

## RULES AND REGULATIONS

Any exporter who obtains an order dated after August 15, 1974 and before September 24, 1974, for export of ferrous scrap to a country that has received an additional allocation, may submit an application for an export license whether or not he has a past history of exporting scrap to the country involved. The application must be clearly marked "Contingency Allocation." No exporter may apply for licenses for any one country for more than the amount shown in the column designated "Limitation Per Exporter." If applications are received from an exporter for export to a country of a quantity that exceeds that country's "Limitation Per Exporter" or "Type A Limitation", the applicant will be contacted to determine which of his applications should be reduced in quantity or returned without action. Applications received by the Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230 after 5 p.m. e.d.t. Monday, September 23, 1974, will not be considered.

Licenses will not be issued under these rules before September 24, 1974. In the event that applications for licenses are received for quantities in excess of the total quantity allocated to a particular country or its Type A Limitation, the Department of Commerce will request advice and guidance from such country as to the consignee(s) that should receive preference. Such advice will be considered along with other factors, such as the type and location of the scrap involved, etc., in deciding which applications to license.

In addition to the requirements set forth above, the applications must conform to the requirements for submission set forth in § 877.4 of the Export Administration Regulations. Applications must be submitted on Forms DIB-622P or FC-419 and DIB-623P or FC-420. Such applications must be accompanied by: (1) A photocopy or certified copy of the order (if the order is not from the ultimate consignee, a copy of the contract between the purchaser or other parties involved and the ultimate consignee must also be submitted in support of the application), and (2) where import permits are required by the country of destination, a statement from the ultimate consignee (or other foreign party to the transaction), or other documentation which indicates to the satisfaction of the Office of Export Administration that the permit has been obtained.

Applications for which the required accompanying documentation is not received by the Office of Export Administration by 5 p.m., e.d.t. September 23, 1974, will not be considered. In order for an application to be acceptable, the ferrous scrap must be described in sufficient detail so that the "Type" it belongs in may be ascertained and verified.

\* Forms are available from any of the Commerce Department's Domestic and International Business Administration District Offices or from the Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230.

Licenses will expire 90 days from the date of issuance. The shipping tolerance for exports shall be 5 percent of the unshipped quantity. Any cancellation of an order automatically revokes the license that was issued against it.

Effective date of action: August 16, 1974.

RAUER H. MEYER,  
Director,  
Office of Export Administration.

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**TITLE 16—Commercial Practices**  
**CHAPTER II—CONSUMER PRODUCT**  
**SAFETY COMMISSION**

**SUBCHAPTER C—FEDERAL HAZARDOUS**  
**SUBSTANCES ACT REGULATIONS**

**PART 1500—HAZARDOUS SUBSTANCES**  
**AND ARTICLES; ADMINISTRATION AND**  
**ENFORCEMENT REGULATIONS**

**Self-Pressurized Household Substances**  
**Containing Vinyl Chloride Monomer;**  
**Classification as Banned Hazardous**  
**Substance**

The purpose of this regulation is to protect public health and safety by the classification of any household substance in a self-pressurized container which has vinyl chloride monomer among its ingredients or in the propellant as a "banned hazardous substance" as that term is used in the Federal Hazardous Substances Act.

Sections 2(f)(1)(A) and (B), 2(g), and 3(a) of the Federal Hazardous Substances Act and section 30(a) of the Consumer Product Safety Act authorize the Commission to classify as a toxic "hazardous substance" any substance or mixture of substances which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface. Provisions of section 2(q)(1)(B) authorize the Commission issue regulations to classify a "hazardous substance" which is packaged or suitable for use in households as a "banned hazardous substance" if the Commission determines that notwithstanding any cautionary labeling which may be required under that act, the degree or nature of the hazard involved in the presence or use of the substance in households is such that public health and safety can be adequately served only by keeping that substance out of channels of interstate commerce.

In the FEDERAL REGISTER of May 23, 1974 (39 FR 18115), the Commission proposed a regulation to classify as banned hazardous substances those self-pressurized household products that contain vinyl chloride monomer. This proposal was made by the Commission after consideration of the following:

1. Information concerning deaths of several employees of the B. F. Goodrich Chemical Company who had died from a rare form of liver cancer and who had an average exposure of approximately 19 years to vinyl chloride monomer, at unknown concentrations, and variable exposures to other volatile chemicals.

