

JONATHAN E. KELLER
JEROME H. HECKMAN
HARLES M. MEEHAN
WILLIAM H. BORGHESE, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MORRONE

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D. C. 20038

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

August 29, 1975

No. 2

TO: All Members of VCM/PVC Mailing Lists

Ladies and Gentlemen:

Enclosed herewith, so that you will not have to wait until next Wednesday to see the long anticipated Food and Drug Administration proposal to prohibit certain PVC food contact applications, are the following materials:

1. A reproduction of the proposal in type-written form. We obtained our copy from FDA late yesterday afternoon and have reviewed the same in a cursory fashion. We are not attempting to give you any comprehensive evaluation here since this would prevent our making an immediate mailing, and might also be ill-advised in light of the short time we have had for study of the situation.

The one thing we would like to say to you is please do not believe everything you may be reading in the lay press. The stories we have seen thus far totally distort the picture and oversimplify it so as to give rise to the impression that the ubiquitous Mr. Nader has won another major victory. Having read the proposal, my own opinion is that there is considerable flexibility in its tone and the actual substance. Indeed, I confess to some optimism that it may yet be very possible to develop or re-present data to the Food and Drug Administration which would permit coverage of some sort for semi-rigid

SPI-24455

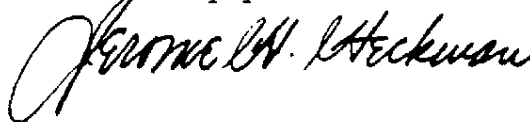
August 29, 1975
Page Two

and rigid PVC food packaging materials, including bottles. We will have more to say about this in due course but, meanwhile, we suggest that all of you read the enclosed document with the positive possibilities in mind. This is particularly important because our ultimate success or failure could well depend on your ingenuity and willingness to work on more sophisticated test methods and supply up to date extraction study results.

2. Also enclosed so that you can see for yourselves what type of press releases were the bases for these stories you have been reading or hearing in the media are the official HEW News Release of August 29, 1975 and the SPI Release which was prepared so that it could be supplied to the press essentially simultaneously with HEW's. I think you will agree after you look these Releases over that much of the press coverage has been terribly distorted. To say the least, this matter of having to suffer along with the publicity problem is most frustrating; it would seem that the substance of any situation has little to do with what the press reports.

Until we are in touch again, we will do our best to try to answer the questions we know you will be asking of us. We would also welcome any comments or suggestions you might care to make.

Cordially yours,



Enclosures

SPI-24456

HEW



NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

75-30

Embargoed for Friday A.M.
August 29, 1975

(Food and Drug Administration,
MALBIN--(202)--245-1144
(Home)--(202)--337-1526

The Food and Drug Administration today proposed to prohibit certain plastic food packaging and other food-contact materials made with vinyl chloride (VC).

Vinyl chloride, ordinarily a gas, has been shown to cause cancer when inhaled by humans and is suspected of having a similar potential when .. ingested.

The FDA proposal, to be published for public comment in the September 3, 1975, issue of the FEDERAL REGISTER, would ban the use of vinyl chloride plastics in bottles, blister packs, boxes and other semi-rigid and rigid packaging that comes in contact with food. The proposal would also prohibit VC plastics in coatings applied to fresh citrus fruits to retain freshness.

The proposed regulation would continue to permit VC plastics in pliable (plasticized) film-type wraps, gaskets, cap liners, tubing and package coatings which come in contact with food.

The action is based on evidence that residues of vinyl chloride may migrate into food from the semi-rigid, rigid and generally heavier VC plastics. No such migration has been found from the flexible and generally thinner VC plastics. A principal reason for the difference appears to be the plasticizing process used only in making the flexible materials. This process greatly reduces the residual VC, thus removing the migration problem.

-MORE-

SPI-24457

The FDA proposes no restriction at this time on the widespread use of vinyl chloride plastics in potable water pipes. Present evidence shows little likelihood that VC migrates from pipes being used to transport potable water. This is due to the low solubility of VC in water, the short time of contact, the large volume of water in contact with the pipe, and the comparatively low temperatures of exposure (most such pipes are underground.) In addition, whatever VC might conceivably migrate would be expected to dissipate during aeration and agitation of the water at the tap.

Continued FDA approval for VC use in water pipes, however, would be contingent upon additional confirmatory studies to be started within 60 days after the final regulation.

