

tended to contact food, including food-packaging materials, coatings, parts for food processing equipment, flexible tubing, and water pipes.

Polyvinyl chloride has several properties that make it useful for packaging, such as clarity, resistance to water and many chemicals, capability of acting as a barrier to gas and water, capability of being sealed by heat, and capability of being molded into deep shapes. Approximately 300 million pounds of polyvinyl chloride are used each year in the packaging of food, making it (after polyethylene) the second most commonly used plastic for packaging food. The production of water pipe is one of the single largest uses of polyvinyl chloride, accounting annually for over 400 million pounds of resin. In addition, the polymers of vinyl chloride have also been found useful as packaging materials for other products within FDA's jurisdiction, including drug products, blood, and cosmetics. Vinyl chloride polymers are also used as components of certain medical devices.

Early investigatory work reviewed by Dr. A. J. Lehman, then Chief of the Division of Pharmacology, Food and Drug Administration, indicated that polyvinyl chloride was insoluble in various solvent systems used to simulate food. Consequently, there was little concern about the safety of food-contact articles made from polyvinyl chloride. In 1950, Dr. Lehman reported to the Association of Food and Drug Officials:

We consider as the most important single physical characteristic of a film its solubility or the leaching out of any of its constituents in the common media with which the plastic may come in contact. If nothing can be extracted when tested with representative food-type solvents (lard-oil, vinegar, sodium bicarbonate, meat juices, water, etc.) under conditions somewhat more rigorous than might be experienced under practical usage, we usually have no objections to use of the film in situations where direct contact with food may result. Toxicological problems relate more to the plasticizers employed to give the film certain desirable characteristics than to the film itself. Plasticizers are legion, but to develop one which is nontoxic and yet efficient is not easy of accomplishment.

Reports of this work were published by Dr. Lehman in "Chemicals in Food: A report to the Association of Food and Drug Officials on Current Developments," *Quarterly Bulletin of the Association of Food and Drug Officials of the United States*, 15(2):82, 1951, and "Food Packaging," *Ibid.*, 20(4):159, 1956.

MIGRATION OF VINYL CHLORIDE TO FOOD

In early 1973, representatives of Echenley Distillers, Inc., Cincinnati, Ohio, reported to FDA their having found vinyl chloride in distilled alcoholic beverages, such as vodka and gin, packaged in polyvinyl chloride bottles. The findings of their migration studies were subsequently confirmed by FDA and led to a proposal concerning the use of polyvinyl chloride. This proposed regulation, published in the *Federal Register* of May 17, 1973 (38 FR 12931), would have precluded use of polyvinyl chloride

resin in articles for use in contact with alcoholic foods and was based on: (1) The finding that residual vinyl chloride in polyvinyl chloride bottles was being extracted by bottled distilled spirits and wines, and (2) the fact that no available animal feeding studies established a safe level of consumption when vinyl chloride was extracted from containers into food. At that time there were no data that indicated that polyvinyl chloride articles in contact with nonalcoholic foods would result in migration of residual vinyl chloride into the food and accordingly, there was no reason to consider restriction of such use.

The existence of residual vinyl chloride in articles made from vinyl chloride polymers is related to the manufacturing process and the physical structure of the polymers. The raw vinyl chloride becomes the packaging material consisting of polyvinyl chloride or one of the copolymers of vinyl chloride through a series of distinct steps. The first step is the polymerization of the vinyl chloride to form a polymer, e.g., polyvinyl chloride resin. This resin is then blended with a number of other substances that may include plasticizers, stabilizers, lubricants, and processing aids to form a compounded material ordinarily referred to as a "compound," e.g., a polyvinyl chloride flexible film "compound" or a polyvinyl chloride bottle "compound." This "compound" is then used by the fabricator to produce the finished article that is used in contact with food.

The individual molecules of polyvinyl chloride may be visualized as short strands of thread. The individual molecules are attracted to each other by physical forces that tend to hold them together so strongly that the polyvinyl chloride, by itself, is rigid. The polymeric material contains an exceedingly large number of polyvinyl chloride molecules, which are intermingled and provide a number of open spaces (interstices) among the individual molecules.

The origin of the possibility that vinyl chloride may migrate to food is its incomplete polymerization into polyvinyl chloride. Estimates indicate that somewhat less than 90 percent of the vinyl chloride is converted to polyvinyl chloride. Most of the remaining 10 percent vinyl chloride is either vented to the atmosphere, or recovered by techniques, such as vacuum stripping, and reused. However, some vinyl chloride remains in the polyvinyl chloride resin following its polymerization and isolation. At one time as much as 2000 parts per million (ppm) residual vinyl chloride remained, but with new processing methods, as little as 1 to 3 ppm remain. It is theorized that the vinyl chloride becomes physically trapped among the interstices of the polymer "threads."

This model permits an explanation of the varying degrees to which vinyl chloride is removed from the different forms of the polymer. A large amount of the vinyl chloride that fails to polymerize never becomes trapped in the resin; it either finds its way out of the resin mass, due to its volatility, or can be removed by vacuum stripping. Most, if not all, of

the remaining vinyl chloride may be removed in the preparation of polyvinyl chloride "compound" for such flexible plastic materials as baskets, films, and tubing. In preparing these "compounds" the polyvinyl chloride resin is mixed and heated with as much as 50 to 90 parts of plasticizer per hundred parts of resin. The addition of the plasticizer "opens" the spaces between the polymer "threads," and the heat tends to drive out the remaining vinyl chloride molecules. Further opportunity for removal of vinyl chloride is provided during the fabrication of the "compound" into articles because heat is usually used in the process. By contrast, it is much more difficult for the vinyl chloride molecules to escape from rigid and semirigid polyvinyl chloride articles because they contain little or no plasticizer and are generally thicker than plasticized articles. Many rigid articles have been analyzed and found to contain residual vinyl chloride. However, FDA has not been able to detect vinyl chloride in any of the plasticized, flexible polyvinyl chloride products it has analyzed.

Even in the case of rigid unplasticized polyvinyl chloride, there is a loss of vinyl chloride during fabrication into articles. Once fabricated, the polyvinyl chloride articles continue to lose vinyl chloride by diffusion. Data have been developed showing a gradual loss of residual vinyl chloride from polyvinyl chloride articles during their storage prior to use. This diffusion phenomenon continues to occur when the polyvinyl chloride is used in contact with food. If vinyl chloride is present, a certain amount may be expected to migrate to the food. In the case of semirigid and rigid articles that contain high levels of residual vinyl chloride, this amount has been shown to be substantial. However, in the case of coatings, films, and other plasticized food-packaging materials in which the amount of residual vinyl chloride is extremely small, there appears to be little likelihood that vinyl chloride would reasonably be expected to be present in the food.

The migration of vinyl chloride may be viewed as a simple diffusion phenomenon: The vinyl chloride is leaving the location of highest concentration, the plastic article, and moving to a location of lower concentration, whether it be the surrounding air or the food contained in the article. This hypothesis appears to be supported by the work of scientists at Ethyl Corp. ("VCM extraction from PVC bottles," *Modern Packaging*, pp. 43-42, April 1973). Their data indicate that the vinyl chloride levels in the plastic article and its food content eventually reach a point of equilibrium. However, there continues to be a loss of residual vinyl chloride to the surrounding atmosphere so that the level in the plastic article becomes lower relative to the level in the food inside it. When this occurs, there is a migration of vinyl chloride from the food into the plastic article. This is represented by a decrease in the concentration of vinyl chloride that can be detected in the food. The ob-

(3) Long varieties. U.S. No. 2, or better grade, 1 1/4 inches minimum diameter.
(3) All varieties. Size B, if U.S. No. 1, or better grade.

(b) Maturity (skinning) requirements.

(1) Russet Burbank and Red McClure varieties. For U.S. No. 2 grade not more than "moderately skinned" and for other grades not more than "slightly skinned."

(2) All other varieties. Not more than "moderately skinned."

(c) Inspection. (1) No handler shall handle any potatoes for which inspection is required unless an appropriate inspection certificate has been issued with respect thereto and the certificate is valid at the time of shipment. For purposes of operation under this part it is hereby determined pursuant to paragraph (d) of § 945.40, that each inspection certificate shall be valid for a period not to exceed 8 days following the date of inspection as shown on the inspection certificate.

