TX 00462 HC2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 175, 176, 177, 179, and 181

[Docket No. 75N-0190]

Vinyl Chloride Polymers; Withdrawal of Proposal

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the notice of proposed rulemaking that would have restricted the uses of vinyl chloride polymers in contact with food. The agency is taking this action because, based upon new scientific and legal developments, FDA has decided that the actions outlined in the proposal no longer represent the appropriate course of regulatory action.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food and Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 3, 1975 (40 FR 40529), FDA proposed to prohibit some uses of vinyl chloride polymers (homo- and copolymers), including their use in semirigid and rigid food-contact articles such as bottles and sheet, and to interim list the use of these polymers in water pipe.

Since publication of the proposal, there have been a number of significant developments that bear on the agency's position concerning regulation of vinyl chloride polymers. The major developments include: (1) Vastly improved production technology has made it possible for manufacturers to succeed in reducing the level of residual vinyl chloride monomer in vinyl chloride polymer by a factor of nearly 1 million; (2) the agency has developed a policy concerning the regulation of food and color additives that may contain carcinogenic impurities; and (3) FDA now believes that developments in scientific technology and its experience with risk assessment procedures make it possible for the agency to determine whether the use of additives that contain carcinogenic impurities is safe. As a consequence of these developments, many of the issues raised by the September 1975 proposal and by the comments on that proposal are moot. FDA now believes that the use of vinyl chloride polymers can be regulated provided that such polymers meet certain limitations on the levels of residual vinyl chloride monomer.

In the Federal Register of March 15, 1977 (42 FR 14302), FDA reorganized and republished regulations formerly codified in 21 CFR Part 121. In the present document, FDA will refer to the old Part 121 section numbers and, if appropriate, to the recodified section numbers.

Elsewhere in this issue of the Federal Register, FDA is proposing: (1) To provide for the safe use of vinyl chloride polymers; (2) to codify all known prior sanctions of vinyl chloride polymers; (3) to provide for the use of certain previously unregulated vinyl chloride polymers in manufacturing vinyl chloride bottles; and (4) to delete vinyl chloride-vinylidene chloride copolymers from the list of materials that may be used as coatings on fresh citrus fruit (21 CFR 172.210).

FDA received 190 comments on the September 1975 proposal. One hundred fifty-four of these comments did not include any data on the use of vinyl chloride polymers. Of these comments, 86 supported the proposal; 57 expressed concern about the risk associated with the use of vinyl chloride polymers; and 11 opposed the proposed ban on rigid and semirigid vinyl chloride polymers. The remaining 36 comments did submit data or legal arguments for FDA's consideration.

In addition, the docket contains 15 supplements to comments; 21 letters from industry, professional societies, public interest groups, and individuals; 11 memoranda of meetings; and 11 memoranda of telephone conversations. None of the additional letters and memoranda contained data, but the 15 supplements to comments contained scientific data that FDA reviewed and evaluated.

All comments received in response to the proposal are addressed in this document.

A. Nomenclature

1. One comment stated that vinyl chloride should be referred to as "vinyl chloride monomer" or as "VCM" in the various proposed regulations to prevent any misunderstanding about what particular substance is being prohibited. The comment further stated that the identification of vinyl chloride monomer should include its chemical formula (C_2H_3Cl), its alternative name "chloroethene," and its Chemical Abstracts Registry Number (CAS Reg. No.).

FDA agrees that it should use the CAS Reg. No. and the term "vinyl chloride monomer" to identify the monomer. It has done so in the proposal published elsewhere in this issue of the Federal Register. The term "chloroethene" is not a commonly used term for vinyl chloride. FDA concludes that vinyl chloride is adequately defined by its chemical formula and its CAS Reg. No.

2. One comment stated that vinyl chloride-vinylidene chloride copolymer should be renamed vinylidene chloride-vinyl chloride copolymer to reflect the relative dominance of the monomers. It noted that vinylidene chloride is the more dominant monomer in copolymers of vinyl chloride and vinylidene chloride.

FDA concludes that vinyl chloride-vinylidene chloride copolymers should continue to be so named. Vinyl chloride has customarily been the first monomer cited in industry usage and in food additive regulations when referring to copolymers, regardless of the major component. Although there may be some advantage to naming copolymers by the predominance of monomers, renaming the copolymers would only lead to confusion and unnecessary paperwork.

B. Administrative—Legal

3. Five comments stated that FDA did not have the statutory authority to issue food additive regulations prescribing conditions of use for a substance that may not reasonably be expected to become a component of food. The comments claimed that there was no expectation of migration of vinyl chloride monomer into food from the use of vinyl chloride polymer packaging.

Section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) defines a food additives as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, and including any source of radiation intended for any such use) * * *" (21 U.S.C. 321(s)). Section 409(d) of the act (21 U.S.C. 348(d)) authorizes FDA to establish regulations prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used.

Vinyl chloride polymer becomes a component of food (a food additive) when the unreacted vinyl chloride monomer trapped in the polymer matrix migrates from the polymer to food. The data, both experimental and theoretical, produced by industry and by FDA laboratories about vinyl chloride polymers demonstrate that, under

normal conditions of use, migration of vinyl chloride monomer will occur from all types of vinyl chloride polymer food-contact articles, regardless of the levels of the monomer in the articles. The amount of vinyl chloride monomer that migrates to food will depend on the initial residual monomer content, the time and temperature of exposure to food, the thickness of the polymer, and such other properties of the polymers as their permeability and whether they have been plasticized.

One example of the work done on vinyl chloride monomer is that of Ethyle Corp. In a series of reports dating from January 17, 1975, Ethyl proposed and utilized a diffusion model that accurately predicted levels of vinyl chloride monomer migration into food simulating solvents. Based on this model's success in predicting the observed levels of monomer migration, Ethyle's diffusion model can be relied upon to predict the level of such migration even when the monomer is not detectable by current analytical capabilities.

On the basis of existing theories, diffusion models, and available experimental data, FDA concludes that vinyl chloride monomer is capable of migrating into food from vinyl chloride polymers in more than insignificant amounts. The use of models capable of predicting monomer migration has been addressed in *Monsanto* v. *Kennedy*, 613 F.2d 947 (1979), where the court stated: "Nor is it necessary that the level of migration be significant with reference to the threshold of direct detectability, so long as its presence in food can be predicted on the basis of a meaningful projection from reliable data."

FDA has further concluded that, given the fact that vinyl chloride monomer has been shown to be a carcinogen, the projected vinyl chloride monomer migration from vinyl chloride polymers under the conditions of use currently specified in its regulaions is not so small as to present no public health or safety concerns. The agency finds, however, that safety can be assured through the establishment of limits on residual monomer concentrations, as proposed elsewhere in this issue of the Federal Register. The agency, therefore, is exercising its authority under section 409 of the act to promulgate regulations that would prevent the marketing of polymers with unsafe levels of vinyl chloride monomer.

4. One comment contended that there was no reasonable expectation of migration and, also, that the polymers were not food additives. The comment requested a hearing if its point of view was not incorporated into the agency's final action on vinyl chloride polymers.

FDA disagrees with this comment. FDA has explained why it has concluded that the vinyl chloride monomer will migrate in response to the preceding comment. In regard to a request for a public hearing, section 409(f)(1) of the act provides that, within 30 days after publication of a final order on a food additive, any person adversely affected by the order may file objections to the order and may request a public hearing on the matter. There are no provisions in section 409 of the act for requesting a public hearing in response to a notice of proposed rulemaking, although this request may be made in response to final regulations on this subject.

