

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 1964, Dr. Lehman reported to the Association of Food and Drug Officials:

We consider as the most important single physical characteristic of a film its continuity or the lack thereof of any of its constituents in the contact media with which the plastic may come in contact. If nothing can be extracted when tested with representative food-type solvents (lard-oil, vinegar, molasses, kerosene, must, juice, water, etc.) under conditions comparable with rigorous tests which to experienced food packers mean, we usually have no objection 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(3): 83, 1961, and "Food Packaging," *Ind. 20(4): 180, 1964.*

MIGRATION OF VINYL CHLORIDE TO FOOD

In early 1973, representatives of Schenley 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 12881), 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 polymer. 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 polymer 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 the 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 60 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 self-rigid 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 Kghy Corp. ("VCM extraction from PVC bottles," *Modern Packaging*, pp. 43-45, 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 as 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 dashed line in the concentration of vinyl chloride that can be detected in the food. The ar-

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

(b) Maturity (skinning) requirements.

(1) Russet Burbank and Red McChes 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 § 944.40, 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 appropriate 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 § 944.40 but such shipments shall be subject to assessment.

(a) 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.

(4) 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.

(5) 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 (§§ 91.1540-91.1564 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, shoestrings, 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.

(b) Applicability to imports. Pursuant to section 96 of the act and § 944.1, import regulations (1 CFR 944.1), Irish potatoes of the red skinned round type, except certified seed potatoes imported into the United States during the period September 28, 1973, through June 30, 1978, 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, 1978, shall be not more than "moderately skinned."

Dated: August 28, 1973.

CHARLES R. BRANN,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

(FR Doc 73-23249 Filed 8-28-73; 8:40 am)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

(Docket No. 73-008)

PRE-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 12621) to establish a regulation under § 121.3000 (21 CFR 121.3000) to identify the criteria for the safe use of pre-sanctioned polyvinyl chloride resin as a component of food packaging material in contact with nonacidic 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. 1055, 72 Stat. 1743-1738 (21 U.S.C. 348, 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, 1973.

Dated: August 27, 1973.

A. M. SCHWARTZ,
Commissioner of Food and Drugs

(FR Doc 73-23249 Filed 8-28-73; 8:40 am)

[21 CFR Part 121]

(Docket No. 73-0109)

VINYL CHLORIDE POLYMERS IN CONTACT WITH FOOD

Notice of Proposed Rulemaking

The Food and Drug Administration (FDA) is proposing regulations to restrict the use 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 tap. The proposed regulation would prohibit all other uses of vinyl chloride polymers in food-contact articles, including painted and rigid articles such as bottles and bowls, because in those uses vinyl chloride may reasonably be expected to become a component of food. Interested persons have until November 2, 1973 to submit comments.

Use of Vinyl Chloride

Vinyl chloride is a chemical with the following structure:



It has a boiling point of -14° C (6.8° 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 900 units.

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

views and 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 lead 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 free unadsorbed vinyl chloride molecules left to migrate. His theory is supported by the results of equilibrium studies on which powdered polyvinyl chloride came 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.

Substanty Dittler reported levels of vinyl chloride as high as 20 ppm in veins and 20 ppm in fat. Confirmatory work on samples of the same material by FDA showed levels of 11 ppm vinyl chloride in veins and 12 ppm in fat. Since that time FDA has received many additional reports of findings of vinyl chloride in various types of food packages in polyvinyl chloride bottles. Currently, these reports have not included adequate information to evaluate accuracy, such as an adequate description of the methodology, including circumstances; data from recovery studies verifying the claimed sensitivity; data showing confirmation by mass spectrometry; and identification of the plastic material. It should be noted that analysis for vinyl chloride requires careful analytical techniques to ensure accurate 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. 20544.) 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) (as 20

parts per billion) and in polyvinyl chloride as low as 0.25 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, including analysis of various types of foods for the presence of vinyl chloride, refinement of the methodology for detection, and review of the toxicological aspects. Minutes of these meetings and the information reported are on public display at the office of the Hearing Clerk, Food and Drug Administration, Room 4-02, 5000 Palmer Lane, Rockville, MD 20850.