"FDA and the scientific community agree that vinyl chloride poses certain risks to human health," said Alexander M. Schmidt, M.D., Commissioner of Food and Drugs.

"Furthermore," said Dr. Schmidt, "there are available alternatives to the materials we propose to ban for use in contact with foods.

"The risk, therefore, is one that we as a nation can avoid. It is on this basis that the FDA proposes to act.

"We believe the proposal offered today for consideration by the American public deals practically, positively and constructively with the problem as we understand it," said the FDA Commissioner.

"In our best judgment, the situation does not warrant issuance of these regulations without an opportunity for public comment. Neither does it require recall and destruction of foods already packaged," concluded the Commissioner.

About 300 million pounds of VC plastic are used each year in the packaging of food, making it, after polyethylene, the second most commonly used plastic for this purpose. About 400 million pounds of VC plastic are used in the production of water pipes.

Until 1973, there was little concern about the safety of food-contact articles made from VC plastic because there was no evidence that vinyl chloride migrated from the plastic into the food.

In 1973, however, industry scientists reported that VC migrated from rigid polyvinyl chloride bottles into distilled alcoholic beverages. Upon confirmation of this finding, the FDA proposed that such plastics be limited to contact use with non-alcoholic foods. The U.S. Department of the Treasury then withdrew its approval for the use of PVC plastic bottles for distilled alcoholic beverages.

Since 1973, additional investigations have shown VC migration from packaging into food products such as vegetable oil, vinegar, and liquid vitamin supplements.

The regulations proposed today deal only with vinyl chloride contamination of food. Additional decisions will be made concerning use of vinyl chloride plastics in the cosmetic, drug and medical device fields.

Sixty days will be allowed for public comment on the proposed regulations, now scheduled to become effective 30 days after final publication in the FEDERAL REGISTER. Comments may be filed with the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.

#####

NOTE TO CORRESPONDENTS: Text of proposal available from the Press Office, Food and Drug Administration, HFI-45, Room 3807, 200 C Street, S.W., Washington, D.C. 20204.

SP

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.
250 PARK AVENUE • NEW YORK, NEW YORK 10017 • 212 687 2675

CONTACT: Jerry Blizin
(202) 638-2800

FOR IMMEDIATE RELEASE: AUG. 28, 1975

SPI WILL ASK FDA FOR HEARING
ON PVC FOOD PACKAGING RULES

WASHINGTON -- The Society of the Plastics Industry Inc. today said it will ask the Food and Drug Administration for a full hearing on its proposed rules which may ultimately govern polyvinyl chloride food packaging materials. The FDA proposal was released today.

"While the FDA proposal in effect reaffirms the safety of many PVC food packaging materials, such as can liners, gaskets and most meat wraps, we believe the Commission has acted with 'undue panic' in regard to the possibility of vinyl chloride migration into food from PVC bottles," said Ralph L. Harding, Jr., SPI president.

Harding said the fact that the FDA proposal contemplates interim regulations for use of PVC water pipe shows the agency recognizes the theoretical possibility of vinyl chloride migration to be non-existent and is therefore asking for more data to demonstrate this.

- more -

SPI-24460

"At the same time," he added, "the FDA proposal to withdraw the prior sanction on bottles is incomprehensible to us in light of the data the industry has submitted, which we believe will uphold our contention that there is no practical possibility of vinyl chloride monomer migration."

Vinyl chloride monomer is the gaseous raw material for polyvinyl chloride. The monomer can be carcinogenic to workers who breathe the gas at high concentrations over long periods of time.

However, industry has already taken steps to drastically reduce the amount of monomer which could remain in the finished plastic. It has already submitted data showing that today's bottle compounds contain less than 1 part per million of vinyl chloride monomer -- which means that the actual possibility of migration is nil.

"Our position is that FDA should not attempt to compute how many angels can be gathered on the head of a pin, or indulge in similar theoretical abstractions. We believe that if they evaluate the new data, our position will be upheld," Harding said.

SPI also pointed out that today's FDA proposal is not final. It is a proposal and SPI is confident that further proceedings will prove the complete safety of all PVC food packaging materials.