\* 2. A report by Professor Cesare Mal-

toni of the Instituto di Oncologia, Bologna, Italy, concerning the effect of exposure of rats, mice, and hamsters to vinyl chloride at concentrations of 10,000; 6,000; 2,500; 500; 250; and 50 parts per million. The results available from this study on February 15, 1974, included instances of liver tumors observed in groups of animals exposed to vinyl chloride at concentrations as low as 250 parts per million.

3. A petition from the Health Research Group requesting the Commission to prohibit the use of vinyl chloride as a propellant for consumer products in self-pressurized containers. In addition to the reports of deaths of B. F. Goodrich employees and the animal experiments conducted by Prof. Maltoni, this petition cited additional animal studies, testimony of medical experts, and medical literature in support of the position that exposure to vinyl chloride monomer is associated with liver cancer and with other diseases. The text of the petition was published in the Commission's notice of May 23, 1974.

4. An Emergency Temporary Standard for Exposure to Vinyl Chloride published in the FEDERAL REGISTER on April 5, 1974 (39 FR 12342), by the Occupational Safety and Health Administration to set an occupational exposure limit of 50 parts per million of vinyl chloride monomer in air; and a proposal by that agency published in the Federal Register on May 10, 1974 (39 FR 16898), to establish the standard for employee exposure to vinyl chloride monomer at no detectable level.

5. A notice of proposed rulemaking published by the Commissioner of Food and Drugs in the FEDERAL REGISTER on April 23, 1974 (39 FR 14215), applicable to the use of vinyl chloride monomer as an ingredient of self-pressurized drug and cosmetic products, in which the Commissioner announced determinations that vinyl chloride presents an unnecessary hazard to public health when used as an ingredient in self-pressurized cosmetic products, and that such use should be banned; and that vinyl chloride when used as an ingredient in self-pressurized drug products is not generally recognized as safe and effective and requires an approved new drug application as a condition to marketing.

6. An emergency suspension order applicable to pesticide spray products containing vinyl chloride published in the FEDERAL REGISTER on April 26, 1974 (39 FR 14753), by the Environmental Protection Agency which stated that preliminary results of experiments indicate that angiosarcoma (of the liver) had been observed in mice exposed to vinyl chloride in concentrations as low as 50 parts per million. This notice also stated that under some conditions of use of aerosol products in households, the concentration of propellant in the air could be as high as 400 parts per million.

In response to the Commission's notice of May 23, 1974, comments concerning the proposed regulation were received from two manufacturers, Rust-Oleum and Sprayon Products, Inc.; one trade

association, the National Paint and Coatings Association; two groups representing consumers, Consumers Union and the Massachusetts Public Interest Research Group; and four individuals.

Comments from the two consumer groups and the four individuals favor promulgation of the regulation as proposed. Comments from the two manufacturers and the trade association do not object to the proposal to the extent that it would prohibit introduction into interstate commerce of self-pressurized household products containing vinyl chloride monomer. These comments do object to the absence of language in the proposed regulation to limit the class of banned hazardous substances to those self-pressurized products containing vinyl chloride monomer which are introduced into interstate commerce after the effective date of the regulation. If such language were added to the proposed regulation, self-pressurized products with vinyl chloride monomer which were introduced into interstate commerce before the effective date of the regulation would not be banned hazardous substances, and would not be subject to repurchase under provisions of section 15 of the Federal Hazardous Substances Act and the regulations issued by the Commission (16 CFR 1500.202). The arguments advanced in these comments for the addition of language to limit the class of banned products to those introduced into interstate commerce after the effective date of the regulation, and the Commission's response to those arguments are as follows:

1. *Minimal risk to health.* The comments under consideration claim that the cases cited by the Commission's notice of May 23, 1974, of chemical workers who were exposed to vinyl chloride monomer and who died of angiosarcoma of the liver involved instances where employees were exposed to relatively high concentrations of vinyl chloride for periods of several years. Use of self-pressurized products, particularly spray paints, in and around households by consumers involves brief periods of exposure on an infrequent basis. The thrust of this argument is that no showing has been made that exposure of consumers to vinyl chloride monomer from the propellant of self-pressurized containers involves the same degree of risk of developing angiosarcoma of the liver that is incurred by employees exposed to vinyl chloride monomer in occupational settings.