Data reported by SPI indicated that vinyl chloride could migrate to consumable foods from polyvinyl chloride bottles. Analysis of two samples of vegetable oil packed in polyvinyl chloride bottles revealed the presence of vinyl chloride at levels of 1.5 and 0.5 ppm. Reported results of analysis of additional samples of foods, drugs, and chemicals disclosed varying levels of vinyl chloride, e.g., vitamin D3 (0.25 ppm), mineral oil (10 ppm) and approximately 2 ppm from two other samples, a vitamin supplement (approximately 1 ppm), and a mouthwash (170 ppm). The vinyl chloride was reported from a series of other materials using an analytical method reportedly sensitive to 10 ppb. These latter samples had been collected from containers possibly other sources of various polyvinyl chloride formulations or an ordinary building site.

In early 1974, the British Ministry of Agriculture, Fisheries, and Food reported finding vinyl chloride in concentrations ranging from 10 to 60 ppb in fruit cans and from 10 to 40 ppb in cooking oil. The Canadian Health Protection Branch of the Ministry of Health and Welfare reported finding vinyl chloride ranging from 0.5 to 0.4 ppm in seven samples of apple cider vinegar. It also reported vinyl chloride in samples of various wines (less than 0.01 to 0.02 ppm), gin (0.25 to 0.5 ppm), and malt vinegar (1.5 ppm).

Data from experimental work using food-simulating solvents, i.e., distilled water, 5 percent acetic acid, ethanol, and n-hexane, support these earlier data showing migration of vinyl chloride to foods of foods other than alcoholic beverages. The data show that the use of alcohol and n-hexane as solvents representing alcohols 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 5 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 stock, coatings, masters or flexible tubing. Reports of analysis of extractives from such articles have shown no detectable vinyl chloride. Analysis 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 0.25 ppm residual vinyl chloride.

The lack of findings of extractable vinyl chloride from film is not surprising. For theoretical calculations indicate that if film contained residual vinyl chloride 100 percent extraction of the residual vinyl chloride from a 1 mil (0.001 inch) film would result in 2 ppm vinyl chloride in food. These calculations assume that 10 grams of food contact each square inch of film, the film weighs 30 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 from the air as well as the food, and much lower levels of migration have been reported to occur under actual conditions of use. In the event where they would be completely absent. The data concerning this conclusion indicate the issue of extractable vinyl chloride from these types of containers is extremely complex and that more data are needed before any firm conclusions can be drawn.

The greatest likelihood for migration of vinyl chloride occurs up to from polyvinyl chloride bottles and other rigid or semirigid polyvinyl chloride articles that are subjected for one-time use. A wide variety of products have been packaged in such containers, including vegetable oil, vinegar, broth, and liquid vitamin supplements. Large quantities of packaged foods are packaged in rigid and semirigid containers containing vinyl chloride polymers. Jell-O, honey, and other containers are frequently packaged in individual serving containers composed of vinyl chloride polymers. These various articles range in thickness from approximately 7 mils to 20 mils. Containers with a thickness of 7 to 12 mils were reported in a submission from the American Food Institute to contain 6 to 100 ppm residual vinyl chloride and to yield 4 to 20 ppm vinyl chloride when extracted by n-hexane. Plastic articles with a thickness of 10 to 21 mils were reported by the American Food Institute to contain 6 to 177 ppm residual vinyl chloride and to yield 2 to 227 ppm vinyl chloride when extracted by n-hexane.

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 rapid, 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 extractable 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 leach into water from water pipe would be expected to dissipate during the aeration and agitation that occur at the tap.

TOXICITY OF VINYL CHLORIDE

FDA is unaware of any reliable laboratory 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 critical issue of safety, namely carcinogenicity, since it was a short-term feeding study. Lifetime studies are necessary to evaluate properly the potential for long-range effects, such as carcinogenicity.

