $1,254,000 (3 percent discount rate) and at $477,000 to $1,074,000 (10 percent discount rate) for alternative 2, and at $448,000 to $1,330,000 (3 percent discount rate) and $389,000 to $1,155,000 (10 percent discount rate) for alternative 4.

V. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS-120004). The record includes basic information considered by EPA in developing this proposed rule. EPA will supplement the record with additional information as it is received. The record now includes the following:

1. Economic analysis of proposed amendments to 40 CFR Part 707

VI. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a regulatory impact analysis. EPA has determined that this proposed rule would not be a "major" rule because it would not have an effect on the economy of $100 million or more, and would not have a significant effect on competition, costs, or prices.

This proposed rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this proposed rule would not have a significant impact on a substantial number of small businesses. This rule would decrease the reporting burden upon small businesses subject to the reporting requirements of TSCA section 12(b). This proposed rule would not add any economic burden to small businesses.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB Control Number 2070-0030.

The proposed rule would reduce the number of notices required from the public by approximately 1700 to 2300 submissions. Public reporting burden for the collection of information under 40 CFR Part 717 is estimated to average 5 to 1.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Total public reporting burden is expected to decrease as a result of this proposed rule by approximately 850 to 3,450 hours (1,700 submissions x .5 hours to 2,300 submissions x 1.5 hours).

Send comments regarding the burden estimate or any other aspect of this collection of information to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked Attention: Desk Officer for EPA. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 707

Chemicals, Environmental protection, Exports, Hazardous substances, Imports, Recordkeeping and reporting requirements.


Vctor J. Kimm,
Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Part 707 be amended as follows:

PART 707—(AMENDED)

a. The authority citation for Part 707 would continue to read as follows:

Authority: 15 U.S.C. 2611(b) and 2012.

b. By revising § 707.65(a)(2) and (c) to read as follows:

§ 707.65 Submission to agency.

(a) (2) (i) The notice when data are required under section 5(b), an order has been issued under section 5, a rule has been proposed or promulgated under section 5 or 6, or an action is pending or relief has been granted under section 5.
or 7 must be for the first export or intended export to a particular country in a calendar year;

(ii) The notice when data are required under section 4 must be for the first export or intended export to a particular country;

(c) Notices shall be marked “Section 12(b) Notice” and sent to the TSCA Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington DC 20460.

By revising § 707.70(a) and adding an OMB control number at the end of the section to read as follows:

§ 707.70 EPA notice to foreign governments.

(a) (1) Notice by EPA to the importing country shall be sent no later than 5 working days after receipt by the TSCA Document Processing Center of the first notification for each regulated chemical when data are required under section 5(b), an order has been issued under section 5, a rule has been proposed or promulgated under section 5 or 6, or an action is pending or relief has been granted under section 5 or 7.

(2) Notice by EPA to the importing country shall be sent no later than 5 working days after receipt by the TSCA Document Processing Center of the first notification for each regulated chemical when data are required under section 4.

(Approved by the Office of Management and Budget under OMB control number 2070-0030)

[FR Doc. 89–16293 Filed 7–11–89; 8:45 am]
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- Legal staff: 523-4534
- Library: 523-5240
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<table>
<thead>
<tr>
<th>CFR Number</th>
<th>Pages Affecting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CFR</td>
<td>1823</td>
</tr>
<tr>
<td></td>
<td>1910</td>
</tr>
<tr>
<td></td>
<td>1941</td>
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<tr>
<td></td>
<td>1942</td>
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<tr>
<td></td>
<td>1943</td>
</tr>
<tr>
<td>3 CFR</td>
<td>1944</td>
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<tr>
<td></td>
<td>1945</td>
</tr>
<tr>
<td></td>
<td>1951</td>
</tr>
</tbody>
</table>

