

FRIDAY, JULY 29, 1977

PART V



CONSUMER PRODUCT SAFETY COMMISSION

RESPIRABLE FREE-FORM ASBESTOS

Proposed Rulemaking



BON - 01241



CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Part 1145]

RESPIRABLE FREE-FORM ASBESTOS

Proposed Rules to Regulate Consumer Patching Compounds and Artificial Emberizing Materials (Embers and Ash) Containing Respirable Free-Form Asbestos, Under the Consumer Product Safety Act

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to regulate consumer patching compounds and artificial emberizing materials (embers and ash) containing respirable free-form asbestos under the Consumer Product Safety Act (CPSA) instead of the Federal Hazardous Substances Act (FHSA), to address the risk of cancer associated with inhalation of asbestos fibers. According to the CPSA, the Commission may not regulate under the CPSA a risk of injury that could be eliminated or reduced to a sufficient extent under the FHSA, unless the Commission finds by rule that it is in the public interest to do so. The Commission has preliminarily found that it is in the public interest to regulate these products under the CPSA.

DATES: Comments concerning this proposal must be received by August 29, 1977.

ADDRESS: Comments should be sent to: Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT:

John Liskey, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207 (301-492-8557).

SUPPLEMENTARY INFORMATION: The purpose of this notice is to propose a rule under section 30(d) of the Consumer Product Safety Act, (CPSA), 15 U.S.C. 2079(d), to regulate consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos under the CPSA. Although the risk of injury from lung cancer and mesothelioma associated with these products could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1274, the Commission has preliminarily determined that it is in the public interest to regulate these products under the CPSA.

The Commission believes that it is in the public interest to regulate these consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos under the CPSA rather than the FHSA, since the rulemaking proceedings appropriate to regulate these products under the FHSA are likely to be lengthy and resource-consuming.

The Commission also believes it is in the public interest to regulate these products under the CPSA since it may be more difficult for interested persons to participate in rulemaking proceedings under the FHSA than the CPSA because the proceedings under the FHSA are likely to be more complex and formal.

In order to ban hazardous household substances under section 2(q)(1)(B) of the FHSA, the Commission must follow the provisions of section 701(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 371(e). Section 701(e) of the FFDCA provides for a two stage rulemaking. After the Commission proposes a regulation, analyzes comments, and issues a final regulation, adversely affected persons may submit objections to the rule and request a public hearing on the objections. If the objections are legally valid, those parts of the regulation objected to are stayed and a hearing is held to receive evidence that is relevant and material to the issues raised by the objections.

After completion of the hearing, the Commission may issue a final regulation. However, this regulation must be based only on substantial evidence of record obtained at the hearing, and must set forth detailed findings of fact on which the order is based. The Commission's past experience with formal rulemaking under section 701(e) has been that these proceedings are lengthy, resource-consuming, and often inefficient in eliciting information on which the Commission may make a decision.

In contrast, section 9(a)(2) of the CPSA requires bans to be issued in accordance with the informal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553). Although the CPSA requires the Commission to provide an opportunity for oral presentation of comments before issuing a ban, the oral presentation required by section 9(a)(2) is informal and nonadversarial. A ban under section 8 of the CPSA, while providing an adequate opportunity for public participation, is less likely to involve extensive delay, since the Commission is not required to utilize formal rulemaking. In addition, since the proceedings under section 8 of the CPSA are less complex and formal than those under the FHSA, the Commission is more likely to obtain participation from interested persons, including consumers, than if the rulemaking is conducted under the FHSA.

The Commission has also preliminarily determined that it is in the public interest to regulate consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos under the CPSA rather than the FHSA, since the CPSA, unlike the FHSA, provides that persons who knowingly violate the Act are subject to civil penalties. The civil penalty provision may provide additional incentive for compliance under the CPSA.

However, if the Commission does decide to regulate these products under section 8 of the CPSA, the Commission

recognizes that automatic repurchase of banned hazardous products would not be available, as it is in the case of a ban under the FHSA. Under section 15 of the FHSA, 15 U.S.C. 1274, and the accompanying regulations at 16 CFR 1500.202 and .203, hazardous substances that have been banned must be repurchased by the manufacturers, distributors, and retailers of the hazardous substance, regardless of whether the substance was banned at the time of its sale. In contrast, a ban under section 8 of the CPSA that bans products distributed in commerce on the effective date of the ban would not provide for repurchase of the banned hazardous products distributed in commerce.

PROPOSAL

The Commission therefore proposes below to regulate consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos under the CPSA instead of the FHSA.

Accordingly, pursuant to provisions of the Consumer Product Safety Act (Sec. 30(d), Pub. L. 92-573, 86 Stat. 1231, as amended 90 Stat. 510; 15 U.S.C. 2079(d)), the Commission proposes that Title 16, Chapter II, Subchapter B, Part 1145 be amended by adding the following new § 1145.4:

§ 1145.4 Consumer patching compounds containing respirable free-form asbestos; risk of cancer associated with inhalation of asbestos fibers.

The Commission finds that it is in the public interest to regulate the risk of cancer associated with inhalation of asbestos fibers from consumer patching compounds under the Consumer Product Safety Act rather than under the Federal Hazardous Substances Act, because of the desirability of avoiding possibly lengthy, resource-consuming, and inefficient rulemaking proceedings under the Federal Hazardous Substances Act and because of the availability of civil penalties under the CPSA.

The Commission also believes that the complexity and formality of the rulemaking proceedings under the FHSA, in contrast to rulemaking proceedings under the CPSA, may make it difficult for interested persons to participate.

Therefore, consumer patching compounds containing asbestos shall be regulated under the CPSA.

(Sec. 30(d), Pub. L. 92-573, 86 Stat. 1231, as amended, 90 Stat. 510 (15 U.S.C. 2079(d)).

§ 1145.5 Emberizing materials (embers and ash) containing respirable free-form asbestos; risk of cancer associated with inhalation of asbestos fibers.

The Commission finds that it is in the public interest to regulate the risk of cancer associated with inhalation of asbestos fibers under the Consumer Product Safety Act rather than under

¹ Editorial Note: Part 1145 consisting of §§ 1145.1 and 1145.2 was proposed at 41 FR 33638 (August 10, 1976). Section 1145.3 was proposed at 42 FR 36984 (July 13, 1977).

the Federal Hazardous Substances Act because of the desirability of avoiding possibly lengthy, resource-consuming, and inefficient rulemaking proceedings under the Federal Hazardous Substances Act and because of the availability of civil penalties under the CPSA. The Commission also believes that the complexity and formality of the rulemaking proceedings under the FHSA, in contrast to rulemaking proceedings under the CPSA, may make it difficult for interested persons to participate. Therefore, emberizing material containing respirable free-form asbestos shall be regulated under the CPSA.

(Sec. 30(d), Pub. L. 92-573, 86 Stat. 1231 as amended, 90 Stat. 510 (15 U.S.C. 2079(d)))

Interested persons are invited to submit, on or before August 29, 1977 written comments regarding this proposal. Written comments and any accompanying data or material should be submitted preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the Office of the Secretary, Third Floor, 1111 18th St. NW., Washington, D.C. during working hours Monday through Friday.

Dated: July 26, 1977.

SHELDON D. BUTTS,
Assistant Secretary, Consumer
Product Safety Commission.

[PR Doc. 77-21843 Filed 7-28-77; 8:45 am]

[16 CFR Parts 1304 and 1305]

RESPIRABLE FREE-FORM ASBESTOS

Proposal To Ban Certain Patching Compounds and Artificial Emberizing Materials (Embers and Ash)

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed banning rules.

SUMMARY: In this document, the Commission proposes to ban two consumer products containing asbestos that can be inhaled (respirable, free-form asbestos): (1) consumer patching compounds used to join or repair interior walls and ceilings (mixing of the product before it is applied and sanding of the product after it is applied releases asbestos fibers that can be inhaled) and (2) artificial emberizing materials (embers and ash) made with respirable free-form asbestos for use in fireplaces to simulate live embers and ash. Based on information discussed in this notice, the Commission believes that certain types of cancer may result from inhaling asbestos fibers released during the use of these products.

Part A of the preamble to this document deals with the general characteristics of asbestos that are applicable to both products proposed to be banned. Part B deals with consumer patching compounds. Part C deals with artificial emberizing materials.