5. Two comments stated that no final action to ban rigid and semirigid vinyl chloride polymers should be taken until an examination has been made of the potential migration from currently produced vinyl chloride polymers that contain low levels of residual vinyl chloride monomer.

FDA has reviewed the data on the migration of vinyl chloride monomer from polymers that contain varying levels of residual monomer (Division of Chemistry and Physics memorandum dated July 27, 1979). The agency concludes that migration of the monomer into food will occur if there is any residual monomer in the polymer. The new proposed regulations published elsewhere in this issue of the Federal Register reflect this determination.

6. Two comments objected to permitting any use of vinyl chloride polymers in contact with food because of the presence of a carcinogen (vinyl chloride monomer) in these polymers. The comments claimed that, by permitting the use of these polymers, FDA was, in effect, setting a tolerance for a carcinogen at the level of sensitivity of the analytical methods to detect vinyl chloride monomer. The comment stated that all uses of vinyl chloride polymers should be banned until manufacturers can produce vinyl chloride polymers that contain no vinyl chloride monomer.

FDA agrees that vinyl chloride polymers with unsafe levels of vinyl chloride monomer should not be permitted on the market. However, FDA does not believe that banning vinyl chloride polymers is necessary because these polymers now can be manufactured with residual vinyl chloride monomer levels that are at least one million times lower than the residual monomer levels in polymers that were marketed in the early 1970's. Additionally, since the publication of the 1975 notice of proposed rulemaking, scientific developments, such as improved risk assessment procedures, have led FDA to reconsider how it regulates food and color additives when the additive as a whole contains carcinogenic impurities but has not been shown to be a carcinogen in appropriate testing. As a result of its reconsideration, the agency has decided that it can approve or list the use of such additives when an assessment shows that the risk from the use of these additives, with their carcinogenic impurities, is so low that there is a reasonable certainty of no harm from their use. The application of this approach to vinyl chloride polymers is described in detail in the notice of proposed rulemaking appearing elsewhere in this issue of the Federal Register.

7. Four comments suggested that proposed § 121.2009 *Vinyl chloride polymer resins*, which listed the prior-sanctioned uses of vinyl chloride polymers, should be revised to permit the use of polymers listed in that section in articles that will contact all types of food or should be revised to allow the use of additional types of articles produced from vinyl chloride polymers.

The agency finds that such a revision is inappropriate. Proposed § 121.2009 was intended to be a listing of those uses of vinyl chloride polymers that are the subject of prior sanctions, i.e., those uses that were approved by FDA or the U.S. Department of Agriculture (USDA) before September 6, 1958. The list of such uses cannot be altered or expanded to include additional uses without proof that those additional uses were approved by FDA or USDA before that date.

Therefore, the agency cannot expand the prior-sanctioned uses of vinyl chloride polymers to cover contact with all types of food as proposed in these comments.

In the 1975 proposal, FDA listed those prior sanctions for which it could find evidence and explicitly solicited evidence of any additional sanctions. No evidence of other prior sanctions was submitted to FDA. FDA, however, located in its own files evidence of four additional prior sanctions. (1. Letter to Firestone Plastics Co., Pottstown, PA, dated April 20, 1951, permitting the use of vinyl chloride resins as films for food packaging. 2. Letter to Firestone Plastics Co., Pottstown, PA, dated October 5, 1956, permitting the use of rigid polyvinyl chloride (homopolymer) sheet for packaging poultry. 3. Letter to Firestone Plastics Co., Pottstown, PA,

dated February 21, 1957, permitting the use of vinyl chloride and vinyl chloride-acetate resins for "food wrapping purposes." 4. Letter of Borden Co., Santa Barbara, CA, dated August 15, 1957, permitting the use of vinyl chloride polymers as tubing for food-contact use.) The agency has included these sanctions in its proposal published elsewhere in this issue of the **Federal Register**. The agency believes that all valid prior sanctions of vinyl chloride polymers are set forth in the new proposal.

8. Two comments stated that the wording of proposed § 121.2009(a)(3) should be revised to provide a proper description of the materials used for coating conveyor belts. The comments asserted that these materials are blends of vinyl chloride homopolymer and butadiene or butadiene/acrylonitrile copolymer rather than "vinyl chloride/butadiene" or "vinyl chloride/butadiene/acrylonitrile" copolymer, as described in the proposal.

The original letters received by FDA on the conveyor belt coatings referred to the coatings as "resins," a term broadly applied to any thermoplastic material. Although the letters that FDA wrote in response refer to the conveyor belt coatings as copolymers, the coatings were never identified as copolymers by the manufacturers. The agency, in reviewing these records, finds that the records contain no data that would limit the prior sanctions to copolymers rather than blends.

Accordingly, in the proposal published elsewhere in this issue of the **Federal Register**, FDA has revised § 181.37 (proposed as § 121.2009(a)(3)) to use the term "resin," rather than "copolymer," to refer to both the resin blend and the copolymer.

9. One comment stated that all food packaged in vinyl chloride polymers or prepared with equipment in which the food will come into contact with vinyl chloride polymers should be so labeled.

FDA has considered this comment and has concluded that the requested labeling is not necessary to ensure the safety of foods that contact vinyl chloride polymers. In a notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**, FDA sets forth proposed regulations that contain limitations on the amount of residual vinyl chloride monomer that may be present in various types of vinyl chloride food contact surfaces. FDA also sets forth in that proposal the basis on which it has tentatively concluded that vinyl chloride polymers that meet the proposed limitations are safe for food-contact use. Therefore, there is no need to label foods that have contacted vinyl chloride polymers.

10. One comment stated that the use of vinyl chloride polymers as coatings on fresh citrus fruits, which is permitted under 21 CFR 121.1179 (now 21 CFR 172.210), has been discontinued.

After publication of the 1975 proposal, the major producer of vinyl chloride-vinylidene chloride copolymers informed FDA that it was unaware of any market for the coatings on fresh citrus fruit (Telecommunication, M. Flood to J. Cobler, September 30 and October 3, 1983, Dow Chemical Co.). On the basis of this information, the agency is proposing elsewhere in this issue of the **Federal Register** to revoke the regulation for the use of vinyl chloride polymers as coatings on fresh citrus fruit.

11. Four comments were received objecting to the inclusion of rigid and semirigid polymers in § 121.106 *Substances prohibited from use in human food* (now 21 CFR Part 189).

FDA has now completed its evaluation of all safety data pertinent to the use of rigid and semirigid vinyl chloride polymers and has tentatively concluded that safe conditions of use can be prescribed for these polymers. Therefore, rather than banning the use of these polymers, elsewhere in this issue of the **Federal Register**, FDA is proposing to approve certain uses of these substances.

C. Chemistry

12. Seven comments stated that one or more of the proposed regulations should be revised to permit all uses of vinyl chloride polymers for which there is no reasonable expectation of migration of vinyl chloride monomer to food.

Five of these comments contained data for calculations to support the contention that when a food-contact article does not contain detectable levels of vinyl chloride monomer, the potential amount of migration of this monomer is so insignificant as to make it unreasonable to expect that vinyl chloride polymer will become a component of food. One comment further stated that a regulation permitting the use of all vinyl chloride polymers when there was no detectable residual vinyl chloride monomer in the food-contact articles or not detectable migration of vinyl chloride monomer to food would adequately protect the public health.