(2) No handler may transport or cause the transportation by motor vehicle of any shipment of potatoes for which an inspection certificate is required unless each shipment is accompanied by a copy of the inspection certificate applicable thereto and the copy is made available for examination at any time upon request.

(d) Special purpose shipments. (1) The grade, size, maturity and inspection requirements of paragraphs (a), (b) and (c) of this section and the assessment requirements of this part shall not be applicable to shipments of potatoes for:

(1) Livestock feed;
(2) Relief or charity; or
(3) Canning, freezing, and "other processing" as hereinafter defined.

(2) The grade, size, maturity and inspection requirements of paragraphs (a), (b) and (c) of this section shall not be applicable to shipments of seed pursuant to § 945.6 but such shipments shall be subject to assessment.

(e) Safeguards. Each handler of potatoes which do not meet the grade, size, and maturity requirements of paragraphs (a) and (b) of this section and which are handled pursuant to paragraph (d) for any of the special purposes set forth therein shall:

(1) Prior to handling, apply for and obtain a Certificate of Privilege from the committee.

(2) Furnish the committee such reports and documents as requested, including certification by the buyer or receiver as to the use of such potatoes, and

(3) Bill each shipment directly to the applicable processor or receiver.

(f) Minimum quantity. For purposes of regulation under this part, each person may handle up to but not to exceed 1,000 pounds of potatoes without regard to the requirements of paragraphs (a), (b) and (c) of this section, but this exception shall not apply to any shipment which exceeds 1,000 pounds of potatoes.

(g) Definitions. The terms "U.S. No. 1," "U.S. No. 2," "slightly skinned," and "moderately skinned" shall have the same meaning as when used in the U.S.

Standards for Potatoes (31 FR 1540-51, 1566 of this title, effective September 1, 1971, as amended), including the tolerances set forth therein. The term "other processing" has the same meaning as the term appearing in the act and includes, but is not restricted to, potatoes for dehydration, chips, shoestring, starch, and flour. It includes only that preparation of potatoes for market which involves the application of heat or cold to such an extent that the natural form or stability of the commodity undergoes a substantial change. The act of peeling, cooling, slicing, dicing, or applying material to prevent oxidation does not constitute "other processing." Other terms used in this section shall have the same meaning as when used in Marketing Agreement No. 97, as amended, and this part.

(h) Applicability to imports. Pursuant to section 46 of the act and 1990 I, import regulations (21 CFR 950.1), Irish potatoes of the red skinned round type, except certified seed potatoes imported into the United States during the period September 29, 1974, through June 30, 1975, shall meet the grade, size, and quality requirements specified in paragraph (a) of this section, and during the effective date of this handling regulation through October 31, 1975, shall be not more than "moderately skinned."

Dated: August 28, 1975.

CHARLES R. BRADEN,
Deputy Director, Food and Veterinary Division, Agricultural Marketing Service.

(FR Doc 75-25240 Filed 8-29-75; 8 45 am)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

(Docket No. 75M-0100)

PRIOR-SANCTIONED POLYVINYL CHLORIDE RESIN

Termination of Notice of Proposed Rulemaking

The Commissioner is withdrawing a proposal published in the *Federal Register* of May 17, 1973 (38 FR 12311) to establish a regulation under § 121.2009 (21 CFR 121.2009) to identify the criteria for the safe use of prior-sanctioned polyvinyl chloride resin as a component of food packaging material in contact with nonalcoholic food.

Since publication of the proposal, additional information has been received concerning the use of polyvinyl chloride in food packaging materials which indicates that this proposal was too narrow in its scope. Published elsewhere in this issue of the *Federal Register* are proposed regulations concerning the use of vinyl chloride polymers in contact with all types of food.

Accordingly, the Commissioner hereby withdraws the proposal published on May 17, 1973, and terminates the rule making proceeding begun by that proposal.

This action is taken pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 701(a), 52 Stat. 1655, 72 Stat. 1785-1788 (21 U.S.C. 343, 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Effective date. This order shall be effective September 3, 1975.

Dated: August 27, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs

(FR Doc 75-25240 Filed 8-29-75; 8 45 am)

[21 CFR Part 121]

(Docket No. 75M-0100)

VINYL CHLORIDE POLYMERS IN CONTACT WITH FOOD

Notice of Proposed Rulemaking

The Food and Drug Administration (FDA) is proposing regulations to restrict the uses of vinyl chloride polymers in contact with food. The proposal permits the continued use of vinyl chloride polymers in food packaging and other food-contact articles where the potential for migration of vinyl chloride is diminished to the extent that it may not reasonably be expected to become a component of food. The proposal includes an interim food additive regulation for the use of water pipe made from vinyl chloride polymers. The interim regulation would be in effect pending development of additional data to determine if vinyl chloride may reasonably be expected to be in potable water that is drawn from the pipe. The proposed regulation would prohibit all other uses of vinyl chloride polymers in food-contact articles, including semirigid and rigid articles such as bottles and sheets, because in those uses vinyl chloride may reasonably be expected to become a component of food. Interested persons have until November 2, 1975 to submit comments.

Use of Vinyl Chloride

Vinyl chloride is a chemical with the following structure:



It has a boiling point of -14°C (8.8°F) and consequently it is ordinarily a gas. This property led to its use as a propellant for aerosol products such as cosmetics, drugs, and pesticides. Vinyl chloride is polymerized to form polyvinyl chloride in which the basic monomeric unit is repeated:



In this formula, n represents the number of monomeric units that may be present, a sum which normally exceeds 800 units.

Vinyl chloride homopolymers and copolymers are used in the production of articles or components of articles in-

vious end point indicated by this hypothesis is that there would be no vinyl chloride in the food or in the plastic article at that distant point in time when it has all migrated to the surrounding atmosphere.

A modification and extension of this hypothesis has been proposed by Professor Seymour Gilbert, Ph.D., Department of Food Science, Rutgers University, New Brunswick, N.J. Dr. Gilbert's work indicates that there are active sites in rigid polyvinyl chloride that tend to adsorb and hold on to vinyl chloride molecules. At high vinyl chloride concentrations these active sites are covered by a very small part of the total vinyl chloride and the remainder tends to migrate from the polyvinyl chloride in accordance with the usual diffusion theory. He postulates that at vinyl chloride concentrations of less than 1 ppm in the polyvinyl chloride, not all the active sites are covered and thus there are few undesorbed vinyl chloride molecules left to migrate. His theory is supported by the results of equilibrium studies in which powdered polyvinyl chloride resins containing no vinyl chloride were added to food-simulating solvents containing known concentrations of vinyl chloride. Vinyl chloride was found to be taken up by the resin and its concentrations in the food-simulating solvents were reduced to a much greater extent than would be explained by simple diffusion or partitioning.

Schenley Distillers reported levels of vinyl chloride as high as 20 ppm in vodka and 25 ppm in gin. Confirmatory work on samples of the same material by FDA showed levels of 11 ppm vinyl chloride in vodka and 12 ppm in gin. Since that time FDA has received many additional reports of findings of vinyl chloride in various types of food packaged in polyvinyl chloride bottles. Generally, these reports have not included suitable information to evaluate accuracy, such as: an adequate description of the methodology, including chromatograms; data from recovery studies verifying the claimed sensitivity; data showing confirmation by mass spectroscopy; and identification of the plastic material. It should be noted that analysis for vinyl chloride requires careful analytical techniques to assure credible findings. The analysis becomes progressively more difficult as the concentration of vinyl chloride decreases.

The problems involved with the analysis for vinyl chloride are emphasized by the difficulties that firms have encountered in obtaining consistent results during "round-robin" studies in which a number of laboratories have analyzed the same material. FDA has developed a method for the determination of vinyl chloride in polyvinyl chloride and in food-simulating solvents. (Copies are available from the Division of Food and Color Additives, Food and Drug Administration, 200 C St., SW., Washington, D.C. 20204.) This method is considered to be capable of measuring levels of vinyl chloride in food-simulating solvents as low as 20 parts per billion (ppb) (in 50

percent ethanol) and in polyvinyl chloride as low as 0.33 ppm.