**Executive Orders**

- Proposed Rules:
  - 23983
  - 28019, 28428, 28820
  - 28429
  - 28964

**Proclamations**

- 28934, 28442

**Proposed Rules:**

- 27864, 28009
- 28654
- 28964
- 29139
- 29438

**Public Inspection Desk**

- 28139
- 28428
- 28820
- 28429
- 28964

**Federal Register**

- 28019, 28020, 28411,
- 28964
- 29329

**Federal Register Pages and Dates, July**

<table>
<thead>
<tr>
<th>Pages</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>27955-28016</td>
<td>1989-07-12</td>
</tr>
<tr>
<td>28017-28408</td>
<td>1989-07-12</td>
</tr>
<tr>
<td>28409-28864</td>
<td>1989-07-12</td>
</tr>
<tr>
<td>28965-28994</td>
<td>1989-07-12</td>
</tr>
<tr>
<td>28995-29098</td>
<td>1989-07-12</td>
</tr>
<tr>
<td>29099-29316</td>
<td>1989-07-12</td>
</tr>
<tr>
<td>29317-29528</td>
<td>1989-07-12</td>
</tr>
</tbody>
</table>
## Proposed Rules:

### 15 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>28010</td>
</tr>
<tr>
<td>771</td>
<td>28011</td>
</tr>
<tr>
<td>774</td>
<td>28065</td>
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<tr>
<td>786</td>
<td>28011</td>
</tr>
</tbody>
</table>

### 30 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>28443</td>
<td></td>
</tr>
</tbody>
</table>

### 31 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>103</td>
<td>28416</td>
</tr>
<tr>
<td>344</td>
<td>28752</td>
</tr>
</tbody>
</table>

### 33 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>29033</td>
</tr>
<tr>
<td>117</td>
<td>29035</td>
</tr>
<tr>
<td>135</td>
<td>29035</td>
</tr>
</tbody>
</table>

### 37 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>201</td>
<td>28769</td>
</tr>
</tbody>
</table>

### 38 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td>28445</td>
</tr>
</tbody>
</table>

### 39 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>111</td>
<td>28769</td>
</tr>
</tbody>
</table>

### 40 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>52</td>
<td>28660, 28310</td>
</tr>
<tr>
<td>82</td>
<td>28062, 2936</td>
</tr>
<tr>
<td>131</td>
<td>28662</td>
</tr>
<tr>
<td>228</td>
<td>29034</td>
</tr>
<tr>
<td>271</td>
<td>28677</td>
</tr>
<tr>
<td>761</td>
<td>28418</td>
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<tr>
<td>763</td>
<td>29460</td>
</tr>
</tbody>
</table>

### 42 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>57</td>
<td>28065</td>
</tr>
</tbody>
</table>

### 43 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
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<tbody>
<tr>
<td>5450</td>
<td>29357</td>
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<tr>
<td>5460</td>
<td>29357</td>
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</tbody>
</table>

### 46 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>49 CFR</td>
<td>28677, 28678, 29039</td>
</tr>
<tr>
<td>74</td>
<td>29040</td>
</tr>
<tr>
<td>90</td>
<td>28678</td>
</tr>
</tbody>
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### 48 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
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<tbody>
<tr>
<td>29278</td>
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### 49 CFR

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<th>Section</th>
<th>Proposed Rules:</th>
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<tr>
<td>29278</td>
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</table>

### LIST OF PUBLIC LAWS

Last Last July 11, 1989
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H.R. 2177/Pub. L. 100-53
To authorize the exchange of certain Federal public land in Madison County, Illinois. (July 6, 1989; 103 Stat. 144; 2 pages) Price: $1.00

H.J. Res. 276/Pub. L. 100-54

H.J. Res. 298/Pub. L. 100-55
Designating July 14, 1989, as "National Day To Commemorate the Bastille Day Bicentennial." (July 7, 1988; 103 Stat. 148; 1 page) Price: $1.00

28 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>106</td>
<td>28065</td>
</tr>
</tbody>
</table>

29 CFR

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1910</td>
<td>28054, 28154, 29142</td>
</tr>
<tr>
<td>1915</td>
<td>29142</td>
</tr>
<tr>
<td>1917</td>
<td>29142</td>
</tr>
</tbody>
</table>
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   (Street address)

   ____________________________________________
   (City, State, ZIP Code)

   __________________________
   (Daytime phone including area code)

3. Please choose method of payment:

   □ Check payable to the Superintendent of Documents
   □ GPO Deposit Account
   □ VISA, or MasterCard Account

   ____________________________________________
   (Credit card expiration date)

   __________________________
   (Signature)

Thank you for your order!