The Commission does not regard the health hazard posed by use of self-pressurized products containing vinyl chloride to be minimal. The emergency suspension order published by the Environmental Protection Agency on April 26, 1974, and cited in the Commission's notice of the proposed regulation, contained information that vinyl chloride may be present in the air in concentrations as great as 400 parts per million after household use of self-pressurized containers with vinyl chloride in the propellant, and that tumors have been induced

in mice after exposure to vinyl chloride monomer in concentrations as low as 50 parts per million. Since publication of the Commission's notice of the proposed regulation, the Commission has learned that during hearings conducted by the Occupational Safety and Health Administration of the Department of Labor on June 28 through July 11, 1974, testimony was presented to the effect that angiosarcoma has been observed among rats exposed to vinyl chloride monomer in concentrations as low as 50 parts per million, and among hamsters exposed to vinyl chloride monomer in higher concentrations.

To date the Commission has learned of 24 confirmed cases of angiosarcoma among the 10,000 to 20,000 persons exposed to vinyl chloride in the course of their employment. The rate of incidence of angiosarcoma among persons who work with vinyl chloride is approximately one case per 1,000 persons, compared with a rate of approximately one case per 10,000,000 persons among the total population of the United States.

The comments under consideration state that on previous occasions both the Commission and the Food and Drug Administration have issued regulations to classify items as banned hazardous substances which are applicable to items introduced into interstate commerce after a specified date, and that the Commission would be justified in exercising its discretion to give prospective application to the proposed regulation because the health risk posed to consumers by the products affected by the proposed regulation is minimal.

The comments from the manufacturers and the trade association contain no information to establish that a level of exposure to vinyl chloride monomer exists for human beings which presents no risk of developing angiosarcoma of the liver. In the absence of any information concerning the existence of a safe level of human exposure to vinyl chloride monomer, and in view of the information now available to the Commission about results of animal experiments and human exposure to vinyl chloride monomer, the Commission concludes that the risk of serious personal illness or injury from the use of self-pressurized products containing vinyl chloride monomer in households is not speculative or minimal, and therefore declines to exercise any discretion which the Commission may have to make the classification of banned hazardous substance applicable only to those products introduced into interstate commerce after the effective date of the regulation.

2. *Purpose of repurchase provisions.* The comments under consideration also urge that the purpose of the provisions of section 15 of the Federal Hazardous Substances Act requiring repurchase of banned hazardous substances was to place the economic loss which results when products are declared to be banned hazardous substances on the manufacturers of those products rather than on distributors and retailers. These com-

ments state that nothing in the legislative history of the act indicates that provisions of section 15 were intended to provide a mechanism for retrieving products from consumers. After consideration of the text of section 15, the legislative history of the act, and the Commission's regulations to implement section 15 (16 CFR 1500.202), the Commission concludes that in the enactment of section 15 Congress did not intend simply to provide retailers and distributors a means to recover economic losses which may result when a product is declared to be a banned hazardous substance, but also contemplated that the provisions of section 15 would facilitate the removal of products which were classified as banned hazardous substances from households.

3. *Absence of immediate hazard.* Finally, the comments from the two manufacturers and the trade association argue that the repurchase provisions of section 15 of the act should be invoked only when an immediate hazard is posed to the health of consumers. In view of the reports, data, and information discussed above concerning the association of exposure to vinyl chloride monomer with development of angiosarcoma of the liver and other illnesses, the Commission concludes that the potential hazard of exposure to vinyl chloride monomer from self-pressurized products used in households is sufficiently serious and immediate to warrant repurchase under provisions of section 15 and the regulations issued by the Commission to remove them from consumers' households.

Having considered the comments concerning adding a provision to the proposed regulation to limit its application to those self-pressurized household products containing vinyl chloride monomer which are introduced into interstate commerce after the effective date of the regulation, the Commission concludes that no such addition should be made.

After consideration of all comments and relevant information discussed above, the Commission has determined that self-pressurized household products containing vinyl chloride monomer are toxic hazardous substances within the meaning of section 2(f) and (g) of the Federal Hazardous Substances Act because vinyl chloride monomer, when inhaled, has the capacity to produce substantial illness, specifically cancer. Ample evidence in the form of scientific studies and chemical reports is available to establish the carcinogenicity of vinyl chloride monomer by inhalation and to demonstrate that human exposure to vinyl chloride monomer can result in angiosarcoma of the liver, a highly malignant, irreversible neoplasm. Because no safe level of human exposure to vinyl chloride monomer has been established, the Commission finds that adequate cautionary labeling cannot be written under the Federal Hazardous Substances Act for self-pressurized household products containing vinyl chloride monomer. The formulation of proper labeling under that act requires consideration of the possibility of latent