On December 20, 1973, representatives of FDA and the Society of the Plastics Industry, Inc. (SPI) met to discuss chemical information concerning vinyl chloride that SPI had submitted with its comments of October 15, 1973, on the original proposal of May 17, 1973. In response to questions raised at this and subsequent meetings, members of the SPI have obtained information about polyvinyl chloride, a chemical analysis of various types of foods for the presence of vinyl chloride, refinement of the methodology for detection, and review of the toxicological aspects. Memoranda of these meetings and the information reported are on file for display at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-43, 1005 Fishers Lane, Rockville, MD 20852.

Data supplied by SPI indicated that vinyl chloride could migrate to consumable foods from polyvinyl chloride bottles. Analysis of two samples of vodka bottled in polyvinyl chloride bottles revealed the presence of vinyl chloride at levels of 11 and 12 ppm. Reported results of analysis of additional samples of foods, drugs, and consumer products varying levels of vinyl chloride, e.g., vinegar (0.1 ppm), ethanol (1.5 ppm) and non-alcoholic beer (2 ppm) from two other sources, a vitamin supplement (approximately 1 ppm), and a mouthwash (174 ppm). No vinyl chloride was reported from a series of water samples using an analytical method reportedly sensitive to 10 ppb. These latter samples had been collected from drinking water after treatment of chlorine residual levels less than 1 ppm.

In early 1971, the British Ministry of Agriculture, Fisheries, and Food reported finding vinyl chloride in concentrations ranging from 15 to 60 ppb in fruit samples and from 15 to 65 ppb in cooking oils. The Canadian Health Protection Branch of the Ministry of Health and Welfare reported finding vinyl chloride ranging from 0.9 to 8.4 ppm in seven samples of apple cider vinegar. It also reported vinyl chloride in samples of various wines (one less than 0.001 to 0.50 ppm), gin (0.72 to 0.1 ppm), and malt vinegar (1.5 ppm).

Data from experimental work using food-simulating solvents, i.e., distilled water, 3 percent acetic acid, ethanol, and n-heptane, support these earlier data showing migration of vinyl chloride to types of foods other than alcoholic beverages. The data show that the use of alcohol and n-heptane as solvents representing alcoholic and fatty foods, respectively, results in the highest levels of vinyl chloride extractives as compared to the amounts extracted by distilled water (representing aqueous foods) and 3 percent acetic acid (representing acidic foods). All of these data are on public display in the office of the Hearing Clerk, Food and Drug Administration.

The available data indicate that certain applications of vinyl chloride do not present a realistic possibility of vinyl chloride migration. The Commissioner is unaware of any findings of vinyl chloride

migration from film, cap liners, containers, canisters or flexible tubing. Results of analyses of extractives from such articles have shown no detectable vinyl chloride. Analyses of these plastic articles themselves have shown no detectable vinyl chloride using analytical methods reported to be capable of detecting a level as low as 1 ppm residual vinyl chloride. No residual vinyl chloride was found in FDA analysis of polyvinyl chloride blood bags and flexible tubing using a method capable of detecting 0.33 ppm residual vinyl chloride.

The level of findings of extractable vinyl chloride from film is not surprising. The reported conclusions indicate that 1 film contained residual vinyl chloride. The correct information of the residual vinyl chloride from a 1 mil (0.001 inch) film would result in 1 ppm vinyl chloride in food. These calculations assume that 18 grams of food contact each square inch of film, the first yields 10 milligrams per square inch per mil thickness, and the film contains 1 ppm residual vinyl chloride. However, these assumptions are exaggerated, e.g., the vinyl chloride will migrate into the air as well as the food, and much more levels of migration than that would be expected to occur under actual conditions of use, in the point where they would be extremely small. The data substantiate this conclusion because the levels of extractable vinyl chloride from some have been shown to approach 100 percent. In these cases where actual values have been presented the entire theoretical residual vinyl chloride level and level of extraction of vinyl chloride.

The greatest likelihood for migration of vinyl chloride occurs to be from polyvinyl chloride bottles and other rigid or semirigid polyvinyl chloride articles that are intended for use with food. A wide variety of products have been packaged in such containers, including vegetables, oils, vinegar, honey, and liquid vitamins. Residues of vinyl chloride in food-simulating solvents are partitioned to rigid and semirigid containers composed of vinyl chloride polymers (PVC, hard, and soft) and are immediately partitioned to the food-simulating solvents composed of vinyl chloride polymers. These partition ratios in chloroform from approximately 1 mill to 20 mill depending on the thickness of 1 to 12 mils were reported to a meeting from the American Meat Institute to contain 0 to 150 ppm residual vinyl chloride and to yield 4 to 20 ppm vinyl chloride when extracted by n-heptane. Rigid articles with a thickness of 10 to 21 mils were reported by the American Meat Institute to contain 0 to 127 ppm residual vinyl chloride and to yield 2 to 221 ppm vinyl chloride when extracted by n-heptane.

Water pipe is a use of polyvinyl chloride that presents little likelihood that vinyl chloride will become a component of potable water. The pipe's rigid, relatively thick wall would be expected to have a potential for high levels of residual vinyl chloride; data show that the level of residual vinyl chloride attainable in water pipe may vary from less than

10 ppm to more than 100 ppm. However, the potential for extraction of vinyl chloride from potable water pipe is greatly reduced because of the low solubility of vinyl chloride in water, the short time of contact, the large volume of water in contact with the pipe, and the comparatively low temperatures of exposure. The primary use of polyvinyl chloride potable water pipe is from water mains to buildings where a large volume of water flow occurs, and the temperature of exposure is lowered because the pipe is buried. Moreover, the small amount of vinyl chloride that might migrate into water from water pipe would be expected to dissipate during the aeration and settling that occur at the tap.

Toxicity of Vinyl Chloride

FDA is unaware of any suitable toxicity data from animal feeding studies that demonstrate a safe level of ingestion of vinyl chloride. Results of a 90-day feeding study with rats were submitted to FDA in October 1974. However, that study was not conclusive and, furthermore, could not resolve the prime issue of safety, namely carcinogenicity. Since it was a short-term feeding study, lifetime studies are necessary to evaluate properly the potential for low-dose effects, such as carcinogenesis.

Considerable data exist concerning the toxic effects of vinyl chloride from atmospheric exposure, especially by inhalation and occupational contact. At the Commission meeting on April 22, 1974, proposal (39 FR 14019) to prohibit the use of vinyl chloride as an ingredient in drug and cosmetic aerosol products:

There is ample evidence that vinyl chloride inhalation can result in severe toxicity manifested by an array of symptoms including unconsciousness as a result of high concentrations by inhalation. Cardiac arrest, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported to animals.

The results from studies by Tortorison, et al., on the chronic effects of vinyl chloride on laboratory animals (T. R. Tortorison, P. Oren, and V. K. Howe, "The Toxicity of Vinyl Chloride as Determined by Repeated Exposure of Laboratory Animals," *American Industrial Hygiene Association Journal*, 22(5), 244-251, 1961) indicated slight effects in rats exposed to atmospheres containing 100 and 200 ppm vinyl chloride. An exposure of 50 ppm was considered to be a "no-effect" level. Published scientific reports implicate vinyl chloride as a causative agent for "acroosteolysis" of the hands and feet as well as systemic effects among industrial workers engaged in the manufacture of vinyl chloride. Dr. P. L. Viola, in studies, exposed rats to an atmosphere containing 2 percent (20,000 ppm) vinyl chloride vapors for 4 hours per day for 9 days per week for 1 year (P. L. Viola, A. Bigotti, and A. Casato, "Oncogenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride," *Cancer Research*, 31: 516-522, May 1971), he reported that rats subjected to such exposure developed tumors of the skin, lungs, and bones. Copies of these reports are on file with

the Hearing Clerk, Food and Drug Administration.