A number of these comments discussed specific processes used to remove "all" residual vinyl chloride monomer from vinyl chloride polymers. According to the comments, these processes produced polymers in which there were either very low levels (i.e., 2 to 50 parts per billion (ppb)) or no detectable amount of residual vinyl chloride monomer because the steps taken during these fabrication processes were adequate to remove all of the residual vinyl chloride monomer.

On the basis of all available evidence, FDA has concluded that under normal use conditions, migration of vinyl chloride monomer will occur from all types of vinyl chloride polymer articles (see response to comment 3). The amount of vinyl chloride monomer that will migrate is determined by the nature of the articles (e.g., film, bottle, or coating); the residual vinyl chloride monomer content; and the conditions of use (time and temperature of exposure to food).

The agency is aware that over the past 10 years, the manufacturers of vinyl chloride polymer products have succeeded in reducing the levels of residual vinyl chloride monomer by a factor of nearly a million. However, the data that FDA has received from industry clearly establish that vinyl chloride polymers still contain measurable levels of vinyl chloride monomer, and that available diffusion theory relates the level of monomer in the polymer to the level of monomer in the food, even though the level may be below current analytical detection limits. Therefore, FDA concludes that regulation should be based on safe upper limits of migration rather than the level of detectability.

13. One comment stated that as the level of residual vinyl chloride monomer in a vinyl chloride polymer is reduced, there is a corresponding reduction in the migration of the monomer. The comment theorized that there are sites in a polymer to which some monomer can attach. These sites are called "active binding sites." The comment asserted that these active binding sites prevent migration of the monomer when there is less than 0.1 part per million of residual monomer. The comment argued that as a result, FDA had no authority to regulate the polymer when it contained such low levels of the monomer.

FDA finds that the available experimental data on the process of migration of vinyl chloride monomer from vinyl chloride polymers do not support this theory (Division of Chemistry and Physics memorandum dated July 27, 1979).

FDA's evaluation of the data on vinyl chloride migration that were submitted as comments to the 1975 proposal by Ethyl Corp. revealed that under normal use condition, migration of vinyl chloride monomer will occur from all

types of vinyl chloride polymers, regardless of the monomer level in the polymers. Although the alternative "active site" theory, if correct, would predict zero migration of vinyl chloride monomer to food at some minimum residual monomer level, no experimental data have been submitted to FDA that would confirm the theory. A more detailed discussion of the migration issue is contained in the notice of proposed rulemaking published elsewhere in this issue of the Federal Register.

14. One comment outlined a mathematical model that reportedly predicted the extractable levels of vinyl chloride monomer from any level of residual vinyl chloride monomer in vinyl chloride polymers. The comment stated that, based on the model and the low concentration of residual vinyl chloride monomer in its product, there is not a reasonable possibility of migration of vinyl chloride monomer.

FDA disagrees and finds, upon evaluation of the model, that the model predicts zero migration only if there is no monomer in the food container (Division of Chemistry and Physics memorandum dated July 27, 1979). FDA is not aware at this time of any manufacturing process that can produce vinyl chloride polymers without some level of residual vinyl chloride monomer being present. The diffusivity of the vinyl chloride monomer is discussed briefly in comment 12 and at length in the notice of proposed rulemaking published elsewhere in this issue of the Federal Register.

15. Three comments stated that the proposed regulations should be revised to exempt specific types of packaging such as laminates and packaging for dry solids. The comments stated that food packaged in such containers would not be expected to contain vinyl chloride monomer as a result of migration from the packaging materials.

As discussed in response to comment 12, the agency concludes that use of vinyl chloride polymers as components of the types of packaging materials described in these comments will result in low levels of migration of vinyl chloride monomer. However, the agency is proposing to permit such use of vinyl chloride polymers, with limitations on the levels of residual vinyl chloride monomer, as set forth in the proposed rule published elsewhere in this issue of the Federal Register.

16. One comment stated that the restrictions on the use of rigid and semirigid articles should be revised to permit their use with dry food, or that the proposed restrictions in the regulations for adjuvants should be eliminated.

As explained in the proposal published elsewhere in this issue of the Federal Register, based on the improvements in the manufacturing process for vinyl chloride polymers and on other scientific and legal developments, FDA now believes that it can approve the use of vinyl chloride polymers in rigid and semirigid articles not only with dry food but also with aqueous, alcoholic, and fatty foods. Because FDA is no longer proposing to ban these uses of rigid and semirigid vinyl chloride polymers, the question of restriction of adjuvants for use in rigid and semirigid vinyl chloride polymers is moot. However, FDA is proposing to delete certain adjuvants currently regulated for use in vinyl chloride/vinylidene chloride copolymer coatings for fresh citrus fruit. The use of this copolymer for coating fresh citrus fruit was discontinued several years ago and there is no longer a need for the regulation. The deletion of this use of these adjuvants from FDA's regulations has no effect on their other regulated uses.

D. Toxicology

17. One comment stated that the use of vinyl chloride polymers in rigid and semirigid food-contact articles should be permitted on an interim basis pending the outcome of studies necessary to demonstrate the safety of such polymers. The comment stated that FDA had based the proposed regulations on preliminary reports, speculation, and rumors, and that animal feeding studies to demonstrate the toxicity of vinyl chloride monomer when ingested were now underway and were expected to be completed within 30 months.

Since this comment was submitted, FDA has received four reports of completed bioassay studies on the carcinogenicity of vinyl chloride monomer. These include: (1) Feron et al. chronic rat oral study performed at the CIVO Institute TNO in the Netherlands (*Food and Cosmetics Toxicology*, 19:317–330, 1981); (2) Maltoni et al. rat study on vinyl chloride monomer by both oral ingestion and inhalation routes of exposure (*Annals of the New York Academy of Sciences*, 246:195–218, 1975; *Environmental Health Perspectives*, 41:3–29, 1981); (3) The British Industrial Biological Research Association unpublished rat study on vinyl chloride monomer administered in the drinking water for up to 152 weeks (the final report entitled "An Investigation Into the Carcinogenic Potential of Vinyl Chloride Monomer When Administered to Rats in the Drinking Water for Up to 152 Weeks," dated 1980); (4) CIVO Institute TNO second unpublished rat study on vinyl chloride monomer (the final report entitled "Lifespan Oral Carcinogenicity Study of Vinyl Chloride in Rats," dated September 1983).

The agency has determined that vinyl chloride monomer is a carcinogen via oral route of exposure on the basis of the results from these studies.

Elsewhere in this issue of the Federal Register, FDA is proposing to establish safe conditions of use for vinyl chloride polymers. FDA believes that vinyl chloride polymers can be regulated under the agency's carcinogenic impurities policy, which is described elsewhere in this document and in the accompanying notice of proposed rulemaking. FDA has used this policy to regulate food and color additives that contain carcinogenic impurities but which themselves have not been found to be carcinogenic.

The agency's proposed regulations published elsewhere in this issue of the Federal Register deal with the uses of vinyl chloride polymers including rigid and semirigid articles and the specific limitations that are needed to ensure their safe use.

E. Environmental Impact

18. One comment stated that, under the proposed regulations, products expected to substitute for vinyl chloride polymer products would have far greater environmental impacts than vinyl chloride polymer. In addition, the comment suggested that vinyl chloride polymer could be efficiently burned in properly designed and operated incinerators.