Considerable data exist concerning the toxic effects of vinyl chloride from atmospheric exposure, especially by inhalation and occupational contact. As the Commissioner pointed out in his April 23, 1974, proposal (39 FR 14282) to prohibit the use of vinyl chloride as an ingredient in drug and cosmetic contact products:

There is ample evidence that vinyl chloride inhalation can result in acute toxicity manifested by an array of symptoms, including unconsciousness as a result of high concentrations by inhalation. Chronic effects, lung changes, and carcinogenic changes in the bone, liver, and kidney have also been reported in animals.

The results from studies by Turkheim, et al., on the chronic effects of vinyl chloride on laboratory animals (T. R. Turkheim, F. Olyn, and V. E. Rowe, "The Toxicity of Vinyl Chloride as Determined by Repeated Exposure of Laboratory Animals," *American Industrial Hygiene Association Journal*, 35(5), 554-561, 1974) 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 "neoplasms" of the bone and (not as well as systemic effects among industrial workers engaged in the manufacture of vinyl chloride. Dr. F. L. Vieto, in studies, exposed rats to an atmosphere containing 3 percent (30,000 ppm) vinyl chloride vapors for 4 hours per day for 5 days per week for 1 year (F. L. Vieto, A. Bivetti, and A. Casata, "Oncoepidemiologic Response of Rat Skin, Lung, and Bone 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 18, 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 3674), Dr. Claude Malinow discussed preliminary results from his investigations directed at clarifying the type and degree of carcinogenic effects of vinyl chloride, as previously reported by Dr. Vieto. Dr. Malinow's investigations involved various types and levels of exposure to vinyl chloride, including: (1) An attempt to reproduce the conditions of Dr. Vieto's experiment using a level of 30,000 ppm; (2) experiments using atmospheric exposure to vinyl chloride vapors at levels ranging from 50 to 10,000 ppm; (3) an experiment investigating the effects upon inhalation (inhalation) of vinyl chloride; and (4) experiments investigating endoparasitoid and subcutaneous routes of administration. Dr. Malinow is a Professor, "Carcinogenicity Symposium," *Cancer Research*, 34:261-268, 1974 and "Le polychlorure de vinyle: un cancerogène pulmonaire," *Archives Françaises de Cancer*, 10: 1-11, 1974. In addition to this, Dr. Malinow reported that experiments were also being conducted using mice and hamsters.

At the February meeting, Dr. Malinow discussed his preliminary findings of the development of angiomas of the liver, along with other types of tumors, at levels of atmospheric exposure as low as 200 ppm. At the New York Academy of Sciences meeting, May 10-11, 1974 ("Carcinogenicity Symposium of Vinyl Chloride: Current Status," *Annals of the New York Academy of Sciences*, 244:220-223, January 21, 1975), he subsequently reported the development of angiomas 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 either low levels 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 36880), establishing standards for industrial exposure to vinyl chloride, the Occupational Safety and Health Administration stated:

These investigations have induced angiomas of the liver in rats and mice at exposure concentrations of 10 ppm and in hamsters at higher concentrations of exposure. Additional tumors involving other organs, including the kidneys, lungs, and skin, at exposed animals, were also observed in long-term studies in mice of mixed strains.

As noted above, the Food and Drug Administration issued a proposal on April 23, 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 24, 1974 (39 FR 28287), 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 24, 1974 (39 FR 14282), and the Consumer Product Safety Commission banned the use of other self-inflating household products containing vinyl chloride by a notice published in the *Federal Register* of August 21, 1974 (39 FR 28137).

Dr. Claude Malinow has issued a preliminary report concerning the progress of his studies investigating the effects of vinyl chloride when inhaled (Claude Malinow, Adrienne Chapiro, Lawrence G. Grant, Francois Chazot, "Inhalation of Acetylene in Rats, in Strains A and B, and in Strains C and D, and in Strains E and F," *Cancer Research*, 35: 1500-1503, 1975). Dr. Malinow's study involves the administration to rats by inhalation of vinyl chloride in an effort to establish a dose-response level of 50 milligrams per kilogram of body weight, 10.5 milligrams per kilogram of body weight and 2.5 milligrams per kilogram of body weight. The study was initiated with 40 male and 40 female rats at each dose level, plus a control group of the same number. After 10 weeks, the administration of these rats that had died revealed one rat in the highest dose group to have angiomas of the thyroid, and a rat in the 10.5 milligrams dose level was found to have angiomas 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 1976. In addition, Dr. Malinow has indicated an experiment using lower dose levels.