Reporting at the February 15, 1974, fact-finding hearing, which was called by a notice that the Occupational Safety and Health Administration published in the Federal Register of January 30, 1974 (39 FR 2574), Dr. Cesare Maltoni discussed preliminary results from his investigations directed at clarifying the type and degree of carcinogenic effects of vinyl chloride as previously reported by Dr. Viola. Dr. Maltoni's investigations involved various types and levels of exposure to vinyl chloride including: (1) An attempt to reproduce the conditions of Dr. Viola's experiments using a level of 20,000 ppm; (2) experiments using atmospheric exposure to vinyl chloride vapors at levels ranging from 10 to 10,000 ppm; (3) an experiment demonstrating the effects upon ingestion (inhalation) of vinyl chloride; and (4) experiments involving long-term exposure and reproductive studies of subpopulations (C. Maltoni & G. Zaccaria, "Chronic Effects of Vinyl Chloride," *Science*, 182: 1485, 1973 and "A preliminary study of the carcinogenicity of vinyl chloride and other monochlorinated ethylenes," *Journal of the National Cancer Institute*, 41: 1411, 1973). In addition to this, Dr. Maltoni reported that experiments were also being conducted using mice and hamsters.

At the February meeting, Dr. Maltoni discussed his preliminary findings of the development of angiosarcomas of the liver, along with other types of tumors, at levels of atmospheric exposure as low as 10 ppm. At the 200 ppm level, all the New York University students attending, May 10-11, 1974 ("Chronic Effects of Vinyl Chloride," *Cancer Research*, 34: 193-194, January 11, 1974), he subsequently reported the development of angiosarcomas of the liver and other types of tumors at levels of atmospheric exposure as low as 10 ppm. Further, he announced that additional experiments were being started. The experiments are using larger numbers of animals and lower dose levels of inhalation exposure. Inhalation exposure studies using subpopulations of low level of vinyl chloride are also in progress at Industrial Hygiene Research Laboratories (IHRL) under the sponsorship of the Manufacturing Chemists Association. In discussing these two studies in regulations, published in the Federal Register of October 4, 1974 (39 FR 25820), establishing standards for industrial exposure to vinyl chloride, the Occupational Safety and Health Administration stated:

These investigators have induced angiosarcomas of the liver in rats and mice at exposure concentrations of 50 ppm and in hamsters at higher concentrations of exposure. Additional tumors involving other organs, including the kidneys, lungs, and skin of exposed animals, were also observed in frequencies much in excess of control animals.

As noted above, the Food and Drug Administration issued a proposal on April 22, 1974, concerning the use of vinyl

chloride as a propellant in aerosol drugs and cosmetics. At the same time, manufacturers were requested to recall any outstanding stocks of such products from the market. A final regulation was published in the Federal Register of August 20, 1974 (39 FR 30630), prohibiting the use of vinyl chloride as a propellant in cosmetic aerosols and requiring an approved new drug application for the marketing of aerosol drugs containing vinyl chloride as a propellant.

In separate actions, the Environmental Protection Agency, banned the use of vinyl chloride as a propellant in certain pesticide aerosols by notice published in the Federal Register of April 30, 1974 (39 FR 14733), and the Consumer Product Safety Commission banned the use of other self-inflating aerosol products containing vinyl chloride, by a notice published in the Federal Register of August 21, 1974 (39 FR 30111).

Dr. Cesare Maltoni has issued a preliminary report concerning the progress of his studies investigating the effects of vinyl chloride when inhaled (Cesare Maltoni, Adriano Citterio, Luciano Geronzi, Francesco Citterio, "Chronic Effects of Vinyl Chloride on Rats," in *Report to a Symposium on the Toxicity of Vinyl Chloride*, 1973). Dr. Maltoni's study involves the administration to rats by inhalation of vinyl chloride in an effort to simulate an average level of 50 milligrams per kilogram of body weight, 16 hours and per kilogram of body weight and 2.5 milligrams per kilogram of body weight. The study was initiated with 40 males and 40 female rats of each strain level, plus a control group of the same number. After 52 weeks the examination of these rats that had died revealed the rat in the highest dose group to have angiosarcomas of the thymus, 50% and rat in the 2.5 milligrams dose level was found to have angiosarcomas of the liver. No tumors were reported in the 2.5 milligrams dose group or in the controls. The experiment is continuing with an anticipated completion date in early 1975. In addition, Dr. Maltoni has indicated an experiment using lower dose levels.

After evaluating all the data, the Commissioner concludes that it is likely that when the Maltoni study has been completed, it will show that vinyl chloride is carcinogenic when inhaled. He notes that these results are consistent with the finding that inhalation of vinyl chloride has been shown to produce cancer. The Commissioner acknowledges that the finding of angiosarcoma in one rat in each of the two highest dose levels may be regarded by some persons as inconclusive evidence that vinyl chloride is carcinogenic when inhaled. However, Dr. Maltoni reports that, to his knowledge, no spontaneous angiosarcomas of rats have been reported in the literature. Additionally, Dr. Maltoni reports that angiosarcomas of the thymus and of the liver have never occurred spontaneously in their colony of Sprague-Dawley rats. The Commissioner concludes that the preliminary data from the incomplete ingestion studies, when combined with the

other data already available concerning the hazards of vinyl chloride, are sufficient to warrant the actions proposed in this proposal.

Proposed Action

Under section 201(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n)), a substance is excluded from the definition of "food additive" if its use was sanctioned by FDA prior to September 6, 1958. A number of uses of vinyl chloride polymers were so sanctioned and consequently are "prior sanctioned."

Subsequent to the enactment of the Food Additives Amendment of 1958, FDA issued letters stating that polyvinyl chloride resin was generally recognized as safe in specific compositions including rigid and semirigid articles intended to contact food. These letters were based on the premise that the uses and data cited in the letters articles for films and coatings could be interpreted to extend to other food-contact articles containing polyvinyl chloride.

In addition, since 1958, a variety of uses of vinyl chloride polymers in food-contact articles have been approved by the issuance of food additive regulations in 21 CFR Part 121, Subparts D and F. [121.1179 Coatings on fresh meat fruit; 121.2507 Cellophane; 121.2516 Laminates and polymeric coatings; 121.2520 Adhesives; 121.2521 Vinyl chloride-polyethylene copolymers; 121.2524 Polyethylene phthalate polymers; 121.2528 Components of paper and paperboard in contact with soups and fatty foods; 121.2543 Packaging materials for use during the irradiation of prepackaged foods; 121.2545 Textiles; 121.2550 Closures with sealing gaskets for food containers; 121.2560 Resins and polymeric coatings for polyethylene films; 121.2571 Components of paper and paperboard in contact with dry food; 121.2591 Semirigid and rigid acrylic and modified acrylic plastics; 121.2608 Vinyl chloride-styrene and other copolymers; 121.2609 Vinyl chloride-ethylene copolymers; 121.2621 Vinyl chloride-heptene-1 copolymers; 121.2621 Microporous polymeric filters.

The safety of a substance used in food-contact articles may be reevaluated at any time. Use of a prior-sanctioned substance may be prohibited or limitations may be established for its safe use under section 402(a) of the act (21 U.S.C. 342 (a)) when the Commissioner determines that such use may be injurious to health. For a substance used pursuant to a food additive regulation, under section 409 of the act (21 U.S.C. 348) approval must be revoked when a fair evaluation of the data before the Commissioner fails to establish that the substance is safe under its conditions of use. In the case of a substance that is neither prior-sanctioned nor the subject of a food additive regulation, use may continue only as long as the substance is generally recognized as safe.

The Commissioner has reviewed the uses of vinyl chloride polymers in light of (1) the available data concerning the safety of vinyl chloride and (2) the like-

lihood of the migration of vinyl chloride to food. Although testing for the carcinogenicity of vinyl chloride upon ingestion is not complete, the Commissioner concludes, as discussed above, that sufficient data have been accumulated to establish the likelihood that it will be shown to be carcinogenic and therefore to require appropriate action to restrict the use of vinyl chloride polymers. The Commissioner concludes that the use of vinyl chloride polymers should be prohibited where there is a reasonable expectation of any migration of vinyl chloride into food.

This conclusion is consistent with the requirements of the act for all uses of vinyl chloride polymers, whether prior-sanctioned, approved food additives, or based on the expectation that they are generally recognized as safe.

The Commissioner interprets section 402(a) of the act, which prohibits use of food-contact articles that may transfer food injurious to health, as requiring a showing of both possible migration and possible harm. The Commissioner concludes that the criterion for action in section 201(n) of the act is appropriately used in applying section 402(a) of the act. Consequently, a substance or device is considered a prior-sanctioned food-contact article where within the terms of section 201(n) of the act it may reasonably be expected to become a component of food where the carcinogenic potential of vinyl chloride upon ingestion is already sufficiently well documented to warrant a determination that it may, if present, render food injurious to health. The only prior-sanctioned uses of vinyl chloride polymers that may continue to be authorized are those where there is no reasonable expectation of migration.