The agency's proposal, set forth elsewhere in this issue of the Federal Register, provides conditions for the safe use of regulated and prior-sanctioned vinyl chloride polymers. This proposed action is in contrast to the 1975 proposal, which would have prohibited certain uses of vinyl chloride polymers. FDA has prepared two documents, an environmental assessment and a finding of no significant impact, that evaluate the potential impact, both adverse and beneficial, expected from the increased use of vinyl chloride polymers. These documents consider the environmental factors addressed in the comment's submission. The environmental assessment and the finding of no significant impact may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

F. Economic Impact

19. One comment stated that the proposed regulations appeared to be more restrictive than necessary to assure protection of the public health from ingestion of vinyl chloride and discussed shortcomings and omissions in FDA's analysis of potential economic impact of the regulations. Another comment contained data concerning the economic impact the proposed regulations would have upon the firm.

FDA has considered these data and comments in preparing the economic assessment on the proposed regulations published elsewhere in this issue of the Federal Register. The economic assessment may be seen at the Dockets Management Branch (address above).

G. Conclusions

Since the publication of the September 1975 proposal, there have been significant scientific and legal developments that have caused FDA to reconsider its proposed regulations on the use of vinyl chloride polymers. Improvements in the manufacturing process have enabled vinyl chloride polymer manufacturers to lower greatly the levels of residual vinyl chloride monomer in the polymers. This development, along with procedures for risk assessment, now make it possible for the agency to establish safe conditions of use for vinyl chloride polymers. Details of the scientific and legal developments as well as the risk assessment are set forth in the notice of proposed rulemaking published elsewhere in this issue of the Federal Register.

The agency has also developed a policy for providing for the safe use of food additives and color additives containing low levels of carcinogenic impurities. This policy was set forth in an advance notice of proposed rulemaking published in the Federal Register of April 2, 1982 (47 FR 14463). The use of this policy was upheld by the U.S. Court of Appeals in *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984), a case involving FDA's decision to list permanently the use of D&C Green No. 5. This color additive contains a carcinogenic impurity, but when the additive as a whole was tested in laboratory animals it did not induce cancer. This policy is explained in detail in that document (47 FR 14463).

Accordingly, FDA is withdrawing the proposal published in the Federal Register of September 3, 1975 (40 FR 40529). Published elsewhere in this issue of the Federal Register is a notice of proposed rulemaking that would authorize the safe use of regulated and prior-sanctioned vinyl chloride polymers.

This action is taken 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 the Commissioner of Food and Drugs (21 CFR 5.10).

Dated: January 27, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86-2236 Filed 1-31-86; 8:45 am]

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21 CFR Parts 172, 175, 176, 177, 179, and 181

[Docket No. 84N-0334]

Proposed Uses of Vinyl Chloride Polymers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to provide for the safe use of vinyl chloride polymers. The agency is proposing: (1) To provide for the safe use of certain vinyl chloride polymers by establishing limits on the amount of residual vinyl chloride monomer that they may contain; (2) to codify all known prior sanctions for vinyl chloride polymers; (3) to provide for the use of certain previously unregulated vinyl chloride polymers in manufacturing vinyl chloride bottles; and (4) to delete vinyl chloride-vinylidene chloride copolymers from the list of materials that may be used as coatings on fresh citrus fruits. Elsewhere in this issue of the Federal Register, FDA is withdrawing the proposal on vinyl chloride polymers that it published in the Federal Register of September 3, 1975 (40 FR 40529).

DATE: Comments by April 4, 1986.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

The purpose of this proposal is to provide for the safe use of vinyl chloride polymers in contact with food.

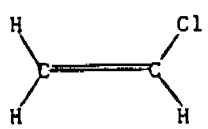
Vinyl chloride is a chemical with the formula C_2H_3Cl used as a monomer in the production of polymers. Other monomers are chemically bonded to this monomer by the process of polymerization to form larger, more complex molecules called "polymers." When all of the monomers that are polymerized together are molecules of the same substance, the resulting molecule is called a "homopolymer." The vinyl chloride homopolymer is sometimes called "polyvinyl chloride" (CAS Reg. No. 9002-86-2).

When molecules of different chemicals are polymerized together, the resulting molecule is called a "copolymer." Thus, when ethylene molecules are polymerized to vinyl chloride molecules, the resulting copolymer is called "ethylene vinylidene chloride."

Elsewhere in this issue of the Federal Register, FDA is withdrawing an earlier proposal on vinyl chloride polymers that it published on September 3, 1975. Responses to comments received on the September 3, 1975 proposal are set forth in the withdrawal document.

II. Regulatory History

Vinyl chloride (CAS Reg. No. 75-01-4) is a chemcial with the following structure:



; C_2H_3Cl, Molecular weight: 62.5

A wide variety of vinyl chloride polymers, including homopolymer and various copolymers, are available for use in the production of articles intended to contact food, including food-packaging materials, coatings, plastisols, gaskets, parts for food-processing equipment, flexible tubing, and waterpipe.

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a substance is excluded from the definition of a "food additive" if its use was sanctioned by

FDA before September 6, 1958, the date of the enactment of the Food Additives Amendment. FDA issued several sanctions for uses of vinyl chloride polymers before that date. Those sanctions were in the form of letters, advisory opinions, and articles by FDA scientists that appeared in scientific journals. Although currently there is no list of the prior-sanctioned uses of vinyl chloride polymers in the Code of Federal Regulations, FDA is aware of such sanctions for their use as components of film for food wraps, as components of can enamels, and as components of certain types of rigid food-packaging materials, excluding bottles.

Since the enactment of the Food Additives Amendment in 1958, FDA has approved a variety of uses of vinyl chloride polymers in food-contact articles. The regulations codifying these approvals include: § 172.210 *Coatings on fresh citrus fruit* (formerly § 121.1179); § 175.105 *Adhesives* (formerly § 121.2520); § 175.300 *Resinous and polymeric coatings* (formerly § 121.2514); § 175.320 *Resinous and polymeric coating for polyolefin films* (formerly § 121.2569); § 176.170 *Component of paper and paperboard in contact with aqueous and fatty foods* (formerly § 121.2526); § 176.180 *Components of paper and paperboard in contact with dry food* (formerly § 121.2571); § 177.1010 *Acrylic and modified acrylic plastics, semirigid and rigid* (formerly § 121.2591); § 177.1200 *Cellophane* (formerly § 121.2507); § 177.1210 *Closures with sealing gaskets for food containers* (formerly § 121.2550); § 177.1630 *Polyethylene phthalate polymers* (formerly § 121.2524); § 177.1850 *Textryls* (formerly § 121.2545); § 177.1950 *Vinyl chloride-ethylene copolymers* (formerly § 121.2609); § 177.1960 *Vinyl chloride-hexene-1 copolymers* (formerly § 121.2623); § 177.1970 *Vinyl chloride-lauryl; vinyl ether copolymers* (formerly § 121.2608); § 177.1980 *Vinyl chloride-propylene copolymers* (formerly § 121.2521); § 177.2250 *Microporous polymeric filters* (formerly § 121.2631); and § 179.45 *Packaging materials used during the irradiation of packaged foods* (formerly § 121.2543). The renumbering of these sections occurred as part of a recodification that FDA announced in the Federal Register of March 15, 1977 (42 FR 14302).