###

SPI-24461

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[21 CFR PART 121]

[DOCKET NO. 75N-0190]

VINYL CHLORIDE POLYMERS IN CONTACT WITH FOOD

NOTICE OF PROPOSED RULE MAKING

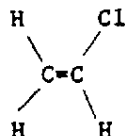
The Food and Drug Administration (FDA) is proposing regulations to restrict the uses of vinyl chloride polymers in contact with food. The proposal permits the continued use of vinyl chloride polymers in food packaging and other food-contact articles where the potential for migration of vinyl chloride 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 tap. 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 (insert date 60 days after the date of publication in the FEDERAL REGISTER) to submit comments.

75-514

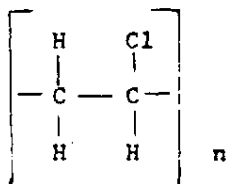
SPI-24462

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 800 units.

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

juice, 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(3):82, 1951, and "Food Packaging," Ibid., 20(4):159, 1956.

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 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 uses.

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 gas 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 2 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 maze, 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 gaskets, 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 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. 45-48, April 1975). 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 obvious 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 unadsorbed 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 sensitivities; 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, DC 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 0.35 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 analyses 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 supplied are on public display at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

Data supplied by SPI indicated that vinyl chloride could migrate to nonalcoholic foods from polyvinyl chloride bottles. Analyses of two samples of vegetable oils packed in polyvinyl chloride bottles revealed the presence of vinyl chloride at levels of 1.6 and 6.5 ppm. Reported results of analyses of additional samples of foods, drugs, and cosmetics disclosed varying levels of vinyl chloride, e.g., vinegar (5 ppb), mineral oil (74 ppb and approximately 2 ppm from two other samples), a vitamin supplement (approximately 1 ppm), and a mouthwash (174 ppb). No vinyl chloride was reported from a series of water samples

using an analytical method reportedly sensitive to 50 ppb. These latter samples had been collected from operating potable water systems of various polyvinyl chloride formulations at six different building sites.

In early 1974, the British Ministry of Agriculture, Fisheries, and Food reported finding vinyl chloride in concentrations ranging from 10 to 80 ppb in fruit squashes and from 10 to 40 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 (less than 0.025 to 0.98 ppm), gin (0.22 to 0.7 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, coatings, gaskets 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 0.35 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 migration of the residual vinyl chloride from a 1 mil (0.001 inch) film would result in 2 ppb vinyl chloride in food. These calculations assume that

10 grams of food contact each square inch of film, the film weighs 20 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 lower levels of migration into food would be expected to occur under actual conditions of use, to the point where they would be extremely small. The data substantiate this conclusion because the levels of extractable vinyl chloride have never been shown to approach 100 percent in those cases where actual values have been presented for article thickness, residual vinyl chloride level, and levels of extraction of vinyl chloride.

The greatest likelihood for migration of vinyl chloride appears to be from polyvinyl chloride bottles and other rigid or semirigid polyvinyl chloride articles that are intended for one-time use. A wide variety of products have been packaged in such containers, including vegetable oils, vinegar, honey, and liquid vitamin supplements. Large quantities of processed meats are packaged in rigid and semirigid containers composed of vinyl chloride polymers. Jelly, honey, and other condiments are frequently packaged in individual serving containers

composed of vinyl chloride polymers. These various articles range in thickness from approximately 7 mils to 30 mils. Semirigid articles with a thickness of 7 to 12 mils were reported in a submission from the American Meat Institute to contain 0 to 180 ppm residual vinyl chloride and to yield 4 to 20 ppb 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 6 to 127 ppm residual vinyl chloride and to yield 2 to 237 ppb 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 agitation 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 long-range effects, such as carcinogenicity.

Considerable data exist concerning the toxic effects of vinyl chloride from atmospheric exposures, especially by inhalation and occupational contact. As the Commissioner pointed out in his April 22, 1974, proposal (39 FR 14215) 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 acute toxicity manifested by an array of symptoms, including unconsciousness as a result of high concentration by inhalation. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported in animals.