Because of the likelihood that vinyl chloride is a carcinogen when ingested, for uses approved by food additive regulations a fair evaluation of the data before the Commissioner fails to establish their safety whenever there is reasonable expectation that vinyl chloride will migrate from the polymers into food. Therefore, the only uses that may continue to be approved are those where there is no reasonable expectation of such migration.

For uses of vinyl chloride polymers that have been generally recognized as safe, where there is a reasonable expectation that vinyl chloride will migrate into food, the evidence of potential carcinogenicity upon ingestion requires the conclusion that general recognition of their safety does not exist. Thus, as to the uses that are prior-sanctioned or approved by food additive regulation, the only permissible uses are those where there is no reasonable expectation of such migration.

In considering whether particular food-contact articles raise a reasonable expectation of migration of vinyl chloride into food, the Commissioner has reached several tentative conclusions upon which this proposal is based.

The Commissioner concludes that there is no reasonable expectation of migration of vinyl chloride from thin plasticized

film because of the method of manufacture and the thickness of most film used for wrapping food (approximately 1 mil). As discussed above, plasticizing the film results in an article essentially free of vinyl chloride, and there is no reasonable expectation that any remaining vinyl chloride actually migrates into food.

The Commissioner also concludes that there is no reasonable expectation of migration of vinyl chloride from jar and bottle cap liners and gaskets. Polyvinyl chloride cap liners and gaskets, which have almost completely replaced the rubber and cork materials formerly used, are of two major types. Some are applied in fluid form as a ring around the part of the cap in contact with the container, and others consist of a circular disc cut from film and inserted so as to cover completely the inside surface of the cap. A majority of these types are "flexible" which are applied as beads and are made from plastic resins containing plasticizers. The Commissioner concludes that these plasticized resins contain about 100 parts polyvinyl chloride and 60 parts plasticizer. Other resins are made by combining these plasticizers with other polyvinyl chloride resins. In addition to removal of residual vinyl chloride in the extruded process, additional vinyl chloride is known to be removed when the plasticized beads are compressed at 304° F for 3 to 5 minutes during extrusion. The small potential for residual vinyl chloride that exists after each processing, together with the fact that a cap liner has only limited contact with food, leads to the conclusion that there is no reasonable expectation of migration of vinyl chloride into food. However, no migration may be expected from cap liners cut from thin plasticized film, for the reasons previously discussed. Moreover, in the case of all cap liners there will be only slight contact with food. Consequently, these factors, the Commissioner concludes that there is no reasonable expectation of migration of vinyl chloride from cap liners.

Can coatings containing polyvinyl chloride are primarily used on the inside of beer and soft drink cans and, to a much lesser extent, inside food cans. Most of the polyvinyl chloride used for can coatings is produced by the solution polymerization process which produces polyvinyl chloride with the lowest residual vinyl chloride content. After conversion of the resin into can coatings, no residual vinyl chloride has been reported, presumably because the thickness of the applied film and the baking it has received, at above 304° F, have caused the removal of the residual vinyl chloride. In such a case, it can be concluded that there is no reasonable expectation of migration of vinyl chloride into food.

Polyvinyl chloride flexible tubing, ranging in internal diameter from 3 to 3 thousandths of an inch to 3 to 4 inches, is highly plasticized. As previously discussed, it is thought that plasticization reduces residual vinyl chloride content to the point where there is no reasonable expectation that any will migrate into

food. In addition, flexible tubing is generally used in applications where food contacts the tubing only briefly and the temperature of the food is often low. These circumstances further reduce the possibility of any migration of vinyl chloride.

Textiles incorporating vinyl chloride polymers in accordance with § 121.2545 (21 CFR 121.2545) are nonwoven sheets prepared from natural or synthetic fibers and bonded with fibrils. The fibrils consist of vinyl chloride-vinyl acetate copolymer resin that is prepared by solution polymerization, a process that has been shown to result in less than 1 ppm vinyl chloride in the resin. The fibrils are formed by precipitating a solvent solution of the copolymer in water and then washing the precipitate until all solvent is removed. The fibril is comminuted with fibers prepared from polyethylene terephthalate resins to facilitate their formation and subsequently heat treated to fuse the fibril and effect bonding. These procedures for manufacturing fibrils should result in a restriction of level of the residual vinyl chloride to the point that the Commissioner concludes that their use would not reasonably be expected to result in vinyl chloride becoming a component of food.

Microporous polymeric filters used in accordance with § 121.2551 (21 CFR 121.2551) are based on polyvinyl chloride resin produced by solution polymerization, which, as noted above, results in low levels of residual vinyl chloride. The filters are prepared by adding sodium chloride to a solvent solution of the resin, resulting in "opening" of the resin and further loss of residual vinyl chloride. The filter is formed by extrusion and calendaring followed by a hot water wash to remove solvent. Each of these steps, together with the process treatment required by § 121.2531, would result in a reduction of any remaining vinyl chloride to the point that the Commissioner concludes that the use of microporous polymeric filters would not reasonably be expected to result in vinyl chloride becoming a component of food.

Adhesives containing vinyl chloride polymers in accordance with § 121.2529 (21 CFR 121.2529) have no contact with food except incidentally at the edges of food-packaging materials. Because of this slight contact, the Commissioner concludes that the continued use of adhesives containing vinyl chloride polymers would not reasonably be expected to result in vinyl chloride becoming a component of food.

However, the data indicate that rigid and semirigid polyvinyl chloride articles intended to contact food (including bottles, blister packs, boxes and pipe, except as noted below for water pipe) may transmit vinyl chloride to the food they contact. Therefore, the Commissioner finds that these uses can no longer be permitted for contact with food.

The use of vinyl chloride polymers as coatings for fresh citrus fruits, which is permitted by § 121.1179 (21 CFR 121.1179), presents the possibility of ingestion of vinyl chloride because the poly-

mers are applied directly to the fruit. Therefore, the Commissioner concludes that the available data do not demonstrate that this use is safe.

Because copolymers of vinyl chloride might also be expected to contain residual vinyl chloride capable of migrating to food, this proposal applies to vinyl chloride copolymers, as well as to the homopolymer, polyvinyl chloride.

In accordance with these considerations, the proposed regulations take the following approach:

1. Food-contacted uses of vinyl chloride homopolymers and copolymers as coatings, resins, cap liners, flexible tubing, and the like used since 1961 will be permitted in such cases, permitting their continued use. This proposal identifies all such uses except those known to the Commissioner. Persons aware of other food-contacted uses should submit proof of the restriction during the period for comment on this proposal.

2. Polymers known to be used in food-contacted uses of vinyl chloride homopolymers and copolymers as resins, cap liners, flexible tubing, and the like used since 1961 will be permitted in such cases, permitting their continued use. This proposal would amend § 121.106 (21 CFR 121.106) of the regulations to provide that these polymers may be used in food-contacted uses since 1961. Such polymers could be used in such cases only after approval of a food additive petition submitted pursuant to § 121.101 (21 CFR 121.101) of the regulations to add them to the list of food additives. Data would be necessary to demonstrate that there is no reasonable expectation that vinyl chloride will become a component of food.

3. Uses of vinyl chloride homopolymers and copolymers as coatings, resins, cap liners, flexible tubing, and the like used since 1961 will be permitted in such cases, permitting their continued use. This proposal would amend § 121.106 (21 CFR 121.106) of the regulations to provide that these polymers may be used in food-contacted uses since 1961. Such polymers could be used in such cases only after approval of a food additive petition submitted pursuant to § 121.101 (21 CFR 121.101) of the regulations to add them to the list of food additives. Data would be necessary to demonstrate that there is no reasonable expectation that vinyl chloride will become a component of food.

4. Food additive regulations permitting the use of vinyl chloride polymers would be amended to permit the continued use of these polymers as coatings (other than those applied directly to food), resins, cap liners, flexible tubing, and plasticized films and to prohibit other uses except in water pipe as discussed below.