On January 4, 1973, representatives of Schenley Distillers met with FDA to report the results of analyses that showed that alcoholic beverages stored in vinyl chloride polymer bottles for periods of up to 9 months had levels of vinyl chloride monomer as high as 20 parts per million (ppm). Other components of the bottles that gave gin and vodka an off-flavor were also extracted, but these components were not identified. By May 10, 1973, FDA chemists had confirmed that vinyl chloride monomer was present in vinyl chloride polymer liquor bottles, and that it migrated into the liquor.

As a result of these findings, FDA published a notice of proposed rulemaking in the Federal Register of May 17, 1973 (38 FR 12931), to restrict the use of vinyl chloride polymer resins to food-packaging materials that were used with nonalcoholic foods.

By March 1974, the agency had received information from various sources suggesting that the migration of vinyl chloride monomer from vinyl chloride polymer resins was not limited to situations in which the polymer was used in food-contact articles for alcoholic beverages. By this time, vinyl chloride monomer had been linked to liver cancer in humans. Therefore, in the Federal Register of April 22, 1974 (39 FR 14215), FDA proposed to ban vinyl chloride as an aerosol propellant in drug and cosmetic preparations and also requested data from industry about the use of vinyl chloride polymers, the residual concentration of vinyl chloride monomer in vinyl chloride polymers, and the migration of vinyl chloride monomer from vinyl chloride polymer containers.

In the Federal Register of August 26, 1974 (39 FR 30830), the agency issued a final rule that prohibited the use of vinyl chloride as a propellant in aerosol cosmetic products and that required that a manufacturer obtain an approved new drug application before using vinyl chloride as a propellant in aerosol drug products. This action was based on evidence that inhalation of high concentrations of vinyl chloride resulted in acute toxicity that was manifested by an array of symptoms, including unconsciousness, cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys.

As a result of the many comments that the agency received on the April 22, 1974 proposal, in the Federal Register of September 3, 1975 (40 FR 40529), FDA proposed further restrictions on the use of vinyl chloride polymers in contact with food.

Under the September 1975 proposal, rigid and semirigid vinyl chloride polymers would have been banned from food-contact use because of possibly unsafe levels of vinyl chloride monomer migration, although continued use of vinyl chloride polymer waterpipe would have been permitted under the an interim regulation.

The September 1975 proposal cited inhalation studies by Dr. Cesare Maltoni, who reported the development of angiosarcomas of the liver along with other types of tumors at levels of atmospheric exposure as low as 250 ppm ("Carcinogenicity Biossay of Vinyl Chloride." *Environmental Research*, 7:387–045, 1974). Since then, vinyl chloride has been shown to be an animal carcinogen both by inhalation and by oral administration and a human carcinogen by inhalation, as discussed below (IARC Monographs, 19:409–412, 1979).

Data Received in Response to Proposal

As a result of the September 3, 1975 proposal, FDA received numerous comments, which are addressed elsewhere in this issue of the Federal Register, and considerable analytical manufacturing and toxicological data bearing on the reduction in the level of vinyl chloride monomer in vinyl chloride polymers. These data led FDA to publish this new proposal on vinyl chloride polymers.

Data submitted by industry in response to the September 1975 proposal showed that manufacturers had succeeded in reducing the vinyl chloride monomer levels in vinyl chloride polymer resin. Before 1975, residual vinyl chloride monomer levels of 1,000 ppm were common. Since then, improved manufacturing procedures have lowered the residual vinyl chloride monomer levels by more than five orders of magnitude.

Although methods for reducing vinyl chloride monomer levels have varied from company to company, such methods generally have involved application of heat and vacuum during processing of the resin. Manufacturers have also taken steps to produce small, porous resin particles, which have facilitated diffusion of the monomer out of the resin.

Substantiation of the reduction in vinyl chloride monomer has been provided by reports of residual vinyl chloride monomer levels of 10 ppb in vinyl chloride polymer bottles (The Society of the Plastics Industry, Inc., November 12, 1982) and an estimated 100 parts per trillion in can coatings (Union Carbide Co., December 12, 1980).

The Society of the Plastics Industry, Inc. (SPI), in a submission (November 12, 1982) on behalf of the vinyl chloride polymer manufacturers, informed the agency "that with respect to vinyl chloride polymer bottles, the industry can provide products with residual

monomer levels not exceeding 10 ppb by weight." The SPI submission further stated "the quantity of vinly chloride available to migrate is so low, and the rate of migration of vinyl chloride from vinyl chloride polymer containers made with a residual [vinyl chloride monomer] content of 10 ppb or less is so slow that the concentration of vinyl chloride in the contents even after an exaggerated shelf-life exposure at moderately elevated temperatures will not exceed the safe (0.073 ppb) level."

To monitor the level of residual vinyl chloride monomer in vinyl chloride polymers, the agency has developed a sensitive gas chromatographic method titled "Head Space Sampling and Gas-Solid Chromatographic Determination and Confirmation of ≥1 ppb Vinyl Chloride Residues in Polyvinyl Chloride Food Packaging" (J.L. Dennison, et al., *Journal of the Association of Official Analytical Chemists*, 61:813–819, 1978). This analytical method has been tested by FDA and by at least one major manufacturer of vinyl chloride polymers and has been found to yield satisfactory analytical results. However, the method has not been tested with all possible vinyl chloride-based food-contact articles. FDA invites comments on the applicability of this analytical method and will consider any comments received in developing a final rule.

III. The Use of Vinyl Chloride Polymers in Food-Contact Articles Will Result in Their Becoming Components of Food

Section 201(s) of the act defines a "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use) * * *" (21 U.S.C. 321(s)).

FDA finds that vinyl chloride polymers used in food-contact articles meet this definition. Existing theory, supported with data produced by indusiy and by FDA laboratories, demonstrates that, under normal conditions of use, vinyl chloride monomer will migrate to food from all types of vinyl chloride polymer food-contact articles.

The migration of vinyl chloride monomer from vinyl chloride polymers can be described by Fick's First and Second Laws of Diffusion, first enunciated in 1855 (Crank, J., "The Mathematics of Diffusion," 2d Ed., pp. 2–4, Oxford Press, London, 1976). The differential equations expressing these laws contain a variable called diffusivity. The form of the differential equations derived from Fick's laws depends on the boundary conditions, i.e., monomer concentration inside and outside the bottle wall, and on the conditions existing at the time of initiation of diffusion of vinyl chloride monomer, such as the intitial residual monomer concentation.

When applied to the particular situation of monomer migration from a bottle, such as vinyl chloride monomer from a vinyl chloride polymer bottle, the diffusion equations derived from Fick's Second Law always predict a finite migration of the monomer based on initial monomer concentration in the bottle wall, provided diffusivity is not zero. Only if diffusivity is zero would no migration be likely.

Based on its review of published experimental results and of theoretical calculations based on numberous systems, FDA believes that the diffusivity of vinyl chloride monomer in vinyl chloride polymer will always be greater than zero, and that migration will occur whenever residual vinyl chloride monomer if present in the polymer.

In a series of reports dating from January 17, 1975, Ethyl Corp. proposed and utilized a diffusion model that it has derived from Fick's Second Law. This model can be used to predict monomer levels in various food simulants when the initial residual vinyl chloride monomer concentration in the bottle wall and the diffusivity are known.

Ethyl Corp. originally applied this diffusion model to extraction data derived from bottles containing residual vinyl chloride monomer at levels of from 80 to 330 parts per million (ppm). This model accurately predicted the level of monomer that migrated into food simulating solvents.