After reviewing all the data, the Commissioner concluded that it is likely that when the Malinow 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 acknowledged that the finding of angiomas 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. Malinow reports that, in his laboratory, no angiomas angiomas of the liver have been reported in the literature. Additionally, Dr. Malinow reports that angiomas of the thyroid and of the liver have been observed 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.

Prior Action

Under section 301(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)), a substance is excluded from the definition of "food additive" if its use was sanctioned by FDA prior to September 8, 1958. A number of uses of vinyl chloride polymers were so approved 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 applications, including rigid and semirigid articles intended to contact foods. These letters were based on the premise that the uses and data cited in the Lettersman articles for film and coatings could be interpreted to extend to other food-contact articles containing polyvinyl chloride.

In addition, since 1954, 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 131. Subparts D and F: § 131.1170 Coatings on fresh citrus fruit; § 131.2267 Cellophane; § 131.2314 Resins and polymeric coatings; § 131.2320 Adhesives; § 131.2321 Vinyl chloride-propylene copolymers; § 131.2324 Polyethylene plastic polymers; § 131.2325 Components of paper and paperboard in contact with aqueous and fatty foods; § 131.2343 Packaging materials for use during the irradiation of prepackaged foods; § 131.2445 Foils; § 131.2500 Clusters with sealing coatings for food containers; § 131.2505 Resins and polymeric coatings for polyethylene films; § 131.2571 Components of paper and paperboard in contact with dry food; § 131.2572 Semirigid and rigid copoly and modified copoly plastic; § 131.2590 Vinyl chloride-ethyl vinyl ether copolymers; § 131.2593 Vinyl chloride-chloroacrylate copolymers; § 131.2595 Vinyl chloride-acrylonitrile copolymers; § 131.2621 Microspheres polymers (flour).

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 limited if it can 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 406 of the act (21 U.S.C. 346) 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 likelihood 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 assumption 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 render food injurious to health, as requiring a showing of both possible migration and possible harm. The Commissioner concludes that the criterion of migration in section 301(a) of the act is appropriately used in applying section 402(a) of the act. Consequently, a prohibition of distribution component of a prior-sanctioned food-contact article comes within the terms of section 402(a) of the act if it may reasonably be expected to become a component of food. Since the regulations prohibit use of vinyl chloride upon ingestion is already sufficiently well demonstrated to warrant a determination that it may, if present, render food injurious to health, the only prior-sanctioned use 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 covered by food additive regulations a fair evaluation of the data before the Commissioner fails to establish their safety wherever 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, when 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 in the case 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 liquid 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 plasticized which are applied as liquid and are made from plastic resins containing thirty percent (1 phr) or less polyvinyl chloride and plasticizer. These plasticizers contain about 100 parts polyvinyl chloride and 50 parts plasticizer. Other gaskets are made by combining these plasticizers with other polyvinyl chloride resins. In addition to removal of residual vinyl chloride in the plasticizing process, additional vinyl chloride is thought to be removed when the product is heated to approximately 200° F for 5 to 6 minutes during application. The effect produced for residual vinyl chloride that enters after such processing, together with the fact that a gasket has only limited contact with food, leads to the conclusion that there is no reasonable expectation of migration of vinyl chloride into food. Similarly, an migration may be expected from cap liners cut from thin plasticized film, for the reasons previously discussed. However, in the case of all cap liners there will be only slight contact with food. Considering 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 jar and bottle caps and, in a much lesser extent, bottle food cans. Most of the polyvinyl chloride used for can coatings is produced by the radical 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 200° 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 disc liners, ranging in internal diameter from 1 to 3 inches and of an inch to 2 to 4 inches, are 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.