The results from studies by Torkelson, et al., on the chronic effects of vinyl chloride on laboratory animals (T. R. Torkelson, F. Oyen, and V. K. Rowe, "The Toxicity of Vinyl Chloride as Determined

by Repeated Exposure of Laboratory Animals," American Industrial Hygiene Association Journal, 22(5), 354-361, 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 3 percent (30,000 ppm) vinyl chloride vapors for 4 hours per day for 5 days per week for 1 year (P. L. Viola, A. Bigotti, and A. Caputo, "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 3874), 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 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 ingestion (intubation) of vinyl chloride; and (4) experiments investigating endoperitoneal and subcutaneous routes of administration. (C. Maltoni & G. Lefemine: "Carcinogenicity Bio-assays of Vinyl Chloride," Environmental Research, 7:387-405, 1974 and "Le potenzialità dei saggi sperimentali nella predizione dei rischi oncogeni ambientali. Un esempio il cloruro di vinile," Accademia Nazionale Dei Lincei, 56:1-11, 1974). In addition to rats, 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 angiosarcoma of the liver, along with other types of tumors, at levels of atmospheric exposure as low as 250 ppm. At the New York Academy of Sciences meeting, May 10-11, 1974 ("Carcinogenicity Bioassays of Vinyl Chloride: Current Results." Annals of the New York Academy of Sciences, 246:195-218, January 31, 1975), he subsequently reported the development of angiosarcoma of the liver and other types of tumors at levels of atmospheric exposure as low as 50 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 similar low levels of vinyl chloride are also in progress

at Industrial Biotech Research Laboratories (IBRL) 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 35890), establishing standards for industrial exposure to vinyl chloride, the Occupational Safety and Health Administration stated:

- These investigators have induced angio-
 sarcoma 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 fre-
 quencies 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 26, 1974 (39 FR 30830), 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 26, 1974 (39 FR 14753), and the Consumer Product Safety Commission banned the use of other self-pressurized household products containing vinyl chloride, by a notice published in the FEDERAL REGISTER of August 21, 1974 (39 FR 30112).

Dr. Cesare Maltoni has issued a preliminary report concerning the progress of his studies investigating the effects of vinyl chloride when ingested (Cesare Maltoni, Adriano Ciliberti, Luciano Gianni, Pasquale Chieco, "Insorgenza Di Angiosarcomi in Ratti, in Sequito A Somministrazione Per Via Orale Di Cloruro Di Vinile," Gli Ospedali della Vita, Anno II, Numero 1, Gennaio-Febbraio 1975). Dr. Maltoni's study involves the administration to rats by intubation of vinyl chloride in an olive oil solution at dosage levels of 50 milligrams per kilogram of body weight, 16.5 milligrams per kilogram of body weight and 3.3 milligrams per kilogram of body weight. The study was initiated with 40 male and 40 female rats at each dosage level, plus a control group of the same number. After 52 weeks, the examination of those rats that had died revealed one rat in the highest dose group to have angiosarcoma of the thymus, and a rat in the 16.5 milligrams dose level was found to have angiosarcoma of the liver. No tumors were reported in the 3.3 milligrams dosage group or in the controls. The experiment is continuing with an anticipated completion date in early 1976. In addition, Dr. Maltoni has initiated an experiment using lower dosage 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 ingested. 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 dosage levels may be regarded by some persons as inconclusive evidence that vinyl chloride is carcinogenic when ingested. However, Dr. Maltoni reports that, to his knowledge, no spontaneous angiosarcomas of rats have been reported in the literature. Additionally, Dr. Maltoni reports that angiosarcoma 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(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)), 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 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 compositions, including

rigid and semirigid articles intended to contact foods. These letters were based on the premise that the uses and data cited in the Lehman articles for film 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 citrus fruit; § 121.2507 Cellophane;
§ 121.2514 Resinous and polymeric coatings; § 121.2520 Adhesives;
§ 121.2521 Vinyl chloride-propylene copolymers; § 121.2524 Polyethylene phthalate polymers; § 121.2526 Components of paper and paperboard in contact with aqueous and fatty foods; § 121.2543 Packaging materials for use during the irradiation of prepackaged foods;
§ 121.2545 Textryls; § 121.2550 Closures with sealing gaskets for food containers; § 121.2569 Resinous and polymeric coatings for polyolefin 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-lauryl vinyl ether copolymers;
§ 121.2609 Vinyl chloride-ethylene copolymers; § 121.2623 Vinyl chloride-hexene-1 copolymers; § 121.2631 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 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 201(s) of the act is appropriately used in applying section 402(a) of the act. Consequently, a poisonous or deleterious 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 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 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 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 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 those types are plastisols which are applied as liquid and are made from paste resins containing finely ground (1 micron or less) polyvinyl chloride and plasticizer. These plastisols contain about 100 parts polyvinyl chloride and 60 parts plasticizer. Other gaskets are made by combining these plastisols with other polyvinyl chloride resins. In addition to removal of residual

SPI-24486

vinyl chloride in the plasticizing process, additional vinyl chloride is thought to be removed when the plastisol is heated to approximately 350° F for 5 to 8 minutes during application. The small potential for residual vinyl chloride that exists 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, no migration may be expected from cap inserts 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. 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 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 thinness of the applied film and the baking it has received, at above 300° 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 2 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.