FDA also has used sensitive analytical methods to measure the levels of vinyl chloride monomer in extracts from vinyl chloride polymers. those methods have shown that, consistent with Ethyl's model, the levels of monomer in the extract could be related to the intitial residual concentration of the monomer in the polymer. For example, FDA conducted a migration study on two lots of unplasticized polymer sheet. One lot contained 0.44 ppm residual vinyl chloride monomer and the other 0.28 ppm. Samples from each lot were extracted with 50 percent ethanol for 19 days at 49 °C (120 °F). Vinyl chloride monomer levels in the extract from the polymer containing 0.44 ppm averaged 2.4 ppb, while vinyl chloride monomer levels in the extract from the 0.28 ppm sheet averaged 1.6 ppb (Diachenko, et al., *Journal of the Association of Official Analytical Chemists*, 60:570–575, 1977).

The Ethyl predicts that there will be migration, albeit below the limits of detection by current analytical techniques, from vinyl chloride polymers that contain vinyl chloride monomer at the level of less than one ppm. According to the model, as migrant concentration in a polymer is reduced, the contribution to diffusion from the interaction among migrants also decreases. In the limiting case of a single migrant molecule, the only interaction that will occur is between the migrating monomer and the polymer. Even though diffusivity will be reduced to a finite constant in this case, it will not become zero. Thus, even when the polymer contains the monomer at very low levels, the presence of the vinyl chloride monomer in food "* * * can be predicted on the basis of a meaningful projection from reliable data." See *Monsanto Co.* v. *Kennedy*, 613 F.2d 947, 955 (D.C. Cir. 1979).

Therefore, based on the evidence before it, FDA concludes that vinyl chloride polymer will become a component of food, and that the extent to which this will be the case depends, at least in part, on the amount of monomer in the polymer. Given these facts and the fact that vinyl chloride monomer has been shown to be a carcinogen, FDA has decided to regulate the use of vinyl chloride polymers under the act (21 U.S.C. 348) to ensure that the polymer that is marketed does not contain unsafe levels of the monomer.

IV. Carcinogenic Impurities Approach to Safety Evaluation

A. Applicable Legal Standards

FDA, in its evaluation of the safety of vinyl chloride polymers, reviewed, as it does with all indirect food additives, the safety of both the polymer and its possible impurities (e.g., starting materials used to manufacture the additive). As stated above, the polymer is likely to contain residual amounts of a carcinogenic compound, vinyl chloride monomer, that is used in the manufacture of the polymer. The level of residual monomer in polymers is an important factor in assessing safety.

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the Food Additives Amendment, a food additive cannot be approved for a particular use unless the data presented to FDA establish that the food additive is safe

for that use. The concept of safety embodied in this requirement was explained in the legislative history of the Food Additives Amendment of 1958. "Safety requires proof of a reasonable certainty that no harm will result from a proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." H. Rept. 2284, 85th Cong., 2d Sess. 1 (1958). This definition of safety is incorporated in FDA's food additive regulations (21 CFR 170.3(i)). The Delaney anticancer clause of the Food Additives Amendment of 1958 (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)) provides further that no food additive can be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA often refused to list a food or color additive that contained or was expected to contain minor amounts of a carcinogenic chemical, even if the additive as a whole had not been shown to cause cancer. As explained below, however, scientific developments and experience with risk assessment procedures have made it possible for FDA, in appropriate circumstances, to approve the use of additives that contain a carcinogenic chemical.

In the preamble to the final rule permanently listing D&C Green No. 6 published in the Federal Register of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent. Since that decision, FDA has listed, on the same basis, the uses of several color additives that contain carcinogenic impurities, including the use of D&C Green No. 6 for coloring contact lenses (48 FR 13020; March 29, 1983) and the use of D&C Green No. 5 (47 FR 24278; June 4, 1982) and of D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982) for coloring drugs and cosmetics. (See also the advance notice of proposed rulemaking published in the Federal Register of April 2, 1982 (47 FR 14402).)

The appropriateness of FDA's decision to list the uses of these color additives is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has not itself been shown to cause cancer. Relying heavily on the reasoning in the agency's decision, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

The Delaney or anti-cancer clause is not triggered unless the additive as a whole is found to induce cancer. An additive that has not been shown to induce cancer but that contains a carcinogenic impurity is properly evaluated under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

Therefore, because vinyl chloride polymers, manufactured from the component vinyl chloride monomer, have not been shown to cause cancer, the anticancer clause does not apply. FDA has evaluated the safety of this additive under the general safety clause, using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemical that may be present as an impurity in the additive. This discussion is presented below.

B. Carcinogenicity Data on Vinyl Chloride Monomer

FDA, since the early 1970's, has been monitoring ongoing animal studies that have investigated the toxicity of vinyl chloride monomer. The agency has reviewed four available oral carcinogenicity studies on vinyl chloride monomer. These four studies are: (1) Cesare Maltoni's vinyl chloride monomer carcinogenicity study (Environmental Health Perspectives, 41:3–29, 1981), (2) the chronic oral study performed by Feron et al. (*Food and Cosmetic Toxicology*, 19:317–333, 1981), (3) The British Industrial Biological Research Association (BIBRA), unpublished study (1980) entitled "An Investigation into the Carcinogenic Potential of Vinyl Chloride Monomer when Administered to Rats in the Drinking Water for up to 152 weeks," and (4) CIVO Institute's TNO unpublished study (1983) entitled "Lifespan Oral Carcinogenicity Study of Vinyl Chloride in Rats."

In the Feron et al. study, Wistar rats were fed a diet containing vinyl chloride monomer in vinyl chloride homopolymer powder or were administered vinyl chloride monomer in soybean oil by gavage. The results of this study show that vinyl chloride monomer is a carcinogen in Wistar rats, inducing neoplastic liver cell nodules, hepatocellular carcinomas, and angiosarcomas of the liver and the lung. The agency chose this study for computation of the risk for human exposure to vinyl chloride monomer because it was a lifetime (135 to 144 weeks) feeding study, and because the individual animal data were available.

In the Maltoni study vinyl chloride monomer was administered by various routes (including oral gavage), doses, and schedules of treatment, to animals of various species, strains, sex, and age. For the oral portion of the study, Sprague-Dawley rats were administered vinyl chloride monomer in olive oil by gavage for 52 weeks (5 times/week) and kept until spontaneous death (136 weeks). The report contains few details on the experimental design. However, the results of the oral portion of this study suggest that vinyl chloride monomer is an animal carcinogen. The results have not been used for the agency's risk assessment because the treatment lasted only 52 weeks. The data from this experiment were also presented by Maltoni at "The Conference to Re-evaluate the Toxicology of Vinyl Chloride Monomer, Polyvinyl Chloride and Structural Analogues" held at the National Institutes of Health, Bethesda, MD, March 20 and 21, 1980, and were published in *Environmental Health Perspectives*, 41:3–29, 1981.

In the BIBRA study, Wistar rats were administered vinyl chloride monomer as solutions in the drinking water for up to 152 weeks. The results show that vinyl chloride monomer is carcinogenic to Wistar rats, inducing predominantly hepatic hemangiosarcomas.