DATES: (1) For consumer patching compounds containing respirable free-

form asbestos, the proposed effective date is 30 days after publication of any final banning rule. Written comments on the proposal must be submitted by August 29, 1977. There will be an opportunity for interested persons to orally present data, views, or arguments on Monday, August 15, 1977 at 10 a.m., at the Commission hearing room, 3rd Floor, 1111 18th Street NW., Washington, D.C. Those wishing to make oral presentations should notify the Office of the Secretary by August 8, 1977.

(2) For artificial emberizing materials containing respirable free-form asbestos, the proposed effective date is the day of publication of any final banning rule. Written comments on the proposal must be submitted by August 29, 1977. There will be an opportunity for interested persons to orally present data, views, or arguments on Monday, August 15, 1977 at 10 a.m. Those wishing to make oral presentations should notify the Office of the Secretary by August 8, 1977.

ADDRESSES: Written comments should be submitted to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Persons wishing to make oral presentations should contact Richard A. Danca in the Office of the Secretary 202-634-7700. All material which the Commission has that is relevant to this proceeding, including any comments that may be received on this proposal, may be seen in, and copies may be obtained from the Office of the Secretary of the Commission, 3rd Floor, 1111 18th Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

John Liskey, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207 (301-492-6557).

SUPPLEMENTARY INFORMATION: The Commission has received the following three petitions requesting the banning of consumer patching compounds and artificial emberizing materials (embers and ash) containing respirable free-form asbestos:

HP 76-11: On July 15, 1976, the Natural Resources Defense Council (NRDC) and Consumers Union (CU) petitioned the Commission under the Federal Hazardous Substances Act (FHSA) to ban consumer patching compounds containing asbestos that are used for drywall taping, spackling and sealing of joints. The petitioners believe that high quantities of asbestos fibers remain in the air after these products are sanded and the fibers substantially increase the risk of mesothelioma and lung cancer.

HP 77-9: On February 9, 1977, the Public Citizens Health Research Group (HRG) petitioned the Commission under the FHSA in part to declare that patching compounds made with tremolitic talc containing asbestos fibers (tremolite asbestos) are banned hazardous products and an imminent hazard to the public health.

HP 77-11: On April 15, 1977, a request from Ms. Rachel Scott, that the Commis-

sion had investigated as a consumer complaint, was joined by the Environmental Defense Fund (EDF). The Commission designated the requests a petition to ban artificial emberizing materials containing respirable free-form asbestos. This product is used on artificial logs and on fireplace floors beneath them to simulate live embers and ashes.

(The parenthetical numbers listed below are citations to a list of documents consulted by the staff; the list appears below just before Conclusion and Proposal.)

The Commission has granted these petitions regarding asbestos, based on information discussed more fully below. The information consists, primarily, of data on exposure of industrial workers to respirable free-form asbestos (6) and also occasional exposures of families of workers and others in locations where free-form asbestos might be prevalent, as well as in other locations (47, 31, 38). Information on exposure of the public to free-form asbestos contained in individual consumer products is limited. However, there is general scientific and medical agreement that there is no known threshold level below which it is safe for people to be exposed to respirable free-form asbestos (35). Therefore, based on the available information the Commission has decided to propose a ban of these two products. In addition, information on other consumer products that may contain respirable free-form asbestos will continue to be developed in order to determine whether further regulation is necessary.

The petitions, relevant scientific and technical information, and Commission conclusions are more fully described below.

Although the three petitions were filed under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261, et seq., and it appears that the risks of injury from lung cancer and mesothelioma described by petitioners are regulatable under the FHSA, the Commission proposes to ban these products under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051, et seq. Section 30(d) of the CPSA, 15 U.S.C. 2064(d), as amended, provides that a risk of injury associated with a consumer product which can be eliminated or reduced to a sufficient extent by action under a transferred Act, such as the FHSA, may nevertheless be regulated under the CPSA if the Commission, by rule, determines that regulation under the CPSA is in the public interest. Also published in this issue of the FEDERAL REGISTER are proposed rules issued in accordance with section 30(d) of the CPSA stating the Commission's finding that it is in the public interest to ban the products described herein under the CPSA.

PART A. BACKGROUND

"Asbestos" is a general term for any of several varieties of mineral fibers composed of silica, oxygen, hydrogen, and other elements such as sodium, calcium, iron, or magnesium. The name is derived from the ancient Greek term for

"Incombustible". There are six basic varieties of asbestos minerals which are found in fiber form: chrysotile (the most common variety, and that ordinarily found in asbestos-containing products), amosite, crocidolite, actinolite asbestos, tremolite asbestos, and anthophyllite asbestos. Most of the world supply of commercial asbestos is chrysotile, the fibrous form of serpentine.

Asbestos minerals all have nonfibrous counterparts of the same chemical composition and crystal structure which are more abundant and widespread than the asbestiform variety but the crystallization of these normally nonfibrous minerals into fibrous forms is a rare occurrence in nature. (June 3, 1977, CPSC/Health Sciences, (7).)

Asbestiform minerals are generally characterized by the following properties: their ability to be broken down into smaller fibrils; great elongation; heat resistance; resistance to biotransformation; flexibility; high-tensile strength, and spinability.

DISEASES RELATED TO ASBESTOS EXPOSURE

It is important to note that the asbestos content of a given product is not necessarily the sole criterion of that product's relative health risk, for in numerous products the fibers are tightly bound or are encapsulated in the product composition. A potential health risk occurs when asbestos fibers become airborne, such as by mixing, sanding, or cleanup operations when using patching compounds. A single individual engaged in such a process may be exposed to potential asbestos fiber inhalation risk and may also cause exposure of other individuals in the vicinity.

Certain malignancies are related to exposure to asbestiform minerals. Both animal bioassay data and epidemiological studies support this conclusion.

All commercially available forms of asbestos which have been tested are carcinogenic in mice, rats, hamsters, and rabbits (IARC, 22).

Some conclusions from a Review (Huff, 21) of the major literature on asbestos are:

1. Under experimental conditions, asbestos is pathogenic in animals. Asbestos is known to be carcinogenic in humans, causing lung cancer, mesotheliomas, and pleural lesions.

2. The mechanisms of pathogenicity are poorly understood. The etiological significance of fiber size or type is controversial, and the physicochemical properties of various asbestos types as related to biological effects are incompletely defined.

3. Little is known about the clearance rates of asbestos from tissues, the transport of asbestos within the organism, or the metabolic alteration of asbestos in the body.

4. Animal models necessary to accurately predict the potential effects of asbestos in humans have not been developed.

5. Quantitative dose-response relationships between asbestos inhalation and related diseases have not been de-

termined for animals or humans, and minimal exposure levels required to cause disease are not known.

6. Malignancies can arise 20 years or more after occupational exposure; however, they also reportedly result from indirect, non-occupational exposure.

7. Available data indicate that asbestos is a widespread environmental pollutant.

The most common diseases that might result from asbestos exposure are:

1. Asbestosis: a diffuse, interstitial, nonmalignant, scarring of the lungs;

2. Bronchogenic carcinoma: a malignancy of the interior of the lung;

3. Mesothelioma: a diffuse malignancy of the lining of the chest cavity (pleural mesothelioma), or of the lining of the abdomen (peritoneal mesothelioma);

4. Cancer of the stomach, colon, and rectum.

Asbestosis may be evidenced, in its advanced stages, by characteristic manifestations on X-ray films, by restrictive pulmonary function, or by clinical signs of finger clubbing or rales (dry, cracking sounds within the lung). Its most important symptom is dyspnea, or undue shortness of breath. The disease is progressive, even in the absence of further exposure, as those inhaled fibers which have been trapped within the lung continue their biological action. In its severe forms, death results from the inability of the body to obtain requisite oxygen or from the heart's failure to pump blood through the scarred lungs.

Mesothelioma tumors are diffuse and spread rapidly throughout the cavity of origin. They have yet to be successfully cured by any type of treatment, including chemotherapy, radiation, or surgery. Death usually results within a year of diagnosis. It may account for one death in several thousand in the absence of an environmental or occupational asbestos exposure. In some groups of asbestos workers, it may account for one death in ten.

Once established, the other asbestos-associated cancers differ little from those occurring in the general population, although there may be variations in the location of the primary site. Appropriate treatment and prognosis follow for the particular tumor. There is very limited long term survival from lung cancer therapy; and only somewhat better from treated cancer of the colon or rectum.