5. Food additive regulations specifically providing for the use of additives in the production of food-contact articles containing vinyl chloride polymers would be amended to be consistent with the proposed restrictions on the use of vinyl chloride polymers.

At the time final regulations are issued, it may be necessary to define the classes of permitted polyvinyl chloride food-contact articles with greater particularity. Thus, based on available data and on information concerning theoretical prospects of migration of vinyl chloride, specifications for permitted articles might be established in terms of thickness, degree

of plasticization, method of polymerization used, vinyl chloride content of the "comonomer" used, heat applied during processing, and similar criteria. Comments should include all available data and information that help to identify particular applications and specifications that assure no reasonable expectation of migration. The Commissioner advises that at the time the final regulations are issued, based on such data and information, it may be appropriate to restrict or eliminate uses that are here proposed to be continued.

Determining whether any food packaging component, such as vinyl chloride, is reasonably expected to become a component of food necessarily involves fine judgment, for which precise standards cannot be articulated. If there is no detectable vinyl chloride in a food-contact article, and there are no detectable extractions of vinyl chloride from the article into food-simulating solvents, and there is a sound theoretical basis for predicting no migration below the detectable level, e.g., the article is plasticized or contact with food is slight, the Commissioner concludes that there is no reasonable expectation of migration. Where vinyl chloride is detected at a very low level in the food-contact article, it may nevertheless be possible to conclude that there is no reasonable expectation of migration into food based on theoretical considerations peculiar to the particular product and use. The Commissioner advises that the detection of vinyl chloride extractives in food-simulating solvents under testing conditions is not evidence for food-contact articles that the residual vinyl chloride in the article may reasonably be expected to migrate into food. The Commissioner concludes that testing conducted with food-simulating solvents is an appropriate method for determining the likelihood of migration from a food-contact article to food. Because of analytical difficulties, food often cannot be readily tested for evidence of migration. For this reason, food-simulating solvents have long been used both by industry and FDA to test food-contact articles.

The Commissioner is aware that the technology for reducing the amount of vinyl chloride in vinyl chloride polymers, or eliminating it altogether, is improving rapidly and that major advances are known to FDA may have been made within recent months. Thus, additional classes of food-contact articles may exist for which it can be concluded that there is no reasonable expectation that vinyl chloride would migrate into food. Comments on this proposal suggesting that such articles do exist should include data, analytical methodology used, and a theoretical analysis of the expectation of migration.

In the case of polyvinyl chloride potable water pipe, the Commissioner concludes that the data available at this time indicate that vinyl chloride may not reasonably be expected to be present in water drawn from a polyvinyl chloride water pipe system. Although data from the testing of polyvinyl chloride water pipe containing static water have shown

migration of vinyl chloride, no vinyl chloride has been detected in samples of water drawn from operating polyvinyl chloride potable water pipe. It is likely that static testing does not reasonably assess the likelihood of the presence of vinyl chloride in water. It is proposed that an interim period of time be provided for the continued use of polyvinyl chloride water pipe, pending development of data from tests appropriate for the determination of the potential for the presence of vinyl chloride in water drawn from a polyvinyl chloride potable water pipe system.

Under the proposal, polyvinyl chloride water pipe would be subject to the provisions of § 121.4003 (21 CFR 121.4003), concerning food additives approved on an interim basis. Within 60 days following the effective date of a final regulation, an interested person would be required to notify FDA that studies have been undertaken to determine whether vinyl chloride may reasonably be expected to be present in water drawn from a system containing polyvinyl chloride pipe. If no such announcement were made, or adequate and appropriate studies were not undertaken, the regulation permitting continued use of polyvinyl chloride water pipe would be revoked.

This announcement provides 60 days for public comment, after which time the comments will be reviewed and final regulations issued. The Commissioner proposes that the regulations become effective 30 days after their promulgation as final regulations. No recall of affected articles is now anticipated to be necessary. The Commissioner concludes that the hazard to the public health is not so immediate as to warrant issuance of these regulations without opportunity for public comment or to require recall and destruction of foods already packaged. The continued use of installed equipment having food-contact surfaces composed of vinyl chloride polymers would be permitted; any residual vinyl chloride is likely to have dissipated to the atmosphere during the period of service.

These proposed regulations deal only with vinyl chloride contamination of food. The Commissioner plans to issue additional announcements in the near future concerning cosmetics, drugs, and medical devices. Also, the proposed regulations would not immediately affect the status of vinyl chloride polymers used in food-contact articles in the household, food service establishments, and food dispensing equipment. Such articles are the subject of a notice published in the *Federal Register* of April 12, 1974 (39 FR 17286), and they will be evaluated in accordance with the terms of that notice.

The Commissioner has carefully considered the environmental effects of the proposed regulations and, because the proposed action would not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. The Commissioner has also carefully considered the inflation impact of the pro-

posed regulations, and has found that the proposed action would not cause a major inflation impact as defined in OMB Circular A-167. Therefore, no inflation impact statement is required. At the time additional announcements concerning cosmetics, drugs, and medical devices are issued, these conclusions will be reevaluated. Data and information concerning environmental and inflation impact may be submitted as a comment on this proposal. Copies of the FDA environmental and inflation impact statements are on file with the Hearing Clerk, Food and Drug Administration.

A petition to ban the use of polyvinyl chloride in food packaging was received by the Commissioner on July 7, 1973 from Public Citizen's Health Research Group, 2000 P St., N.W., Washington, DC 20036. As this proposal on the use of vinyl chloride polymers was being prepared, each of the petitioners' comments has been considered by the drafting of this document. A letter will be sent to the petitioner regarding the petition.

Copies of the records and data referred to above are on file at the office of the Hearing Clerk, Food and Drug Administration, Room 4-09, 1400 Independence Avenue, Rockville, MD 20851.

Published elsewhere in this issue of the *Federal Register* is a notice with-creating a proposed to add § 121.2307 (21 CFR 121.2307) and amending the existing provisions on the use of polyvinyl chloride resin in articles for use in contact with alcoholic foods which was published May 17, 1973 (38 FR 17317).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301(a), 302, 303, 304, 305, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000).

1. In § 121.106 by adding new paragraph (c)(4) as follows:

§ 121.106 Substances prohibited from use in human food.

(c)

(4) Vinyl chloride. (i) Vinyl chloride has the molecular formula $\text{C}_2\text{H}_2\text{Cl}_2$. It is a synthetic chemical not found in natural products and has been used in the production of polymeric substances that may contact food.

(ii) Food containing any added or detectable level of vinyl chloride is deemed to be adulterated in violation of the act.

(iii) The use in food-contact articles of vinyl chloride homopolymers and copolymers is prohibited, except that such use is not prohibited:

(a) In coatings, gaskets, cap liners, flexible tubing, and plasticized films if such use is otherwise in accordance with the requirements of the act and this chapter; or

(b) If specifically permitted in this part.

§ 121.1179 [Amended]

1a. In § 121.1179 Coatings on fresh citrus fruit by deleting and reserving

paragraph (b)(3), and deleting the reference to paragraph (b)(3) from paragraph (b)(4).

2. By adding the following new section to Subpart E, to read as follows:

§ 121.2309 Vinyl chloride polymer resins.

Polyvinyl chloride resins consist of basic resins produced by the polymerization of vinyl chloride. Polyvinyl chloride basic resins have a maximum volatility of not over 3 percent when heated for 1 hour at 105° C. as determined by ASTM Method D 3636-72, and an inherent viscosity of not less than 0.25 as determined by ASTM Method D 1243-62. Vinyl chloride copolymer resins are the polymers produced by the copolymerization of vinyl chloride with other monomeric substances. Vinyl chloride homopolymers and copolymers may be safely used as follows:

(a) Coatings. (1) Polyvinyl chloride for use as a can enamel.

(2) Vinyl chloride-vinyl acetate copolymers for use as a can enamel.

(3) Vinyl chloride-butadiene-acrylonitrile copolymers for use as a component of conveyor belts intended for use with fruit, fruit, vegetable, and fish, and as a component of trailers of power and papermills in contact with meat and dairy.

(4) Vinyl chloride-butadiene chloride copolymers for use as a liner, i.e., coating, for steel pipe.

(b) Plasticized films. (1) Polyvinyl chloride for use in plasticized film in contact with food.