The latest CIVO Institutes TNO study (1983) is actually a repeated study of Feron et al. (1981), but at lower test levels of vinyl chloride monomer. The earlier study (Feron et al., 1981) had shown that liver neoplasia were found to occur at all dose levels. Therefore, in order to provide ideal experimental data for risk extrapolation, a similar life-span oral carcinogenicity study with vinyl chloride monomer in Wistar rats was carried out at lower dose levels at the same laboratory. The results of this study essentially confirmed the results observed in the earlier study in that vinyl chloride monomer, at the lower doses, induced only hepatocellular tumors (neoplastic nodules and hepatocellular carcinomas).

Upon reviewing the results of these studies, the agency concluded that vinyl chloride monomer is an animal liver carcinogen via the oral route of exposure.

An extensive review of the toxicological effects of vinyl chloride monomer has also been presented in International Agency for Research on Cancer (IARC) monograph No. 19 (published February 1979), which was prepared by an IARC evaluation group that met in February 1978. The evaluation group concluded that vinyl

chloride monomer is a carcinogen in animals (both via inhalation and oral routes) and in humans (inhalation). It found that vinyl chloride monomer is carcinogenic by the inhalation route to mice, rats, rabbits, hamsters, and humans. The evaluation group also found that the monomer produces tumors at multiple sites but is most active in induction of the otherwise rare hepatic angiosarcomas.

IARC summarized the data on vinyl chloride monomer as follows (IARC Monographs, Supplement 1, p. 45, 1979):

A. Evidence for Carcinogenicity to Humans (Sufficient)

Vinyl chloride causes angiosarcomas of the liver; it has also been associated with tumors of the brain and lung and of the haematopoietic and lymphatic systems in humans. Reports of increased incidence of tumors of the digestive system, urinary tract, and breast (in women) are inadequate to evaluate the carcinogenicity of vinyl chloride for these sites.

B. Evidence of Carcinogenicity to Animals (Sufficient)

Vinyl chloride is carcinogenic to mice, rats, and hamsters after its administration orally or by inhalation, producing tumors at several sites, including angiosarcomas of the liver.

C. Evidence for Activity in Short Term Tests (Sufficient)

Vinyl chloride induces DNA damage in prokaryotes and in mammalian cells *in vitro*. It was mutagenic to *Salmonella typhimurium* in the absence of an exogenous metabolic activation system and to *Escherichia coli*, *Schizosaccharomyces pombe* and *Saccharomyces cerevisiae* but not to *Neurospora crassa*. It was mutagenic to *Drosophila melanogaster*, inducting sex-linked recessive lethal mutations and to hamster cells *in vitro*. It induced chromosomal aberrations and sister chromatid exchanges in Chinese hamsters exposed *in vivo*. It did not induce dominant lethal or somatic mutations in mice. Vinyl chloride alkylated the liver DNA of rats treated *in vivo*. Chromosomal aberrations and sister chromatid exchanges were induced in workers exposed to vinyl chloride. Most such data were obtained when exposure was to levels of 25 ppm. In follow-up studies, in which workers were exposed to levels that had been reduced to 15 ppm or lower, no aberrations or sister chromatid exchanges were reported. Sister chromatid exchange incidence dropped to a normal level shortly after termination of exposure to higher levels. However, the incidence of chromosomal aberrations returned to normal only after two years. [Thus, although sister chromatid exchanges were not observed in some studies, sampling may have occurred after the level returned to normal.]

The 1979 monograph concluded that, while vinyl chloride monomer is an established animal carcinogen via both inhalation and oral ingestion, its carcinogenic activity in humans has so far been demonstrated only in workers who were involved in the production, polymerization, and processing industries and who were exposed to high environmental concentrations of vinyl chloride monomer vapor. Based on its own review of the data, FDA concurs with this conclusion.

C. Risk Assessment

In assessing the risk presented by vinyl chloride monomer from the use of vinyl chloride polymers, the agency has used risk assessment procedures that are similar to those that it used in evaluating the risk from the minor carcinogenic impurities that may be present in the color additives that FDA discussed above.

The risk evaluation of the carcinogenic constituent has two aspects: (1) Assessment of the probable exposure to the constituent (vinyl chloride monomer) from all the regulated and prior-sanctioned uses of vinyl chloride polymers, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

1. Exposure

The agency has calculated an estimated daily intake for vinyl chloride monomer from known current uses of vinyl chloride polymers as potential well as additional uses taking into account the fraction of the daily diet that might be packaged in materials made of vinyl chloride polymers. Vinyl chloride monomer exposure may be estimated using known vinyl chloride monomer residuals in the vinyl chloride homopolymer or copolymer and survey data for current production levels for these polymers.

The estimated daily intake calculations for vinyl chloride polymers are as follows:

1. *Liquor bottles.* Because this use of vinyl chloride polymers is not permitted by current regulations or by a prior sanction, there are no available marketing data from which the agency might estimate potential vinyl chloride monomer exposure from vinyl chloride polymer liquor bottles. There are several ways of estimating exposure to vinyl chloride monomer from use of these liquor bottles, each using the conservative assumption that all liquor will be packaged in these bottles. In reality, vinyl chloride polymers will compete with other materials such as polyethylene terephthalate and glass, which are currently used for packaging liquor.

A typical vinyl chloride ploymer liquor bottle will weigh approximately 105 grams and have a capacity of 1.75 liters (letter dated August 17, 1983, from The Society of the Plastics Industry, Inc.). If the vinyl chloride monomer residual level is 10 ppb, the proposed limitation in § 177.1975, and if 100 percent migration occurs, the predicted vinyl chloride monomer level in the beverage would be 0.65 ppb. The resulting vinyl chloride monomer levels in the liquor would be below the detection limits of current analytical methods.

The actual migration expected over the shelf life of liquor is likely to be lower based on experimental migration levels from containers having higher residual monomer levels. For example, when bottles containing 0.9 ppm residual vinyl chloride monomer were extracted with 50 percent ethanol for 9 months at 72° F, no vinyl chloride monomer could be detected in the solvent at a level of detection of 10 ppb (Ethyl Corp., report dated September 27, 1976). Therefore, if it is assumed that migration occurs at the level of detection, 5.5 percent of the residual vinyl chloride monomer migrated. Because diffusivity has been shown by Ethyl's work to decrease as the residual vinyl chloride monomer is reduced, the percent migration must also decrease. Therefore, 5.5 percent migration of residual vinyl chloride monomer from bottles containing 10 ppb vinyl chloride monomer is an upper limit. If 5.5 percent of the available vinyl chloride monomer migrates from a 1.75-liter bottle having 10 ppb residual vinyl chloride monomer, the predicted level of vinyl chloride monomer in the packaged food would be 0.036 ppb.

According to available statistics ("Public Revenues from Alcoholic Beverages," p. 26, 1980/1981, Economics and Statistics Division, Distilled Spirits Council of the United States, Inc.), per capita liquor consumption in 1980 was 1.98 gallons or about 19 grams per day. The average vinyl chloride monomer ingested per person per day from this use would be about 0.68 nanogram per day if vinyl chloride monomer migration is 0.036 ppb.

Exposure may also be estimated using the U.S. Department of Agriculture (USDA) Nationwide Food Consumption Survey, 1977–1978. Of the 37,874 individuals surveyed, those who consumed liquor at least once during the 3-day study period consumed an average of 46 grams per day. The 90th percentile intake for users was 98 grams per day. If this latter value is used, vinyl chloride monomer exposure becomes 3.5 nanograms per day. This number is conservative because users who consume liquor less frequently than

once in 3 days were not included in the survey. The 1977–1978 Market Research Corp. of America (MRCA) survey of food consumed over a 14-day period reports an upper 90th percentile level of only 28 grams per day for brandy, whiskey, rum, and vodka.