Textryls 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 fibryls. The fibryls 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 fibryls are formed by precipitating a solvent solution of the copolymer in water and then washing the precipitate until all solvent is removed. The fibryl is commingled with fibers prepared from polyethylene terephthalate resins to facilitate sheet formation and subsequently heat cured to fuse the fibryl and effect bonding. These procedures for manufacturing textryls should result in a reduction of the 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 § 121.2631 (21 CFR 121.2631) are based on polyvinyl chloride resins produced by solution polymerization, which, as noted above, results in low levels of residual vinyl chloride. The filters are prepared by adding silicon dioxide to a solvent solution of the resins, resulting in "opening" of the resins and further loss of residual vinyl chloride. The filter is formed by extrusion and calendering followed by a hot water wash to remove solvent. Each of these steps, together with the preuse treatment required by § 121.2631, 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 § 121.2520 (21 CFR 121.2520) 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 polymers 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 coatings, gaskets, cap liners, flexible tubing, and plasticized films would be identified in regulations permitting their continued use. This proposal identifies all such prior sanctions known to the Commissioner. Persons aware of other prior-sanctioned uses should submit proof of the sanctions during the period for comment on this proposal.

2. Prior-sanctioned uses of vinyl chloride homopolymers and copolymers in semirigid and rigid applications would no longer be permitted except in water pipe as discussed below. This proposal would amend § 121.106 (21 CFR 121.106) of the regulations to so provide. Once these proposed regulations become final, vinyl chloride polymers could be used in semirigid and rigid applications only after approval of a food additive petition, submitted pursuant to § 121.51 (21 CFR 121.51) 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, cap liners, flexible tubing, and plasticized films that are not prior-sanctioned and that are not subject to food additive regulations are not expressly affected by this proposal. Such uses could be continued if they are otherwise generally recognized as safe. A petition to affirm such uses as generally recognized as safe may be submitted pursuant to § 121.40 (21 CFR 121.40).

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, 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 adjuvants 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 "compound" 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 extractives 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 appropriate for food-contact 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-simulating solvents is an appropriate method for ascertaining the likelihood of migration from a food-contact article to food. Because of analytical difficulties, food often cannot be reliably 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 not 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 § 121.4000 (21 CFR 121.4000), 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 satisfy 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 commitment 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 13285), 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 proposed regulations, and has found that the proposed action would not cause a major inflation impact as defined in OMB Circular A-107. 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 assessments 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, 1975 from Public Citizen's Health Research Group, 2000 P St., NW., Washington, DC 20036, as this proposal on the use of vinyl chloride polymers was being prepared. Each 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 reports 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 20852.

Published elsewhere in this issue of the FEDERAL REGISTER is a notice withdrawing a proposal to add § 121.2009 (21 CFR 121.2009) and terminating 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 12931).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 402, 409, 701, 52 Stat. 1042, 1046-1047 as amended, 1049, 1055 (21 U.S.C. 321(s), 342, 348, 371)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 121, as follows:

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

§ 121.106 Substances prohibited from use in human food.

★ ★ ★ ★ ★

(e) ★ ★ ★

(4) Vinyl chloride. (i) Vinyl chloride has the molecular formula C_2H_3Cl . 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:

§ 121.2009 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 3030-72,^{1/} and an inherent viscosity of not less than 0.35 as determined by ASTM Method D 1243-66.^{1/}

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 copolymer for use as a can enamel.

^{1/}

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

(3) Vinyl chloride-butadiene-acrylonitrile copolymer for use as a component of conveyer belts intended for use with fresh fruits, vegetables, and fish, and as a component of coatings of paper and paperboard in contact with meat and lard.

(4) Vinyl chloride-vinylidene chloride copolymer 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 copolymer for use in plasticized film in contact with oleomargarine.