Asbestosis and asbestos cancer, whether it be lung cancer, pleural mesothelioma, peritoneal mesothelioma, cancer of the stomach, colon, or rectum usually do not become clinically evident until more than 20 years have passed from onset of exposure. The long latency period is now widely recognized.

While some such cancers may appear during the second decade following onset of occupational exposure, peak incidence is often not noted until 20 years or more from initial exposure. This is true both with regular, long-term, brief or intermittent exposures. While variations in the time of occurrence may depend upon intensity and duration of exposure, with heavier exposure often being associated

with shorter latency periods, variations among individual cases make it impossible to predict the latency period for the risk of any particular person.

Clinical data are becoming available concerning asbestos lung scarring in individuals exposed at levels much lower than those of occupational circumstances. Among 210 family contacts of former asbestos factory workers, 38% have been reported to have X-ray changes characteristic of asbestos exposure (Anderson, Selikoff, Lillis and Daum, 1975, (1)).

In humans, the latency period for chemical carcinogens may well extend from 20 to 40 years or more. Analogous latency periods have also been demonstrated in animal studies. This means that the disease may undergo a long period of development before a tumor is actually detected.

Cancer development may be influenced by such factors as the differing susceptibility of various body organs. In animal studies it has been found that individual variability in response to carcinogens is great depending upon factors such as age, sex, hormonal status, diet, and genetic factors. Thus, individuals biologically compromised may be more susceptible than other groups.

CANCERS ASSOCIATED WITH ASBESTOS

In December 1972, important new information on the spectrum of asbestos cancers was presented at the Conference on the Biological Effects of Asbestos, sponsored by the International Agency for Research on Cancer of the World Health Organization. At this conference, and subsequently, data on large groups of asbestos workers became available (Selikoff, Hammond and Seidman, 1973 (41); Enterline, de Couffe and Henderson, 1972 (12)). As expected, the high risk of bronchogenic carcinoma and mesothelioma persisted among groups of factory workers. Moreover, these later studies confirmed the excess gastrointestinal cancer that had been suggested earlier, and extended the spectrum of asbestos related cancers.

(1) Lung cancer. The most important cancer afflicting asbestos workers is cancer of the lung, although mesothelioma has attracted considerable attention because of the high frequency among asbestos workers and infrequent occurrence in the population as a whole.

In many groups of asbestos workers, approximately 20% of all deaths are caused by lung neoplasms. This has been true both among asbestos product factory workers (Selikoff, Hammond and Churg, 1972 (42); and Nicholson, 1976 (35)), and among users of these products (Selikoff, Hammond and Seidman, 1973 (41)). The exact percentage varies with circumstances of exposure, age of the workers, duration of the workers' exposure and, perhaps most of all, according to the duration from the onset of their asbestos work history. In addition, the last several years have seen the discovery of another critical variable affecting the incidence of lung cancer among asbestos workers. In 1988, Selikoff and Hammond

(38) reported that lung cancer was not significantly increased in incidence among asbestos workers with no history of cigarette smoking, although when such history was present, the incidence of lung cancer increased markedly over what would be expected among other cigarette smokers. In the absence of asbestos exposure. Thus, these scientists calculated that an asbestos worker who smoked cigarettes had 92 times the risk of dying of lung cancer, as compared with like individuals without cigarette smoking or asbestos work. This finding has been confirmed by larger studies (Hammond and Selikoff, 1972 (17)) where, again, it was found that non-smoking asbestos workers had few lung cancers while those who smoked had much more lung cancer than would have been expected had they not been asbestos workers. Calculations suggest that cigarette-smoking asbestos workers have approximately eight times the risk of developing lung cancer compared to other cigarette smokers who are not occupationally exposed to asbestos.

(2) Pleural and peritoneal mesothelioma. In 1960 Wagner, Skeggs and Marchand (47) demonstrated an important association between asbestos exposure and pleural mesothelioma. This cancer, which appears to be unrelated to smoking, had previously been considered to be a very rare tumor. Numerous reports have confirmed the finding of Wagner and his colleagues that mesothelioma can be commonly associated with asbestos exposure. A subsequent report by Enticnap and Smith, 1964, (13) concerning workers in a British asbestos factory demonstrated that the same tumor could be commonly found in the abdomen (peritoneal mesothelioma), as well as in the chest.

The exact risk of death of these invariably fatal neoplasms has not been as well defined as has lung cancer, although records of cases from hospitals near one large asbestos factory indicate that it must be very common (Barrow, Conston, Livornese and Schalet, 1967, (3)). Information available from the experience of asbestos insulation workers suggests that approximately five to seven percent of deaths may be due to this neoplasm (Hammond, Selikoff and Chung, (17); Selikoff, Hammond and Feldman, 1973, (41)). More recently, it has been suggested that this estimate is too low, on the basis of the experience of workers in a British asbestos factory where calculations predicted that between 10 and 11 percent of deaths would be due to mesothelioma (Newhouse and Berry, 1975, (30)).

A recent study of mesotheliomas diagnosed in a hospital located in the vicinity of a shipyard reported an increased incidence of diffuse malignant mesothelioma since World War II, not only among exposed shipyard workers, but also among individuals with no occupational exposure (Hasan, (20)).

(3) Gastro-intestinal cancer. Gastro-intestinal cancers (cancer of the stomach, colon and rectum) are also increased in incidence among asbestos

workers. A number of studies now indicate that the increase is on the order of two or three times the number of expected tumors (Selikoff, Hammond and Feldman, 1973, (41); Elmes and Simpson, 1971 (9)). Although this increased risk is relatively limited, especially when compared with lung cancer and mesothelioma, it is nevertheless of considerable importance since a two- or three-fold increase in such common tumors becomes an important cause of death for the workers involved.

It has been suggested that other tumors are also increased in incidence among asbestos workers, particularly cancers of the larynx (Stell and McGill, 1973 (45); Newhouse and Berry, 1973 (34)), and of the esophagus (Selikoff, Hammond, and Feldman, 1973 (41)). However, data concerning these neoplasms are less extensive than for lung cancer, mesothelioma and gastro-intestinal cancer and further experiences are awaited. In any case, they are not very common tumors in general and any increase does not weigh heavily on the overall cancer risk of asbestos workers.

OCCUPATIONAL EXPOSURE

Reports of pulmonary fibrosis or lung scarring, from inhalation of asbestos dust in factories began to appear in the literature in the early part of this century and by 1927 this lung scarring disease was known as "asbestosis" (Newhouse, (1)).

In 1930, the British Home Office Survey by Merewether and Price (28), found that approximately half of a population of asbestos factory workers were suffering from pulmonary fibrosis, leading to the introduction of the Asbestos Factory Regulations of 1931. The objective of the Regulations, implemented in 1933, was to reduce the risk of asbestosis.

It was recognized, however, that in addition to asbestos-induced lung scarring, there was also increasing evidence of cancer associated with asbestos exposure. Some workers whose deaths were attributed to asbestosis were also found to have had lung cancer. (Nicholson, (35)).

By 1960, through epidemiological studies, an association between asbestos exposure and mesothelioma had been demonstrated (Wagner (47)) and was soon substantiated by additional epidemiological studies (Newhouse (31), Selikoff (37)) and clinical diagnosis.

In 1968, the Committee of the British Occupational Hygiene Society evaluated worker exposure data in a large asbestos textile mill dating from implementation of the Asbestos Regulations of 1933 which indicated that there was "comparatively little clinical and/or roentgenological evidence of asbestosis" at that factory in a survey completed in 1968. Based on that data, the Committee concluded by setting a dust exposure level at 100 fiber-years/ml (or 2 fibers/ml for 50 years) it would provide a full working lifetime without substantial risk of developing asbestosis. (OSHA, 1975, (5)).

The National Institute of Occupational Safety and Health (NIOSH) relied heavily on the British Standard in its recommendation for promulgation of the asbestos standard set by OSHA in 1972.

Subsequent to the implementation of the OSHA permanent asbestos standard in 1972, results of a new evaluation of the earlier British factory worker population showed many abnormal X-ray findings of the lungs and pleura.

It is reported that there is now an excess lung cancer mortality rate among workers who became employed at the textile mill after 1933 and whose lack of clinical or X-ray evidence of asbestosis led to the development of the British asbestos standard.