Tertiary incorporating vinyl chloride polymers in accordance with § 121.2343 (21 CFR 121.2343) are polymers which are prepared from natural or synthetic fibers and bonded with fibers. The fibers 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 fibers are formed by precipitating a solvent solution of the copolymer in water and then washing the precipitate until all solvent is removed. The fibers are comminuted with fibers prepared from polyethylene terephthalate resin to facilitate sheet formation and subsequently heat cured to form the fibers and sheet bonded. These procedures for manufacturing tertiary should result in a reduction 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.

Microscopic polymeric films used in accordance with § 121.2321 (21 CFR 121.2321) are based on polyvinyl chloride resins prepared by solution polymerization, which, as noted above, results in low levels of residual vinyl chloride. The films are prepared by adding dilute solutions to a solvent solution of the resin, resulting in "spinning" of the resin and further loss of residual vinyl chloride. The film 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 § 121.2321, would result in a reduction of any remaining vinyl chloride to the point that the Commissioner concludes that the use of microscopic polymeric films would not reasonably be expected to result in vinyl chloride becoming a component of food.

Adhesives containing vinyl chloride polymers in accordance with § 121.2323 (21 CFR 121.2323) 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 pipes, except as noted below for water pipes) 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 § 121.1178 (21 CFR 121.1178), 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 conclusions, the proposed regulations take the following approach:

1. Prior-sanctioned uses of vinyl chloride homopolymers and copolymers as container liners, coatings, and films, flexible tubing, and sheeting films would be identified in new rules permitting their continued use. This proposal identifies all such prior-sanctioned uses to the Commissioner. Persons aware of other prior-sanctioned uses should advise the Commissioner during the period for comment on this proposal.

2. Prior-sanctioned uses of vinyl chloride homopolymers and copolymers as container liners and food-contacting articles would be subject to continuing review in order that no migration would be expected to result in vinyl chloride becoming a component of food. This proposal would amend § 121.124 (21 CFR 121.124) of the regulations to provide that these products would be subject to continuing review. This review would be conducted by the Commissioner and would be based on the information for a food additive petition, submitted pursuant to § 121.121 (21 CFR 121.121) of the regulations. In addition to the other required information for a food additive petition, 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, gaskets, and liners, flexible tubing, and sheeting films that are not prior-sanctioned and that are not subject to food additive regulations are not currently authorized by this proposal. Such uses could be continued if they are otherwise generally recognized as safe. A petition to affirm such uses is currently required to date may be submitted pursuant to § 121.43 (21 CFR 121.43).

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), gaskets, and liners, flexible tubing, and sheeting films and to prohibit other uses except in water pipes as discussed below.

5. Food additive regulations specifically providing for the use of additives in the production of food-contacting 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 class of permitted polyvinyl chloride food-contacting 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 an 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 the judgment of the Commissioner. If there is no detectable vinyl chloride in a food-contacting article, and there are no detectable concentrations of vinyl chloride from the article upon food-contacting surfaces, and there is a sound theoretical basis for predicting no migration below the detectable level, e.g., the article is plasticized or treated with food-grade plasticizers, the Commissioner concludes that there is no reasonable expectation of migration. Where vinyl chloride is detected at a very low level in the food-contacting article, it may be necessary to determine whether that level is a reasonable expectation of migration based on theoretical concentrations similar to the migrating product and use. The Commissioner concludes that the detection of vinyl chloride concentrations in food-contacting articles upon testing conditions appropriate for food-contacting articles indicates that the residual vinyl chloride in the article may reasonably be expected to migrate into food. The Commissioner concludes that testing conducted with food-contacting articles is an appropriate method for establishing the likelihood of migration from a food-contacting article to food. Because of analytical difficulties, food often cannot be reliably tested for evidence of migration. For this reason, food-contacting articles have long been used both by industry and FDA in food-contacting 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. They have been made within recent months. Thus, additional classes of food-contacting 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 or uses should include data, analytical methodology used, and a theoretical analysis of the expectation of migration.

In the case of polyvinyl chloride potable water pipes, 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 § 121.6009 (21 CFR 121.6009), 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 communication were made, or adequate and appropriate studies were not undertaken, the regulation permitting continued use of polyvinyl chloride water pipe would be removed.