(2) Vinyl chloride-butadiene-acrylonitrile copolymers for use in plasticized film in contact with aluminum foil.

(3) Vinyl chloride-vinylidene chloride copolymers for use in plasticized film in contact with food.

(4) Vinyl chloride-vinyl acetate copolymers for use in plasticized film in contact with food.

3. In § 121.2307, by amending paragraph (c) by revising the entry in the list of substances for "polyvinyl chloride" to read as follows:

§ 121.2307 Cellulose.

(c)

Linoleum

Polymer (chloride). As the basic polymer for use in contact with food.

(c)

4. In § 121.2311, by amending paragraph (b) by revising the listing entries for "diethylhexyl phthalate" and "diethyl phthalate" to read as follows:

§ 121.2311 Plasticizers in polymeric substances.

(b)

* Copies may be obtained from: American Society for Testing and Materials, 1010 Rose St., Philadelphia, PA 19106.

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Limitations

Dicyclobutyl
phthalate.

For use only:

1. As provided in §§ 121.2507, 121.2520, 121.2522, and 121.2571.

2. Alone or in combination with other phthalates, in plastic film prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 121.2521 or in plastic sheet prepared from polyvinyl acetate. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 percent by weight of total phthalates, calculated as phthalic acid.

Diphenyl phthalate.
For use only:

1. As provided in § 121.2507.

2. Alone or in combination with other phthalates, in plastic film prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 121.2521 or in plastic sheet prepared from polyvinyl acetate. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 percent by weight of total phthalates, calculated as phthalic acid.

5. In § 121.2521, by redesignating the present paragraph (f) as paragraph (g) and adding a new paragraph (f) as follows:

§ 121.2521 Vinyl chloride-propylene copolymers.

- (f) Vinyl chloride-propylene copolymers may be used only in coatings, gaskets, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4009.

6. In § 121.2541, by adding a new paragraph (e) to read as follows:

§ 121.2541 Limitations and/or surface-active agents.

(e) The use of the emulsifiers and/or surface-active agents in any polymeric substance or article subject to any regulation in this Subpart F must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

7. In § 121.2508 (1) by amending paragraph (b) by deleting the limitations for "hydrogenated 4,4'-isopropylidenediphenyl-phosphite ester resins produced by the condensation of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated, 4,4'-isopropylidenediphenol" and "poly(1,1-dibutylphosphonate)idene-1,7-dithiol" having the formula $(C_4H_9O)_2P(=O)S_2$ (where x averages 1.5-2.1), and by inserting the listing for "4,4'-bis-phosphite" and (2) by adding a new paragraph (c) to read as follows:

§ 121.2508 Antioxidants and/or stabilizers for polymers.

(c) List of substances:

Limitations

- (1) 4,4'-bisphosphite. The use of 4,4'-bisphosphite in any polymeric substance or article subject to any regulation in this Subpart F must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) The use of the emulsifiers and/or surface-active agents in any polymeric substance or article subject to any regulation in this Subpart F must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

8. In § 121.2521 by amending paragraph (a) (2) by revising the listing entry for "vinyl chloride" and amending paragraph (a) (3) by revising the listing entry for "polyvinyl chloride" "vinyl chloride copolymers" and "vinyl chloride-vinyl acetate copolymers" to read as follows:

§ 121.2521 Vinyl chloride and vinyl acetate and modified acrylic plastic.

- (a) . . .
- (2) . . .

Vinyl chloride (only in water pipe as permitted by § 121.4009).

(4) . . . Polyvinyl chloride (only in water pipe as permitted by § 121.4009). Vinyl chloride copolymers complying with § 121.2521 (only in water pipe as permitted by § 121.4009).

Vinyl chloride-vinyl acetate copolymers (only in water pipe as permitted by § 121.4009).

9. In § 121.2597 by revising the introductory paragraph to read as follows:

§ 121.2597 Polymer modifiers in semi-rigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admixed, alone or in mixture with other permitted polymers, as modifiers in rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers for use as provided in § 121.4009 for water pipe and/or from vinyl chloride copolymers complying with § 121.2521, § 121.2522, and/or § 121.2597 in accordance with the following prescribed conditions:

10. In § 121.2602 by adding a new paragraph (c) to read as follows:

§ 121.2602 Acrylic stabilizers in vinyl chloride plastics.

(c) The finished food-contact article is in the form of containers, gaskets, cap liners, flexible tubing, plasticized films, or water pipe as permitted by § 121.4009.

11. In § 121.2597, by revising the introductory text of paragraph (a) to read as follows:

§ 121.2597 Polyethylene alcohol esters of carboxylic acids (Carboxylic esters) acetates and acids.

(a) The polyethylene alcohol esters identified in this paragraph may be used as plasticizers in the fabrication of vinyl chloride plastic food-contact articles (containers, gaskets, cap liners, flexible tubing, plasticized films, and water pipe as permitted by § 121.4009) prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 121.2521. Such esters must be of the following specifications and are produced by esterification of polyethylene glycol with carboxylic acids or by esterification of polyethylene glycol with carboxylic acids and subsequent esterification of unreacted carboxylic groups with ethylene glycol.

12. In § 121.2602, by revising paragraph (a) to read as follows:

§ 121.2602 Vinyl chloride-butyl vinyl ether copolymers.

(a) Other specifications and limitations. (1) Vinyl chloride-butyl vinyl ether copolymers may be used only in coatings, gaskets, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4009.

(2) The vinyl chloride-butyl vinyl ether copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Subpart F of this Part 121, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

13. In § 121.2609 by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) as follows:

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§ 121.2609 Vinyl chloride-ethylene copolymers.

(f) Vinyl chloride-ethylene copolymers may be used only in containers, gaskets, can liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4009.

14. In § 121.2623 by revising paragraph (c) to read as follows:

§ 121.2623 Vinyl chloride-butene-1 copolymers.

(c) Other specifications and limitations. (1) The vinyl chloride-butene-1 copolymers identified in this section may be used in containers, gaskets, can liners, flexible tubing, plasticized films, and in water pipe as permitted by § 121.4009.

(2) The vinyl chloride-butene-1 copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Subpart F of this Part 121, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

15. In Subpart H, by adding a new § 121.4008, to read as follows:

§ 121.4009 Vinyl chloride polymers.

(a) Vinyl chloride polymers may be safely used as a component of water pipe on an interim basis, pending the outcome of studies to determine whether vinyl chloride may reasonably be expected to be present at the time of consumption, in potable water drawn from a system utilizing such pipe. The continued use of vinyl chloride polymers in water pipe is subject to the conditions in § 121.4009(c).

(b) Within 60 days of the effective date of this regulation, an interested person shall satisfy the Commissioner in writing that studies have been undertaken that are adequate and appropriate to appraise the potential for the presence of vinyl chloride in potable water drawn from a system utilizing water pipe containing vinyl chloride polymers. These studies shall include: (1) Determination of the lowest attainable level of residual vinyl chloride in potable water pipe; (2) an investigation of the relationship between residual vinyl chloride in water pipe and the amount of vinyl chloride that may be present in water in such pipe under static conditions; and (3) an investigation of the level of vinyl chloride that may be present in water drawn from such a system.

Interested persons may, on or before November 3, 1975, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments regarding this proposal. Comments should be filed in triplicate (except that individuals may submit single copies), and should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office Monday through Friday, from 9 a.m. to 4 p.m., except on Federal legal holidays.

Dated: August 27, 1975.

A. M. SCHWARTZ,
Commissioner of Food and Drugs.
(FR Doc 75-2741 Filed 8-29-75; 4:45 am)

Social Security Administration

[20 CFR Part 405]

[Reg. No. 11]

FEDERAL HEALTH INSURANCE FOR AGED AND DISABLED

Proposed Regulations of Participation by Chinese, Japanese, Koreans, and Public Health Agencies

Comments

In FR Doc 75-2741 appearing at page 40537 in the issue of Thursday, June 19, 1975, a line was dropped from paragraph (c) of § 405.1730(b) in the first sentence of paragraph 1730(b) of the proposed regulations. The word "participation" in the third line of the first sentence should be replaced by the word "coverage" as indicated by a provider of services, a check.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 571]

[Docket 75-42, Phase II]

EXTERIOR MOUNTED BICYCLE CARRIERS

Advance Notice of Proposed Rulemaking

This is an advance notice of proposed rulemaking, issued to solicit comments and information concerning bicycle carriers mounted from bicycle carriers mounted on the exterior of motor vehicles.