Another report of an ongoing study of workers (and their family members) in a factory producing amosite asbestos between 1941 and 1954, when the factory closed, has shown a high incidence of X-ray abnormalities and 2 pleural mesothelioma deaths have thus far been identified (1).

It is also reported that clinical data are becoming available concerning asbestos lung scarring in individuals exposed at much lower than occupational levels. (Anderson, (1)).

It therefore appears that an exposure thought sufficiently low to reduce the risk of asbestosis has not prevented pathogenic changes, including lung cancer and mesothelioma. (Anderson, (1)).

NON-OCCUPATIONAL, INDIRECT OCCUPATIONAL EXPOSURE, OR INTERMITTENT OR BRIEF EXPOSURES

Recent data indicate the occurrence of asbestos cancer from exposure to low levels of asbestos, as in environmental circumstances, or from brief or intermittent exposures to higher levels.

In inhalation exposure experiments, rats exposed to asbestos dust were reported to have developed tumors, including mesotheliomas, from as little as a single 7 hours exposure (48).

Analysis of the history of asbestos exposure among individuals in a large series of cases of mesothelioma in Great Britain and South Africa have provided evidence that brief or intermittent exposure to asbestos may, after the passage of decades, result in mesothelioma (Greenberg and Davies, 1974 (16); Webster, 1973, (49)). In such circumstances, it appears that the lifetime exposure was less than 100 fibers-years/ml. The same discrepancy between present projected exposures and the risks of asbestos cancer exists when considering cases of mesothelioma resulting from household contact with asbestos among members of families or asbestos workers (Gillingham, 1974 (25)), or among residents living in the vicinity of asbestos plants. Of considerable industrial importance has been the recent description of asbestos disease among shipbuilding and ship repair workers, few of whom actually work with asbestos, but many of whom were, in the past, inadvertently exposed to the asbestos dust resulting from the use of asbestos products by a relatively few of their workmates. In 1968, Harries of

the Royal Navy (19) reported cases of mesothelioma among shipyard workers at the Royal Navy dockyard in Devonport, in trades which did not directly involve worker exposure to asbestos, but in which there had been occasional opportunity for exposure merely by virtue of working in the same areas. This original finding has been widely confirmed and numerous cases of mesothelioma have since been reported in former shipyard workers (Whitewell and Rawcliffe, 1970 (50)); McEwan et al, 1970 (27)); Stumphius, 1971 (46); Greenberg and Davies, 1974, (16). Studies of populations of current shipyard workers have shown much radiological evidence of asbestos abnormalities among workers in trades only indirectly exposed to asbestos in the yards (Sheers and Templeton, 1968 (44); Fletcher, 1972, (15)).

Further, evidence has indicated that asbestos also acts as a lung carcinogen at levels much below those which will produce asbestosis. Two surveys of shipyard workers who had X-ray evidence of pleural plaques, but generally not of pulmonary fibrosis, showed a 2.5-fold excess risk of death from lung cancer and high risk of mesothelioma. (Fletcher, 1972 (15); Edge, 1975 (8)). In a study of the mortality experience of a large U.S. asbestos products manufacturing facility, it was found that workers in low dust areas, with a minimum risk of death from asbestosis, had the same high risk of death from various cancers as workers in dustier areas (Nicholson, 1975, (35)).

It is extremely difficult, if not impossible, to document brief exposures reported to have occurred 20 or more years before the onset of symptoms. To determine the type and extent of non-occupational exposure, the investigator must generally rely on relatives or persons other than the exposed patient for exposure history.

(Much of the foregoing information on asbestos-related diseases was prepared by the Occupational Safety and Health Administration (OSHA) and published at 40 FR 47851, October 9, 1975, "Occupational Exposure to Asbestos" has been helpful in preparing this proposal (6)).

CONSUMER EXPOSURE

Reports of the hazard, or potential for hazard, from exposure to asbestos resulting from use of asbestos-containing consumer products are very limited. The only known quantitative study of asbestos levels in products regulated by this Commission was reported by Rohl, et al (1975 (38)), of asbestos fiber concentrations measured during the use of consumer spackling patching and taping compounds. This study indicated that airborne fiber concentrations, exceeding the interim OSHA allowable excursion exposure level, were detected during application and cleanup operations. Fibers were detected in adjacent rooms during mixing operations and it was reported that . . . significant concentrations of asbestos remained suspended and could pervade living quarters for a considerable

duration of time . . . The authors suggest that the use of spackling and other patching compounds (in mixing and sanding and cleanup operations) may expose the user and other members of the household to . . . significant concentrations of asbestos".

Asbestos in the household presents a great risk due to the presence in the household of persons, such as children, who may be particularly vulnerable to carcinogens. It is generally observed that, because of the long latency period, exposure to inhalable asbestos in the home can be life-shortening for children. In this connection, Dr. Paul Kotin of the Johns-Manville Company, stated to an OSHA Advisory Committee that in his laboratory experience, cancer can be most readily induced in the young (14). This point was further clarified at a briefing before the Commission on June 9, 1977 during which Dr. Kotin stated his belief that the young are doubly vulnerable to carcinogens—first, because of a long lifetime ahead and secondly because young children grow at a more rapid rate than adolescents. Thus, he explained, "A rapidly dividing cell, a cell which has a turnover time shorter when compared to another cell, is perhaps more likely to be subject to the action of a carcinogen."

The Commission concludes that exposure to asbestos from either patching compounds or artificial emberizing materials presents an unreasonable risk of injury sufficient that either product standing alone should be banned. The Commission also notes that consumers are exposed to asbestos from sources other than the products proposed for banning. The asbestos fibers are present in the general environment has been demonstrated by studies such as those by Huff (21), Selikoff, and Harwood (38). Consumers who are exposed to asbestos fibers from artificial embers and ash and patching compounds thus receive additional doses of asbestos and can be presumed to face a greater risk than members of the population who are not so exposed, and a greater cumulative risk than if no asbestos were present in the general environment.

A bibliography of additional scientific and medical literature reviewed by the Commission is noted below and an annotated bibliography is available for review in the Office of the Secretary.

"THRESHOLD" LIMIT

Because of the variability of individual response to carcinogens and other factors, the concept of a "no effect" or "threshold level" of exposure may have little real significance on the basis of existing knowledge. While some level, below which exposure to a carcinogen does not cause cancer, may conceivably exist for any one individual, other individuals may have cancer induced by doses so low as to be effectively zero (35).

In the Proceedings of the Nineteenth Meeting of the Interagency Collaborative Group on Environmental Carcinogenesis devoted to Threshold Evaluated held at the National Institute on August

14, 1975 (23), Dr. H. F. Kraybill, Chairman, states that:

Investigators in the field of carcinogenesis have doubted the existence of a threshold for a carcinogen or at least have maintained that there are no acceptable procedures for assessment of a safe-dose for a carcinogen (i.e. threshold). Thus, it has been concluded that it is not feasible to prove or disprove the presence or absence of a threshold-dose through downward extrapolation from the dose-response curve in regions of detectably significant dosage. The conservatism in this direction is prompted by certain realizations as to the self-replicating nature of the cancer cell, the possible existence of irreversible effects, the aspects of lasting alteration induced by a tumor-producing event, the perpetuation of the neoplastic lesion after the original inducer has disappeared from the milieu, and finally, the possibility of cancer induction from a mutation in a somatic cell.

These theoretical concepts have a bearing on the asbestos issue, particularly as the question of the existence, or nonexistence, of a threshold level of carcinogenic effect. A "no effect" level theoretically may exist, but it has not been demonstrated. Therefore, there is no known threshold level below which exposure to respirable free-form asbestos would be considered safe.

OTHER FEDERAL AGENCY ACTIONS TO REGULATE EXPOSURE TO ASBESTOS

The Occupational Safety and Health Administration of the Department of Labor (OSHA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) each has a responsibility to regulate exposure to asbestos.

OSHA regulates exposure to asbestos by workers in all industrial and commercial settings except agriculture. The regulation (29 CFR 1910.1001) states that the 8-hour time-weighted average airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed two fibers, longer than 5 micrometers, per cubic centimeter of air. In 1975, OSHA proposed an amendment to lower exposure to .5 fibers per cubic centimeter of breathing air. An OSHA proposal to regulate exposure by workers in the building construction industries is expected to be ready for publication within the next few months.

FDA has banned the use of asbestos in filters used in the formulation of parenteral drugs (21 CFR 211.40(j)) and, prior to the establishment of the Consumer Product Safety Commission, banned the use of asbestos in fabric used for general wearing apparel. (16 CFR 1500.17(a) (7)).