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 result 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 13, 1974 (39 FR 17308), 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-101. 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, 3000 P St., NW, Washington, DC 20007, as this proposal on the use of vinyl chloride polymers was being prepared. Much of the petitioner's comments has been considered in the drafting of this document. A letter will be sent to the petitioner responding to 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, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20850.

Published elsewhere in this issue of the *Federal Register* is a notice withdrawing a proposal to add § 121.5009 (21 CFR 121.5009) and incorporating the rule making proceeding on the use of polyvinyl chloride resin in articles for use in contact with alcoholic foods, which was begun on May 17, 1973 (38 FR 13021).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201 et seq., 202, 701, 801 Stat., 1941, 1960-1967) as amended, 1968, 1969 (21 U.S.C. 321 et seq., 342, 345, 371) and under authority delegated to him by 21 CFR § 1.139, the Commissioner proposes to amend Part 121, as follows:

1. In § 121.105 by adding new paragraph (c) as follows:

§ 121.105 Substances prohibited from use in human food.

(c)
(4) Vinyl chloride. (5) 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 polyvinyl's substances that may contact food.

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

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

(a) In coatings, paints, varnishes, finishes, 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:

§ 121.5009 Vinyl chloride polymers resin.

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 100° C, as determined by ASTM Method D 3099-72, and an inherent viscosity of not less than 0.50 as determined by ASTM Methods D 1243-68. 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 coat enamel.

(2) Vinyl chloride-vinyl acetate copolymer for use as a coat enamel.

(3) Vinyl chloride-butadiene-acrylonitrile copolymer for use as a component of conveyor belts intended for use with fresh fruits, vegetables, and fish, and as a component of coatings of paper and parchment in contact with food and feed.

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

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

(2) Vinyl chloride-butadiene-acrylonitrile copolymer for use in plasticized film in contact with environments.

(3) Vinyl chloride-chloroacrylonitrile copolymer for use in plasticized film in contact with food.

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

3. In § 121.5041, by amending paragraph (a) by revising the entry in the list of substances for "polyvinyl chloride" to read as follows:

§ 121.5041 Cellulose.

(a)
As the basic polymer for use only in coatings.

4. In § 121.5041, by amending paragraph (b) by revising the listing entries for "chlorinated polyethylene" and "chlorinated polyethylene" to read as follows:

§ 121.5041 Plasticizers in polymeric substances.
(b)

(c)

* Copies may be obtained from: American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

Dichlorovinyl
phthalate.

Limitations

For use only:

1. As provided in § 121.2007, 121.2008, 121.2009, and 121.2071.

2. Alone or in combination with other phthalates, in plastic film prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 121.2007 or in plastic sheet prepared from polyvinyl chloride, from plastic film or sheet that is used in contact with food at temperatures not to exceed 100° F. and shall contain no more than 10 percent by weight of total phthalates, calculated as phthalate in acid.

Dibutyl phthalate.
For use only:

1. As provided in § 121.2009.

2. Alone or in combination with other phthalates, in plastic film prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 121.2007 or in plastic sheet prepared from polyvinyl acetate, from plastic film or sheet that is used in contact with food at temperatures not to exceed 100° F. and shall contain no more than 10 percent by weight of total phthalates, calculated as phthalate in acid.

3. In § 121.2021, 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 § 121.4008.

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

§ 121.2541 Emulsifiers 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 § 121.2006, (1) by amending paragraph (b) by deleting the language for "hydroxyethyl 4,4'-isopropylidenebisphthalate-phosphate ester esters produced by the condensation of 1 mole of triphenyl phosphite and 1.5 moles of hydroxyethyl 4,4'-isopropylidenebisphthalate" and "poly(1,3-bis(4-hydroxyphenyl)-1,3,5-triazine-2,4,6-trisulfonyl)-1,3,5-triazine" having the formula (C₆H₄)₃N₃S₃ (where n is an integer 1-2), and by revising the listing for "4,4'-bispropylidenebisphthalate diethyl (C₆H₄)₂ phosphite" and (2) by adding a new paragraph (c) to read as follows:

§ 121.2544 Antioxidants and/or stabilizers for polymers.