The Traffic Safety Council, Oregon, has submitted the National Highway Traffic Safety Administration (NHTSA) to issue an advance notice of proposed rulemaking concerning exterior mounted bicycle carriers. The NHTSA believes that the request of the petitioner has merit, and that the proposed rulemaking from Federal Motor Vehicle Safety Standard No. 118, Exterior Protection (49 CFR 571.118), and future standards relating to pedestrian safety could be degraded by hazardous exterior mounted bicycle carriers.

Initial applicability of this proposed rulemaking is intended to encompass bicycle carriers for use with passenger cars, multipurpose passenger vehicles, trucks and buses with GVW of 10,000 pounds or less.

The NHTSA is contemplating a rule which will:

1. Require all mounting hardware to be installed in such a manner as to minimize any hazard to pedestrians.
2. Reduce or eliminate sharp edges on bicycle carriers.
3. Prohibit bicycle support arms from projecting beyond a specified distance from the exterior surface of the vehicle

when the bicycle is not being transported.

4. Label all carriers to warn against installation on the front of vehicles.

Information concerning the following areas is specifically requested:

1. The extent of fatalities, injuries, and property damage resulting from exterior mounted motor vehicle bicycle carriers while the vehicle is either moving or parked.
2. Safety and hazard factors found in current designs for exterior mounted motor vehicle bicycle carriers.
3. Economic and other relevant data concerning bicycle carrier volume of use, average unit price, number of manufacturers, and other similar information concerning market characteristics.
4. Motor vehicle insurance rates and coverage for vehicles equipped with exterior mounted bicycle carriers.

Interested persons are invited to submit information, views, and arguments on the issues described and on the need and extent of exterior mounted motor vehicle bicycle carriers. Comments should refer to the docket number and be submitted to: Traffic Section, National Highway Traffic Safety Administration, Room 3196, 400 Seventh Street, S.W., Washington, D.C. 20590. It is requested that one original and 10 copies be submitted.

All comments received before the close of business on the proposed closing date indicated below will be considered, and will be available for examination in the docket at the above address both before and after that date. The NHTSA will respond to the extent material as it becomes available to the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Comment closing date, December 2, 1975.

Proposed effective date, 1 year after publication of rule.

Comments may be filed by mail to: 405.1730(b) of the proposed regulations. The word "participation" in the third line of the first sentence should be replaced by the word "coverage" as indicated by a provider of services, a check.

Issued on August 27, 1975.

Robert L. Carter,
Associate Administrator,
Motor Vehicle Programs.

(FR Doc 75-2741 Filed 8-29-75; 4:45 am)

DEPARTMENT OF LABOR

Wage and Hour Division

[29 CFR Parts 803, 806, 808, 807]

[Administrative Order No. 530]

INDUSTRY COMMITTEES FOR INDUSTRIES IN PUERTO RICO

Changes in Order of Hearings of Industry Committees in Puerto Rico

Administrative Order No. 530, 40 FR 18519, set forth the order of hearings by Industry Committees Nos. 117-A through 127-D and Nos. 128-A through 128-P. At the request of certain interested parties and the agreement of other major parties and pursuant to the authority vested in me under section 8 of the

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

National Park Service

[36 CFR Part 2]

PUBLIC USE AND RECREATION

Proposed Regulations for Public Use

Notice is hereby given that pursuant to the authority contained in the Act of August 20, 1916 (39 Stat. 535 as amended and subsequent law 16 USC § 1-1 of art. 1, the National Environmental Policy Act of 1969 (42 Stat. 1551) (24 USC § 1501) and 16 USC § 1-1 (24 USC § 1501), as amended, it is proposed to amend portions of Part 2 of the Federal Regulations as set forth below.

Existing provisions contained in § 2.2 provide that the Superintendent may "close or restrict public use of all or any portion of a park area, when necessary for the protection of the area or the safety and welfare of persons or property by the posting of appropriate signs indicating the extent and scope of closure." The purpose of the amendment is to detail and clarify the authority of the Superintendent to restrict or restrict public use of any area or facility for those purposes.

The proposed amendment defines "public use limit" as the restriction for the establishment of such limits. Note the factors which are considered in establishing such limits, including the use of natural resources, recreational resources, and the existing authority to post restrictions, provides for adequate public notice of the existence of public use limitation systems; and prohibits public use in violation of public use regulatory systems or in excess of established public use limits.

The establishment of any public use limitation system within any particular unit of the National Park System will be in accordance with the requirements of the National Environmental Policy Act of 1969.

Park Managers will give timely and adequate notice of their operations to reach the many visitors to the National Park System who live and plan their trips at distant locations. Where limitations are imposed both local notice and other appropriate notices through various media will be used to give the majority of visitors a reasonable opportunity to be aware of the existence of the limitation and how they can obtain adequate detailed information.

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to

participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions, or objections regarding the proposed amendments to the Department of the Interior, Washington, D.C. 20540, or to the field office nearest you.

Section 2.2 is proposed to read as follows:

§ 2.2. Closure and public use limits.

(a) Closure of areas. (1) The Superintendent may, in his discretion, close or restrict public use of all or any portion of a park area, when necessary for the protection of the area or the safety and welfare of persons or property by the posting of appropriate signs indicating the extent and scope of closure.

(2) All closures shall be made and shall be adequately posted with signs indicating the extent and scope of closure.

(3) Any closure shall be made and shall be adequately posted with signs indicating the extent and scope of closure. A public use limit shall be established for the purpose of restricting public use of any area or facility for those purposes.

(4) The Superintendent may, in his discretion, close or restrict public use of all or any portion of a park area, when necessary for the protection of the area or the safety and welfare of persons or property by the posting of appropriate signs indicating the extent and scope of closure.

(5) To establish a public use limit, the Superintendent may, in his discretion, close or restrict public use of all or any portion of a park area, when necessary for the protection of the area or the safety and welfare of persons or property by the posting of appropriate signs indicating the extent and scope of closure.

(6) The Superintendent may, in his discretion, close or restrict public use of all or any portion of a park area, when necessary for the protection of the area or the safety and welfare of persons or property by the posting of appropriate signs indicating the extent and scope of closure.

(7) Entry into an area in violation of posted restrictions is prohibited.

JOHN E. COOK,
Acting Director,
National Park Service.

[FR Doc 76-26024 Filed 10-26-76; 6:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 123]

(Direct to 123.100)

FOOD, CHILDREN, POLYMER IN CONTACT WITH FOOD

Extension of Time for Compliance

The Commissioner of Food and Drug Administration, established in the Federal Register of September 1, 1976 as 21 CFR 123.100, to restrict the use of food contact polymers in contact with food. A period of 18 months was provided for compliance. The Commissioner is extending the time for compliance to December 31, 1978.

The Commissioner has received requests for extension of the compliance period, primarily because of the delay in the processing of the data required for compliance. The Commissioner has decided to extend the compliance period to December 31, 1978. The request, in the form of a letter, should be sent to the Commissioner, Food and Drug Administration, 1015 Third Street, N.W., Washington, D.C. 20204.

Food and Drug Administration, 1015 Third Street, N.W., Washington, D.C. 20204. The Commissioner has decided to extend the compliance period to December 31, 1978.

The request is based on the Federal Food, Drug, and Cosmetic Act, 21 CFR 123.100, 21 CFR 123.101, 21 CFR 123.102, 21 CFR 123.103, 21 CFR 123.104, 21 CFR 123.105, 21 CFR 123.106, 21 CFR 123.107, 21 CFR 123.108, 21 CFR 123.109, 21 CFR 123.110, 21 CFR 123.111, and other regulations promulgated by the Commissioner (21 CFR 123.100).

Issued: October 22, 1976.

Sam D. Felt,
Associate Commissioner
for Compliance

[FR Doc 76-26024 Filed 10-26-76; 6:45 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 583]

(Direct to 583.100)

COST INFORMATION REPORTING

Correction

In FR Doc. 75-24538 appearing at pages 4245 to 4246 in the issue of Sep-