EPA regulates asbestos which is released into the air and into the water. These regulations (40 CFR 61, 427, 436) do not set standards for allowable amounts of asbestos in the breathing air but rather minimize or eliminate emissions from industrial locations. These regulations specifically prohibit the presence of asbestos in emissions from plants manufacturing materials for use in building roadways and in manufacturing items such as cloth, textiles, cement, fireproofing and friction products, paper, felt, floor materials, paints, adhesives,

sealants, caulks, and a variety of other items.

ASBESTOS REGULATIONS AFFECTING CONSUMER PRODUCTS IN OTHER COUNTRIES

In June, 1976, Canada banned the sale and importation of asbestos-containing products for use by children. In April, 1976, England introduced a voluntary labeling scheme for products containing asbestos.

In Sweden, the use of asbestos-cement products for new work was prohibited as of July, 1976, and for maintenance in existing structures will be discontinued by the end of 1977. Manufacturing of these products is not prohibited. According to the Swedish Standard for Occupational Exposure:

"The TLV of 25/ml was lowered to 11/ml as of January, 1977, and is scheduled to be further reduced to 0.5 f/ml by 1 January, 1978." (June 27, 1977, Asbestos Information Association (2).)

PART B. PATCHING COMPOUNDS

Asbestos fibers are used in patching compounds to reinforce a material as it cures, to control shrinkage and cracking, and to reinforce the material as the compound is alternately exposed to heat, cold and moisture after curing. Asbestos also provides a measure of sound and heat insulation to the material, and enhances the workability of the compound, particularly during troweling. The properties considered by industry to be most valuable in the preparation of patching compounds are: asbestos is not affected by fungus, mildew, vapor, etc. and it has low density; good adsorption qualities; high resistance to electricity, fire and alkaline substances; low magnetic permeability; and it is not a smooth fiber.

Patching compounds are mixtures of talcs, pigments, clays, casein, ground marble, mica or other similar materials with water and a binding material such as asbestos. Patching compounds are available in dry form (to be mixed with water by the user) or a ready-mix paste form. The product is used to cover, seal or mask cracks, joints, holes and similar openings in the trim, walls, and ceilings, etc. of building interiors.

In patching compounds, asbestos is released when using the dry form and mixing it with water, or by sanding or scraping the dried patching compound in the process of finishing and smoothing the surface as in remodeling and in cleanup operations. Such activities may present a hazard to consumers when the activity is performed either by a consumer or a professional user of these products.

Patching compounds covered by this ban are those that are customarily produced or distributed for sale to or for the personal use, consumption or enjoyment of consumers in or around a permanent or temporary household or residence, a school, in recreation or otherwise. Patching compounds that are labeled as, marketed, and sold solely for industrial use would not be within the scope of this ban. Information available

to the Commission indicates that most patching compounds for industrial use are distributed in such ways that consumers have access to these products. Moreover, merely labeling a patching compound for industrial or professional use only, would not exclude such articles from the ban. If the manufacturer, distributor or retailer fosters or facilitates the product's sale to or use by consumers, the product would be considered a consumer product within the scope of this ban.

Recent court cases have examined the statutory definition of consumer product and indicate that the presence of a product in a consumer environment would be considered a primary determinant of whether that product is a consumer product under the CPSA. In considering the statutory definition and its legislative history in light of these cases, it appears to the Commission that substantially all patching compounds are consumer products under the CPSA.

EVALUATION OF THE RISK

In assessing the degree and nature of the risk of injury to consumers, the Commission has reviewed experimental data and human experience information. In addition, on the basis of data by Rohl, et al. (36), the Commission's Health Sciences staff has calculated an assessment of the risk of consumer exposure which is available at the Office of the Secretary. The calculations are based on the application of a theoretical model (modification of that by Enterline and Henderson, 1976, (11), to epidemiological data cited in the literature. (Stellhoff, Hammond and Seidman, 1973, (41)). For purposes of this assessment, the Commission considered the use of patching compounds by a consumer, for six hours a day four times a year, to be a high yet reasonably foreseeable yearly exposure. The increased risk of death from respiratory cancer induced by this yearly exposure is estimated at between 10 and 2,000 per million. For five years of exposure at these levels, the risk increases geometrically and is estimated at between 1,000 and 12,000 per million. Based on current information, the Commission estimates that the lower estimate of 10 per million is closer to the actual risk for a one year exposure. Nevertheless, in view of the seriousness of the injury and the cumulative effects of asbestos exposure, even this minimum figure represents an unacceptable risk. The Commission believes that reducing exposure to respirable free-form asbestos in the home represents a substantial decrease in risk to consumers, since, for many people, the major exposure to inhalable asbestos is in the home.

INDUSTRY RESOURCE CONSIDERATIONS

ASSESSMENT OF SUBSTITUTES

The elimination of asbestos from patching compounds would necessitate

United States of America v. The Anaconda Co., et al., Misc. No. 77-0024 (D.D.C.), June 15, 1977. *Kaiser Aluminum & Chemical Corp. v. CPAC*, Civ. No. 76-44 (D.Dela.) March 11, 1977.

the use or development of substitutes which are similar to asbestos, or which impart similar qualities to the product. Several substitutes for asbestos in patching compounds are in current use. The primary economic concerns focus on the effect of substitutions on the utility derived from the product (mainly in terms of performance characteristics) and on the prices of patching compounds.

Asbestos possesses a unique combination of strength, pliability, and heat-cold- and moisture-resistant qualities; substitutes which have been tested in these product categories often do not last as long, are less workable, and may take a long time to perfect (asbestos-free spackling compounds were at least five years in development). Some products not readily reformulable may be dropped from the market. Availability of substitutes may also be limited temporarily on a regional basis, depending on the paint and building materials industries' ability to reformulate asbestos-containing products. Many producers are, however, either presently marketing asbestos-free materials or expect to in the near future.

Substitution may also lead to higher costs of production and prices for some of these products. The total cost to most patching compound manufacturers of chemically reformulating products is not expected to be large relative to sales; it is, however, expected that some cost increases will occur which will likely be passed on in the form of higher prices (this may be 10 to 15 percent). (Preliminary Economic Draft study—subsection on Spackling/Joint Compounds, OSHA, (7).)

Inventories of existing products in distribution channels may vary over a wide range. Similarly, inventory turnover cycles at various points in distribution may vary considerably.

These conditions may be further affected by OSHA's course of action on asbestos. Should a commercial-industrial fiber limit standard be imposed, the industry would probably eliminate asbestos from paints and other building materials as well as from patching compounds.

ENVIRONMENTAL ISSUES

The Commission has studied the environmental effects of this proposal as required by the National Environmental Policy Act. An environmental assessment is on file at the Office of the Secretary of the Commission and indicates, by negative declaration, that no significant effects on the environment are foreseen by the proposals issued below.

Asbestos is an ubiquitous mineral fiber that has been used for many years in the U.S. in occupational settings and in building construction. This has led to low-level, but widespread exposure of the public. Asbestos is found in the air, water, and land (in minute concentrations relative to those found in or near asbestos mines or processing facilities).

The elimination of asbestos from patching compounds available to or used or enjoyed by consumers will significantly reduce household fiber release from mixing, sanding, and clean-up. It will not, however, significantly reduce fiber

release or fiber in the general environment from all sources.

Proper disposal of present inventories is also expected to pose no significant problems since it would account for a minor portion of all asbestos disposal.

The potential environmental (i.e., health) effects of the use of substitutes is, however, an issue which merits further study by the Commission and other agencies. No conclusions about the safety of the known substitutes have yet been made. Although the Commission has no evidence that the known substitutes are hazardous, there appears to be some concern in the industry on this point. Laboratory testing may be desirable to verify this point.

The Commission requests comment on other environmental issues as well as those raised here.

EFFECTIVE DATE

The Commission has assessed the possible effects on the relevant industries of banning consumer patching compounds. Staff research indicates that asbestos-free products can probably be in distribution in about six months. The Commission also considered the possible increased hazard to consumers that might result from banning the distribution of patching compounds 30, 180, and 360 days after publication of a final banning rule. The possible increased hazard to consumers that could arise during these different time periods was considered in the context of the assessment that asbestos from patching compounds poses a significant household fiber exposure risk to consumers using or enjoying patching compounds in their homes, although it may not pose a significant environmental fiber exposure hazard. On this basis, the Commission proposes that the manufacture, sale, offering for sale, importation and distribution in commerce of consumer patching compounds be prohibited 30 days after publication by the Commission of a final banning rule. This prohibition would apply to products in inventory as well as to those manufactured after the effective date of the final regulation.