(3) Vinyl chloride-vinylidene chloride 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 § 121.2507, by amending paragraph (c) by revising the entry in the list of substances for "polyvinyl chloride" to read as follows:

§ 121.2507 Cellophane.

★ ★ ★ ★ ★

(c) ★ ★ ★

Limitations ***

★ ★ ★

★ ★ ★

Polyvinyl chloride

As the basic polymer for use only
in coatings.

★ ★ ★

★ ★ ★

★ ★ ★ ★ ★

4. In § 121.2511, by amending paragraph (b) by revising the listing entries for "dicyclohexyl phthalate" and "diphenyl phthalate" to read as follows:

§ 121.2511 Plasticizers in polymeric substances.

* * * * *

- (b) * * *

Limitations

* * *

* * *

Dicyclohexyl
phthalate.

For use only:

1. As provided in §§ 121.2507, 121.2520, 121.2526, 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 § 121.2520.
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 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 § 121.2566, (1) by amending paragraph (b) by deleting the listings for "hydrogenated 4,4-isopropylidenediphenol-phosphite ester resins produced by the condensation of 1 mole of triphenyl

phosphite and 1.5 moles of hydrogenated 4,4'-isopropylidenediphenol" and "poly[(1,3-dibutyldistanthianediylidene)-1,3-dithio] having the formula $[C_8H_{18}Sn_2S_3]_n$ (where n averages 1.5-2)", and by revising the listing for "4,4'-isopropylidenediphenol alkyl (C_{12} - C_{15}) phosphites" and, (2) by adding a new paragraph (c) to read as follows:

§ 121.2566 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) List of substances:

	<u>Limitations</u>
* * *	* * *
4,4'-Isopropylidenediphenol alkyl (C_{12} - C_{15}) phosphites; the phosphorus content is in the range of 5.2-5.6 weight percent.	For use only at levels not exceeding 1.0 percent by weight in rigid polyvinyl chloride as provided in § 121.4009 for water pipe and/or rigid vinyl chloride copolymers complying with §§ 121.2521, 121.2608, or 121.2609.

* * *

* * *

(c) The use of the antioxidants 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 § 121.2591 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 § 121.2521," and "vinyl chloride-vinyl acetate copolymers" to read as follows:

§ 121.2591 Semirigid and rigid acrylic and modified acrylic plastics.

★ ★ ★ ★ ★
(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 semirigid 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, § 121.2608, and/or § 121.2609, in accordance with the following prescribed conditions:

* * * * *

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

§ 121.2602 Octyltin stabilizers in vinyl chloride plastics.

* * * * *

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

11. In § 121.2605, by revising the introductory text of paragraph (a) to read as follows:

§ 121.2605 Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids.

• • • • •

(a) The polyhydric alcohol diesters identified in this paragraph may be used as lubricants in the fabrication of vinyl chloride plastic food-contact articles (coatings, gaskets, cap liners, flexible tubing, plasticized films, and water pipe as permitted by § 121.4009) prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 121.2521. Such diesters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthoffen process) montan wax acids by either ethylene glycol or 1,3-butanediol with or without neutralization of unreacted carboxylic groups with calcium hydroxide:

• • • • •

12. In § 121.2608, by revising paragraph (e) to read as follows:

§ 121.2608 Vinyl chloride-lauryl vinyl ether copolymers.

• • • • •

(e) Other specifications and limitations. (1) Vinyl chloride-lauryl 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-lauryl 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:

§ 121.2609 Vinyl chloride-ethylene copolymers.

* * * * *

(f) Vinyl chloride-ethylene copolymers may be used only in coatings, gaskets, cap 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-hexene-1 copolymers.

* * * * *

(c) Other specifications and limitations. (1) The vinyl chloride-hexene-1 copolymers identified in this section may be used in coatings,

gaskets, cap liners, flexible tubing, plasticized films, and in water pipe as permitted by § 121.4009.

(11) The vinyl chloride-hexene-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 regulations for the article in the finished form in which it is to contact food.

15. In Subpart H, by adding a new § 121.4009, 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 § 121.4000(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 (insert date 60 days after date of publication in the FEDERAL REGISTER), 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 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: AUG 27 1975.

A. M. Schmidt.

A. M. Schmidt
Commissioner of Food and Drugs

SPI-24511