(b) List of substances:

Limitations

4,4'-bispropylidenebisphthalate diethyl (C₆H₄)₂ phosphite. For use only as trace amounts (not exceeding 1.0 percent by weight) in rigid polymeric articles as permitted by § 121.4008 for water pipe and/or food contact containers containing less than 10 percent by weight of total phthalates, calculated as phthalate in acid.

(c) The use of the emulsifiers and/or stabilizers 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 § 121.2007 by amending paragraph (a) (2) by revising the listing entry for "vinyl chloride" and amending paragraph (a) (4) by revising the listing entries for "polyvinyl chloride," "vinyl chloride copolymers complying with § 121.2021," and "vinyl chloride-vinyl acetate copolymers" to read as follows:

§ 121.2007 Rigid and rigid vinyl chloride and modified acrylic plastics.

(a) . . .

(2) . . .

Vinyl chloride (only in water pipe as permitted by § 121.4008).

(4) . . . Polyvinyl chloride (only in water pipe as permitted by § 121.4008). Vinyl chloride copolymers complying with § 121.2021 (only in water pipe as permitted by § 121.4008).

Vinyl chloride-vinyl acetate copolymers (only in water pipe as permitted by § 121.4008).

9. In § 121.2007 by revising the introductory paragraph to read as follows:

§ 121.2007 Polymer emulsifiers in rigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admitted, alone or in mixture with other permitted polymers, as emulsifiers in rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers for use as provided in § 121.4008 for water pipe and/or from vinyl chloride copolymers complying with § 121.2021, § 121.2008, and/or § 121.2009, in accordance with the following prescribed conditions:

10. In § 121.2006 by adding a new paragraph (c) to read as follows:

§ 121.2006 Emulsifiers in vinyl chloride plastics.

(c) The finished food-contact articles in the form of coatings, gaskets, cap liners, flexible tubing, plasticized films, or water pipe as permitted by § 121.4008.

11. In § 121.2006, by revising the introductory text of paragraph (a) to read as follows:

§ 121.2006 Polyethylene alcohol derivatives of carboxylic acid (Carboxylic acid) emulsions can also.

(a) The polyethylene alcohol derivatives identified in this paragraph may be used as emulsifiers in the fabrication of vinyl chloride plastic food-contact articles, coatings, gaskets, cap liners, flexible tubing, plasticized films, and water pipe as permitted by § 121.4008 prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 121.2021. Such emulsifiers must also comply with the specifications and are produced by certain combinations of carboxylic acid (Carboxylic acid) emulsions and other esters of 1,3-bis(hydroxyphenyl) or 1,3-bis(hydroxyphenyl) groups with calcium hypochlorite.

12. In § 121.2006, by revising paragraph (c) to read as follows:

§ 121.2006 Vinyl chloride-hexyl vinyl other copolymers.

(c) Other specifications and limitations. (1) Vinyl chloride-hexyl vinyl other copolymers may be used only in coatings, gaskets, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4008.

(2) The vinyl chloride-hexyl vinyl other 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 in contact food.

13. In § 121.2009 by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) as follows:

PROPOSED RULES

4657

§ 121.2499 Vinyl chloride-ethylene copolymers.

(f) Vinyl chloride-ethylene copolymers may be used only in containers, gas-burners, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4000.

14. In § 121.3025 by revising paragraph (c) to read as follows:

§ 121.3025 Vinyl chloride-butene-1 copolymers.

(c) Other specifications and limitations. (1) The vinyl chloride-butene-1 copolymer identified in this section may be used in containers, gas-burners, cap liners, flexible tubing, plasticized films, and in water pipe as permitted by § 121.4000.

(2) The vinyl chloride-butene-1 copolymer identified in and consisting with this section, when used as components of the load-carrying 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 be used.

15. In Subpart II, by adding a new § 121.4000, to read as follows:

§ 121.4000 Vinyl chloride polymers.