PART C. ARTIFICIAL EMBERIZING MATERIALS (ASH AND EMBERS) CONTAINING RESPIRABLE FREE FORM ASBESTOS

Artificial emberizing materials for fireplaces are generally packaged in "emberizing" kits. The emberizing material is placed under artificial logs in gas-burning fireplace systems or in artificial fireplaces for decorative purposes. The product is also glued to artificial logs, either at a factory, or by a consumer using an emberizing kit. When subjected to high temperatures, the asbestos in this product produces a glow like real embers and ash. Asbestos fibers are released when the emberizing material containing asbestos is sprinkled on the fireplace floor, when glue used by the consumer to attach the material to an artificial log melts at high temperatures, and when ordinary household air currents and downdrafts cause the asbestos in the simulated embers and ash to become

airborne. (Not included in this ban are synthetic logs, generally manufactured of cellulose products and wax, which actually are ignited and consumed by the flames.)

EVALUATION OF THE RISK

Measurements are not available of the amounts of asbestos in the air from asbestos-containing emberizing materials in homes. However, it appears that the amount of airborne asbestos in such homes would increase when air currents in the home are created by downdrafts from a fireplace chimney or other activities that stir air in any room. Since emberizing materials may contain up to 50 percent asbestos, which if not permanently bound into artificial fireplace logs would be in respirable form, the risk associated with emberizing materials is considerable since it continues to exist 24 hours a day.

INDUSTRY RESOURCE CONSIDERATIONS

ASSESSMENT OF SUBSTITUTES

The elimination of asbestos from emberizing material may result in the use of substitutes which are similar to asbestos, or which impart similar qualities to the product. Virtually all of the manufacturers have developed asbestos-free emberizing material as of June, 1977. There are at least three substitutes for asbestos currently being used in artificial emberizing material: fibrous glass, vermiculite and a synthetic fiber with asbestos-like heat-resistant qualities.

It appears that the synthetic-fiber mixture is substantially more costly than the other mixtures, including those containing asbestos. The other two substitute mixtures may be somewhat more costly to produce, depending on local raw material availability, prevailing local prices, etc. The vermiculite-only embers may not be as effective in creating the desired "glowing" look; more of the material may be required to achieve the same degree of effect provided by the asbestos-containing mixture. It is doubtful that the price of emberizing kits will be significantly affected unless a large shift to the use of synthetic-fiber-containing material occurs.

ENVIRONMENTAL ISSUES

The Commission has assessed the environmental effects of this proposal as required by the National Environmental Policy Act. Its assessment is on file at the Office of the Secretary of the Commission and indicates, by negative declaration, that no significant effects on the environment are foreseen by the proposals issued below.

As noted in Part B, asbestos is a ubiquitous mineral fiber that has been used for many years in the U.S. in occupational settings and in building construction. This has led to low-level, but widespread, exposure of the public. Asbestos is found in the air, water, and land (in minute concentrations relative to those found in or near asbestos mines or processing facilities). The elimination of asbestos from emberizing kits is not expected to reduce free fiber emis-

sions significantly, either nationally or regionally (most of the manufacturers are located in California). A significant portion of household fiber release is accounted for by this product, however, in homes so equipped. The Commission will issue guidelines to minimize consumer exposure to floating fibers during a cleanup and disposal of embers. Significant effects are not expected from the ban itself other than increased safety in individual homes.

The potential environmental (i.e., health) effects of the use of substitutes is, however, an issue which merits further study by the Commission and other agencies. There is little information concerning the safety of the ember material substitutes. Further study is currently under way to collect information about these substitutes and to assess the potential health effects of their use. (Fibrous glass and the synthetic fiber are similar in shape and size to chrysotile, for example).

The Commission requests comment on other environmental issues as well as those raised here.

EFFECTIVE DATE

The Commission has assessed the possible effects on the relevant industries of banning artificial fireplace embers containing free asbestos. It appears that many manufacturers have ceased shipment of asbestos-containing merchandise. The Commission has also considered the possible increased hazard that might result from banning the distribution of this product, 30, 180, and 360 days after publication of a final banning rule. The continuing availability of respirable free-form asbestos to consumers during these differing time periods and the necessity for developing and transmitting to the public information on environmentally safe means of removing the product from consumers' homes was also reviewed. Based on these considerations, the Commission proposes that the manufacture, sale, offering for sale, importation and distribution in commerce of artificial fireplace emberizing material (embers and ash) containing respirable free-form asbestos be prohibited on the day of publication by the Commission of a final banning rule. This prohibition would apply to products in inventory as well as to those manufactured after the effective date of the final regulation.

PART D. UNREASONABLE RISK OF INJURY AND FEASIBILITY OF STANDARDS

The Commission finds that these products are being and will be distributed in commerce. The Commission has considered all the information currently available to it on the risks of injury concerning respirable free-form asbestos in the products discussed above including the frequency and severity of injuries and the nature of the risks associated with these products. The Commission preliminarily determines that the presence of respirable free-form asbestos in consumer patching compounds and in artificial emberizing materials (embers

and ash) for fireplaces presents an unreasonable risk of injury to the public from lung cancer and mesothelioma and that no feasible standard under the CPSCA can adequately protect the public from such risk.

The Commission stated in a recently issued consumer product safety rule banning unstable refuse bins (42 FR 30296, June 13, 1977), in discussing the lack of feasibility of a standard, that, "The Commission is not required to look at the entire class of products of which a particular hazardous product is a member. Thus, when the Commission can identify the particular products that present the unreasonable risk of injury by specifying their characteristics in certain performance or design terms, the Commission can ban these articles." With respect to the products now under consideration, the characteristic identified is the presence of respirable free-form asbestos.

The Commission believes that not all patching compounds present an unreasonable risk of injury to the public, only patching compounds containing respirable free-form asbestos. The hazard associated with this product is the free form in which the asbestos appears. While a safe patching compound can be manufactured, it is not possible to manufacture a safe patching compound containing respirable free-form asbestos because a safe level of exposure to free-form asbestos is unknown. Therefore, it does not appear that a standard for patching compounds containing respirable free-form asbestos is feasible at this time.

The product, artificial emberizing materials for fireplaces, containing respirable free-form asbestos, is used only in dry form. Thus, individual asbestos fibers are never bound together. If the asbestos fibers were coated by another material to bind the fibers, it would no longer be the same product. In considering the dry character of the product and the fact that a safe level of exposure to respirable free-form asbestos is not known, it does not appear that a standard for artificial emberizing materials containing respirable free-form asbestos is feasible at this time.

The Commission believes that no standard can render the defined products non-hazardous and concludes that only banning these products can adequately protect the public from unreasonable risks of injury associated with them.

REFERENCES

The parenthetical numbers used in the preamble above refer to the following documents:

1. Anderson, E. A., Lills, R., Daum, S., Fischbein, A. S., and Selikoff, I. J.: Household-Contact Asbestos Neoplastic Risk. *Ann. N.Y. Acad. Sci.* 271:311-323 (1978).
2. Asbestos Information Assoc.: Information from Representative of the Asbestos International Association Conference, Hamburg, Germany, 1976, June 27, 1977 memo.
3. Borrow, M., Conaton, A., Livornese, L. L., and Schiet, N.: Mesothelioma and Its Association With Asbestos. *JAMA* (8): 93-97 (1967).
4. Canada: Consumer & Corporate Affairs, Consumer Standards Directorate, Product

Safety Branch, Asbestos in Toys and Modeling Materials Issue No. 2, June, 1976.

5. Department of Labor, Occupational Safety and Health Administration: Asbestos Dust Standard, 29 CFR 1910.93a.

6. Department of Labor, Occupational Safety and Health Administration: Occupational Exposure to Asbestos, Notice of Proposed Rulemaking, FR Vol. 40, No. 197, pp. 47653-47665, (Oct. 9, 1975).

7. Department of Labor, Occupational Safety and Health Administration: Asbestos Dust in the Construction Industry, Preliminary Draft: Technical Feasibility Assessment, Spackling and Drywall Joint Compounds, p. 1-12 (1977).

8. Edge, J. R.: Asbestos Related Disease in Barrow-In-Furness. *Env. Res.* 11:244-247 (1976).

9. Elmes, P. C. and Stimpson, M. J. C.: Insulation Workers in Belfast 3. Mortality 1940-66. *Br. J. Ind. Med.* 28: 226-236 (1971).

10. England, Health & Safety Exec. Dept. of Prices and Consumer Protection. Asbestos Labeling Scheme, April 1976.

11. Enterline, P., and Henderson, V.: A model for Extrapolating to Low Levels of Asbestos Exposure. Presented at Conference on Problems of Extrapolating the Results of Laboratory Animal Data to Men and Extrapolating the Results from High Dose Level Experiments to Low Dose Level Exposure. Pinehurst, N.C. (March 1976).

12. Enterline, P., DeCoulle, P., and Henderson, V.: Mortality in Relation to Occupational Exposure in the Asbestos Industry. *J. of Occupational Medicine* 14 (12): 897-903 (1972).

13. Enticknap, J. E., and Smither, W. J.: Peritoneal Tumours in Asbestososis. *Brit. J. Ind. Med.* 21:20-31 (1964).

14. Environmental Defense Fund: Petition for Action under section 12 of the CPSCA against fireplace ashes and Logs Containing Asbestos, Footnote 1, May 12, 1977.

15. Fletcher, D.C.: A Mortality Study of Shipyard Workers and Pleural Plaques. *Br. J. Ind. Med.* 29:142-146 (1972).

16. Greenberg, M., and Davies, A. L.: Mesothelioma Register 1967-8, *Br. J. Ind. Med.* 31:91-104 (1974).

17. Hammond, E. C., and Selikoff, I. J., and Churg, J.: Neoplasia Among Insulation Workers in the United States with Special Reference to Intra Abdominal Neoplasia. *Ann. N.Y. Acad. Sci.* 132:519-525 (1966).

18. Hammond, E. C., and Selikoff, I. J.: Relation of Cigarette Smoking to Risk of Death of Asbestos-Associated Disease Among Insulation Workers in the United States, pp. 312-317 International Agency for Research on Cancer (1973).

19. Harries, P. G.: Asbestos Hazard in Naval Dockyards. *Ann. Occup. Hyg.* 11:134-145 (1968).

20. Hasan, Fayal M. et al: The Significance of Asbestos Exposure in the Diagnosis of Mesothelioma: A 28-year Experience from a Major Urban Hospital. *Amer. Rev. Resp. Dis.* 115: 761-768 (1977).

21. Huff, J. E., Hammons, A. S., Dinger, C. A., Whitfield, E. L., and Erickson, G. G.: Asbestos: An overview. *Env. Chemicals-Human and Animal Health 3rd Annual Conference Proceedings.*

22. IARC Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Man. IARC Monographs on the Evaluation of the Carcinogenic Risk to Man: Asbestos. Intl Agency for Research on Cancer, 1977.

23. Interagency Collaborative Group on Environmental Carcinogens, 19th Meeting, NIH, Aug. 14, 1975.

24. Jones, H. E., and Grindon, A.: Environmental Factors in the Origin of Cancer and Estimation of the Possible Hazard to Man. *Pd. Cosmet. Toxicol.* 18:261-268 (1975).

25. Lillington, G. A. et al: Conjugal Malignant Mesothelioma. *New Eng. J. Med.* 291 (11): 583-584 (Sept. 12, 1974).

26. McDonald, J. C., McDonald, A. D., Gibbs, A. W., et al: The Health of Chrysotile Asbestos Mine and Mill Workers of Quebec. *Arch. Env. Health* 28:61 (1974).

27. McEwen, J., Finlayson, A., Mair, A., and Gibson, A.A.M.: Mesothelioma in Scotland. *Br. Med. J.* 4:874-878 (1970).

28. Mereweather, E. R. A., and Price, C. W.: Report on the Effects of Asbestos Dust on the Lungs and Dust Suppression in Asbestos Industry. H. M. Stationery Office, London (1930).

29. National Institute for Occupational Safety & Health: Criteria for a Recommended Standard . . . Occupational Exposure to Asbestos. (1972).

30. Newhouse, M. L., and Berry, G.: The Risk of Developing Mesothelial Among Workers in an Asbestos Textile Factory. XVII International Congress on Occupational Health, Bristol, England (1975).

31. Newhouse, M. L., and Thompson, H.: Mesothelioma of Pleura and Peritoneum Following Exposure to Asbestos in the London Area. *Brit. J. Ind. Med.* 22:281 (1965).

32. Newhouse, M.: Asbestos in the Work Place and the Community. *Ann. Occ. Hyg.* 16:97-107 (1973).

33. Newhouse, M. L., and Berry, G.: Predictions of Mortality from Mesothelial Tumours in Asbestos Factory Workers. *Br. J. Ind. Med.* 33:147-151 (1976).

34. Newhouse, M. L., and Berry, G.: Asbestos and Laryngeal Carcinoma. *Lancet* 2: 615 (1973).

35. Nicholson, W. J.: Case Study 1: Asbestos-The TLV Approach. *N.Y. Acad. Sci.* 271: 152-160 (1976).

36. Rohi, A. N., et al: Exposure to Asbestos in the Use of Consumer Spackling, Patching and Taping Compounds. *Science* 189:551-553 (Aug. 15, 1975).

37. Selikoff, I. J.: Asbestos and Neoplasia. *Am. J. Med.* 42(4): 487-496 (1967).

38. Selikoff, I. J., and Hammond, E. C. III: Community Effects of Non Occupational Environmental Asbestos Exposure. *Am. J. Pub. Health* 58(9): 1858-1868 (1968).

39. Selikoff, I. J., Churg, J., and Hammond, E. C.: The Occurrence of Asbestos Among Insulation Workers in the United States. *N.Y. Acad. Sci.* 132: 139-155 (1966).

40. Selikoff, I. J., Hammond, E. C., and Churg, J.: Asbestos Exposure, Smoking, and Neoplasia. *JAMA* 204(2): 106-112 (1968).

41. Selikoff, I. J., Hammond, E.C., and Seidman, H.: Cancer Risk of Insulation Workers in the United States, pp. 209-216 International Agency for Research on Cancer (1973).

42. Selikoff, I. J., Hammond, E. C., and Churg, J.: Carcinogenicity of Amosite Asbestos. *Arch. Env. Health* 25:183-186 (1972).

43. Selikoff, I. J., Nicholson, W. J., and Lager, A. M.: Asbestos Air Pollution: *Arch. Environ. Health*, 26:1-13, July 1972.

44. Sheers, G.: Effects of Asbestos in Dockyard Workers. *Br. Med. J.* 3:574-579 (1968).

45. Stell, P. M., and McGill, T.: Asbestos and Laryngeal Carcinoma. *Lancet* 2:416-417 (1973).

46. Stumpff, J.: Epidemiology of Mesothelioma on Walcheren Island. *Br. J. Ind. Med.* 28:59-66 (1971).

47. Wagner, J. C., Sleggs, C. A., and Marchand, P.: Diffuse Pleural Mesothelioma and Asbestos Exposure in the North Western Cape Province. *Brit. J. Ind. Med.* 17:260-271 (1960).

48. Wagner, J. C., et al: The Effects of the Inhalation of Asbestos in Rats. *Br. J. Cancer*, 29: 252-260 (1974).

49. Webster, L.: Asbestos and Malignancy. *S.A. Med. J.* 47:165-171 (1952).

80. Whitwell, F. and Rawcliffe, R. M.: Diffuse Malignant Pleural Mesothelioma and Asbestos Exposure. *Thorax* 26:4-22 (1971).

CONCLUSION AND PROPOSAL

Based on the foregoing information, the Commission proposes to declare that consumer patching compounds containing respirable, free-form asbestos and consumer patching compounds containing respirable free-form asbestos are banned hazardous products.

Accordingly, pursuant to provisions of the CPSA (sections 8, 9, 30(d), 86 Stat. 1215-17, 1231, as amended, 90 Stat. 506, 510; 15 U.S.C. 2057, 2058, 2079(d)), the Commission proposes that Title 16, Chapter II, be amended by adding to Subchapter B the following new Parts 1304 and 1305.