(a) Vinyl chloride polymers may be used as a component of water pipe as an interior lining, 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 § 121.4000(c).

(b) Within 60 days of the effective date of this regulation, an interested person shall notify the Commissioner in writing that studies have been undertaken that are adequate and appropriate to evaluate 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 peak 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 1, 1975, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-05, 1400 Fishers Lane, Rockville, MD 20851, written comments regarding this proposal. Comments should be filed in quintuplicate (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, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drug,
(FR Doc. 74-20000 Filed 9-3-74; 9:45 am)

Social Security Administration
[20 CFR Part 405]
(Reg. No. 7)

FEDERAL HEALTH INSURANCE FOR
AGED AND DISABLED

Proposed Conditions of Participation by
Claims, Reimbursement Agencies, and
Public Health Agencies

Corrections

In FR Doc. 74-10000 appearing at page 2022 in the issue of Thursday, June 10, 1974, a line was dropped from paragraph (a) of § 405.1770(b) in the first column of page 2022. Immediately preceding the word "voluntarily" in the third line of (a) insert "initiated by a provider of services, a clinic."

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety
Administration

[49 CFR Part 571]

(Revised 9-24; Status I)

EXTENDED MOUNTED VEHICLE CARRIERS

Advance Notice of Proposed Rulemaking

This is an advance notice of proposed rulemaking, issued to solicit comments and information concerning Federal regulations for motor carriers mounted on the chassis of motor vehicles.

The Public Interest Research Group has petitioned the National Highway Traffic Safety Administration (NHTSA) to issue an advance notice of proposed rulemaking concerning motor carriers mounted on the chassis of motor vehicles. The NHTSA believes that the request of the petitioner has merit, and that the government derived from Federal Motor Vehicle Safety Standard No. 214, Exterior Protection (49 CFR 571.214), and future standards relating to pedestrian safety could be degraded by nonstandard designed motor vehicle bicycle carriers.

Initial applicability of this proposed rulemaking is extended to passenger bicycles carriers for use with passenger cars, multipurpose passenger vehicles, trucks and buses with GVWR of 14,000 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 mirrors, 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 vehicle.

Information concerning the following areas is specifically requested:

1. The extent of installation, injuries, and property damage resulting from carrier mounted motor vehicle bicycle carriers while the vehicle is either moving or parked.

2. Safety and hazard factors found in current designs for carrier mounted motor vehicle bicycle carriers.

3. Estimates and other relevant data concerning bicycle carrier volume of sales, current unit price, number of manufacturers, and other similar information concerning market characteristics.

4. Motor vehicle insurance rates and coverage for vehicles equipped with carrier mounted bicycle carriers.

Interested persons are invited to submit information, views, and arguments on the issues described and on the proposed subject of carrier mounted motor vehicle bicycle carriers. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 4104, 400 Congress Street, S.W., Washington, D.C. 20590. It is requested that comments be submitted by September 1, 1974.

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

Comments closing date: December 1, 1974.

Proposed effective date: 1 year after publication of rule.

When: 101, 114, Pub. L. 93-281, 90 Stat. 747 (16 U.S.C. 1601, 1607) on 101, Pub. L. 93-281, 90 Stat. 747 (16 U.S.C. 1601) description of authority of 49 CFR 571.214 and 571.215.

Dated on August 27, 1974.

Samuel L. Coons,
Assistant Administrator,
Motor Vehicle Program.

(FR Doc. 74-20000 Filed 9-3-74; 9:45 am)

DEPARTMENT OF LABOR

Wage and Hour Division

[29 CFR Parts 500, 502, 503, 507]

(Administrative Order No. 504)

INDUSTRY COMMITTEES FOR INDUSTRIES IN PUERTO RICO

Changes to Order of Hearings of Industry
Committees in Puerto Rico

Administrative Order No. 504, 49 FR 18019, set forth the order of hearings by Industry Committees Nos. 121-A through 127-D and Nos. 128-A through 128-F. At the request of certain interested parties and the agreement of other major parties, and pursuant to the authority vested in me under section 5 of the

ASI 00009292