PART 1304—BAN OF CONSUMER PATCHING COMPOUNDS CONTAINING RESPIRABLE FREE-FORM ASBESTOS

Sec.

1304.1 Scope and application.

1304.2 Purpose.

1304.3 Definitions.

1304.4 Consumer patching compounds as banned hazard products.

1304.5 Effective date.

AUTHORITY: Secs. 8, 9, 30(d), Pub. L. 89-573, as amended, Pub. L. 94-284, 86 Stat. 1215-17, 1231 as amended 90 Stat. 506, 510 (15 U.S.C. 2057, 2058, 2079(d)).

§ 1304.1 Scope and application.

(a) In this Part 1304 the Consumer Product Safety Commission declares that consumer patching compounds containing respirable free-form asbestos and designed for use in such a manner that the asbestos fibers can become airborne under reasonably foreseeable conditions of use are banned hazardous products under sections 8 and 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2057 and 2058). This ban applies to patching compounds which are (1) used to cover, seal or mask cracks, joints, holes and similar openings in the trim, walls, ceilings, etc. of building interiors, which after drying are sanded to a smooth finish and (2) are produced and distributed for sale to or for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation or otherwise.

(b) The Commission has found that (1) these patching compounds are being or will be distributed in commerce; (2) that they present an unreasonable risk of injury; and (3) that no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with these products. The ban applies to patching compounds described in this Part which are in commerce or being distributed in commerce on or after the effective date of the ban.

§ 1304.2 Purpose.

The purpose of this rule is to ban consumer patching compounds containing respirable, free-form asbestos. These products present an unreasonable risk of injury due to inhalation of fibers which increase the risk of developing lung can-

cer and mesothelioma, diseases which have been demonstrated to be caused by exposure to asbestos fibers.

§ 1304.3 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this Part 1304.

(b) "Asbestos" means a group of mineral fibers composed of silica, oxygen, hydrogen and other elements such as sodium, iron, magnesium and calcium in diverse combinations and includes the following minerals: amosite, chrysotile, crocidolite, anthrophyllite asbestos, actinolite asbestos, and tremolite asbestos.

(c) "Free-form asbestos" is that which is not bound, woven, or otherwise "locked-in" to a product by resins or other bonding agents, or those from which fibers can readily become airborne with any reasonably foreseeable use.

(d) "Patching compounds" are mixtures of talc, pigments, clays, casein, ground marble, mica or other similar materials and a binding material such as asbestos which are sold in a dry form ready to be mixed with water, or such combinations in ready-mix paste form.

(e) "Consumer patching compounds" are those that are customarily produced or distributed for sale to or for the personal use, consumption or enjoyment of consumers in or around a permanent or temporary household or residence, a school, in recreation or otherwise. The Commission considers that patching compounds for application in these consumer environments are either distributed for sale to consumers or are for the personal use or enjoyment of consumers.

§ 1304.4 Consumer patching compounds as banned hazardous products.

On the basis that airborne asbestos fibers present the hazards of lung cancer and mesothelioma to the public, consumer patching compounds containing respirable free-form asbestos are banned hazardous products.

§ 1304.5 Effective date.

Thirty days after publication of final rule.

PART 1305—BAN OF ARTIFICIAL EMBERIZING MATERIALS (ASH AND EMBERS) CONTAINING RESPIRABLE FREE-FORM ASBESTOS

Sec.

1305.1 Scope and application.

1305.2 Purpose.

1305.3 Definitions.

1305.4 Artificial fireplace ash and embers as banned hazardous products.

1305.5 Effective date.

AUTHORITY: Secs. 8, 9, 30(d), Pub. L. 89-573, as amended, Pub. L. 94-284, 86 Stat. 1215-17, 1231 as amended, 90 Stat. 506, 510 (15 U.S.C. 2057, 2058, 2079(d)).

§ 1305.1 Scope and application.

In this Part 1305 the Consumer Product Safety Commission declares that artificial emberizing materials (ash and embers) containing respirable free-form asbestos generally packaged in an emberizing kit for use in fireplaces, and

designed for use in such a manner the asbestos fibers can become airborne under reasonably foreseeable conditions of use are banned hazardous products under sections 8 and 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2057 and 2058). This ban applies to artificial emberizing materials available in separate kits or with artificial fireplace logs for use in fireplaces and sprinkled or coated by consumers on the artificial logs to simulate live embers and ashes and give a glowing appearance when subjected to high temperatures. Bags of material containing asbestos and sold separately to be sprinkled on and under artificial logs to simulate burning and glowing ashes also come within the scope of this ban.

§ 1305.2 Purpose.

The purpose of this rule is to ban artificial emberizing materials containing respirable free-form asbestos. These products present an unreasonable risk of injury due to inhalation of fibers which increase the risk of developing lung cancer and mesothelioma, diseases which have been demonstrated to be caused by exposure to asbestos fibers.

§ 1305.3 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this Part 1305.

(b) "Asbestos" means a group of mineral fibers composed of silica, oxygen, hydrogen and other elements such as sodium, iron, magnesium and calcium in diverse combinations and includes the following minerals: amosite, chrysotile, crocidolite, anthrophyllite asbestos, actinolite asbestos, and tremolite asbestos.

(c) "Free-form asbestos" is that which is not bound, woven, or otherwise "locked-in" to a product by resins or other bonding agents, or those from which fibers can readily become airborne with any reasonably foreseeable use.

(d) "Emberizing materials" means an asbestos-containing material generally packed in an "emberizing" kit to be placed under artificial logs in gas-burning fireplace systems or in artificial fireplaces for decorative purposes. The product is also glued to artificial logs, either at a factory or by a consumer using an emberizing kit. (Synthetic logs manufactured of cellulose products which are consumed by flames are not included in this definition.)

§ 1305.4 Artificial fireplace ash and embers as banned hazardous products.

On the basis that airborne asbestos fibers present the hazards of lung cancer and mesothelioma to the public, artificial fireplace ash and embers containing respirable free-form asbestos are banned hazardous products.

§ 1305.5 Effective date.

Date of publication of final rule.

Regarding proposed Parts 1304 and 1305 interested persons are invited to

submit written comments before the close of business August 29, 1977. Comments may be accompanied by written data, views, and arguments and should be submitted preferably in five copies, addressed to Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Received comments and other related material may be seen in the Office of the Secretary, Third Floor, 1111 18th Street NW., Washington, D.C. during working hours Monday through Friday.

Oral presentations. Interested persons will be afforded an opportunity to make an oral presentation of data, views, or arguments in addition to the opportunity to make written comments, on any aspect of the proposed ban on August 15, 1977. The proceedings for the oral presentation will be held at 10 a.m. at the Commission's hearing room at 1111 18th Street NW., Washington, D.C. The procedural regulations for oral presentation, 16 CFR Part 1109, promulgated October 14, 1975 (40 FR 49122), shall govern this proceeding.

All persons wishing to make an oral presentation should notify Richard Danca of the Office of the Secretary, 202-

634-7700, no later than close of business August 8, 1977 for scheduling purpose. A summary or outline of each oral presentation and an estimate of the length of time it will require should be filed with the Office of the Secretary at least two business days prior to the oral presentation.

Section 9(c) of the CPSA (15 U.S.C. 2058(c)) requires the Commission, prior to promulgating a consumer product safety rule, to consider and make certain findings for inclusion in that rule. In order to aid the Commission in this endeavor, the Commission is particularly interested in soliciting either by written comment or through the oral presentation, additional data, views, and arguments as to the following:

1. The degree and nature of the risk of injury the rule is designed to eliminate or reduce;

2. The approximate number of consumer products, or types of classes thereof, subject to the rule;

3. The need of the public for consumer products subject to such rule and the probable effect of such rule upon the utility, cost, or availability of such products to meet that need;

4. Any means of achieving the objective of the rule while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety;

5. The necessity of the rule to eliminate or reduce the unreasonable risk of injury associated with the consumer products subject to the rule;

6. Whether the rule is in the public interest;

7. The feasibility of a consumer product safety standard under the CPSA to protect the public adequately from the unreasonable risk of injury associated with the products which are the subject of this proposed ban;

8. The potential environmental effects of the rule; and

9. Any adverse effects that this proposed ban will have on elderly and handicapped persons.

Dated: July 26, 1977.

SHELDON D. BUTTS,
Assistant Secretary, Consumer
Product Safety Commission.

[FR Doc. 77-21844 Filed 7-28-77; 8:45 am]