2. *Wine bottles.* According to the Distilled Spirits Council of the United States, Inc., 1980 consumption of wine was approximately the same as that of liquor. However, the 90th percentile users' intake reported by USDA is 232 grams per day (USDA Nationwide Food Consumption Survey, 1977–1978). If all this wine contained vinyl chloride monomer at a level of 0.036 ppb (based on the Ethyl Corp. 50 percent ethanol extraction experiments referred to above), ingestion of vinyl chloride monomer would be 8.4 nanograms per day. This number is even more conservative than that calculated for liquor because water does not extract vinyl chloride monomer as well as alcohol, and migration into a beverage containing 14 percent or less alcohol should be lower than migration into beverages containing 50 percent alcohol. Furthermore, as with liquor, the assumption that all wine will be packaged in vinyl chloride polymer bottles is highly conservative. (The corresponding MRCA 14-day survey gives a level of 78 grams per day for the 90th percentile user.)

3. *Oil bottles.* There are vinyl chloride polymer vegetable oil bottles on the market and, although the number of these bottles is small, there are indications that the number will increase. In contrast to the consumption pattern for liquor and wine, fats and oils are consumed by almost the entire population. In 1978, salad and cooking oil consumption (including oils used in commercial salad dressings) averaged 22.6 pounds per person per year ("Fats and Oils Situation," USDA, May 1980) or 28 grams per day per capita. For food items with broad consumption patterns, the 90th percentile users' intake is generally about two times the per capita intake and yields an estimated 56 grams per day for 90th percentile users of salad and cooking oil. (The MRCA 90th percentile level for retail salad and cooking oils is a much lower 5.2 grams per day.)

Experimental results demonstrate that the migration rate of vinyl chloride monomer from a rigid vinyl chloride polymer bottle into a vegetable oil approximates the migration rate into 50 percent alcohol. (See, e.g., extraction results reported by Ethyl Corp. in the April 1975 issue of "Modern Packaging.") From information supplied by The Society of the Plastics Industry, Inc., a typical oil bottle contains 38 ounces of oil and weighs 70 grams. Assuming a migration rate for oil that is identical to that for 50 percent alcohol, the estimated 90th percentile user intake is 2.5 nanograms per day.

4. *Vinyl chloride homopolymer film.* Vinyl chloride monomer levels in plasticized vinyl chloride homopolymer film are lower than those found in rigid vinyl chloride polymer. An upper limit of exposure to vinyl chloride monomer from the film can be obtained by assuming that all of the vinyl chloride monomer in the film migrates into food. For example, a film with a thickness of 1 mil (0.0025 centimeter), a density of 1.26 grams per cubic centimeter, and a vinyl chloride monomer residual of 5 ppb would yield a maximum level in food of 0.010 ppb, if 1 square inch of film contacts 10 grams of food—FDA's usual assumption. Analyses of plasticized film for vinyl chloride monomer have generally shown residual vinyl chloride monomer levels of less than 5 ppb (Dennison, et al., *Journal of the Association of Official Analytical Chemists*, 61:4:813–819, 1978). The assumption of 100 percent migration is likely to be an exaggeration even for use with fatty foods such as meat and poultry, which would extract vinyl chloride monomer to a greater extent than other nonalcoholic foods.

Currently, food packaged in plasticized film is estimated to be about 5 percent of the diet. Industry projections indicate that this percentage may rise to about 7.5 percent in 5 years. FDA used the latter value in computing its estimates.

Considering migration, fraction of the diet packaged in film (7.5 percent), and a total dietary intake of 3.000 grams per day, FDA estimates exposure to vinyl chloride monomer from the use of vinyl chloride homopolymer film to be 2.2 nanograms per day ("Guidelines for Estimating Exposure to Indirect Food Additives," FDA, June 1981).

5. *Vinyl chloride-vinylidene chloride copolymers*—(i) *Films.* Although the use of this type of film with food is more limited than the use of vinyl chloride homopolymer films, residual vinyl chloride monomer levels are higher than those encountered in vinyl chloride homopolymer films. If the vinyl chloride monomer residual is 50 ppb, a level that FDA believes is the lowest level achievable with current technology, a calculation similar to that for homopolymer film yields a level of 0.14 ppb in food from 100 percent migration.

Information submitted by industry indicates that 1.5 percent to 2.8 percent of the total daily diet is packaged in vinylidene chloride-vinyl chloride copolymers. Using the maximum value of 2.8 percent, the migration level of 0.14 ppb, and a total dietary intake of 3.000 grams per day, FDA calculates exposure to vinyl chloride monomer from this use to be 12 nanograms per day.

(ii) *Vinyl chloride-vinylidene copolymer coatings on fresh citrus fruit.* Based on information from a major producer of vinyl chloride-vinylidene chloride copolymer (memorandum of telephone conversation, M. Flood, FDA, and J. Cobler, Dow Chemical Co., September 30 and October 3, 1983), FDA has determined that this copolymer is no longer used as a coating on fresh citrus fruit. Therefore, the agency is proposing to revoke the regulation permitting this use and is not including any contribution of vinyl chloride monomer from this use in its calculation of the estimated daily intake.

6. *Other uses.* FDA has only included the primary probable contributors in estimating the daily intake of vinyl chloride monomer. It has not included other food-contact uses of vinyl chloride homopolymers and copolymers because they contribute such a small amount of vinyl chloride monomer to the diet that, in view of the conservatisms used in estimating exposure from the primary contributors, they can be disregarded. An example of these uses includes vinyl chloride copolymers used as coatings, where heat treatment of the coating after application would reduce vinyl choride monomer in the coating to levels not measurable by current analytical technology. Additionally, uses of vinyl chloride in articles such as water pipe or filters can be disregarded. These articles have a long service life, come into contact with extremely large amounts of water and other food, and will contain small amounts of vinyl chloride monomer. Therefore, FDA believes that these uses will not contribute any measurable amounts of vinyl chloride monomer when used in accordance with the proposed regulations.

To obtain an estimate of the upper limit vinyl chloride monomer exposure from all food-contact uses of vinyl chloride polymers, FDA has summed the upper limit exposures from each of the primary contributors to the exposure. FDA considers it unlikely that a high user of vinyl chloride polymer food-contact products would be exposed at maximum levels of vinyl chloride monomer from each use. Because it is most unlikely that a 90th percentile wine consumer is also a 90th percentile liquor consumer, particularly on a lifetime basis, these two exposure estimates are

not added together. Instead, FDA is using the higher value for wine in the vinyl chloride monomer cumulative calculation. FDA conservatively estimates that the lifetime-averaged individual exposure to vinyl chloride monomer from the probable food-contact use of vinyl chloride polymers will not exceed 25 nonograms per day.

2. Extrapolation of Risk

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose in the animal experiment to the very low doses of possible human exposure. This procedure is not likely to underestimate the actual risk from very low doses. In fact, the estimate of the risk is most likely exaggerated because the extrapolation models used are designed to estimate the maximum possible risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the use of vinyl chloride polymers.

FDA has used data from a carcinogenicity bioassay in which vinyl chloride monomer was administered in the diet of rats to estimate the upper level of human risk from exposure to this impurity from the proposed use of vinyl chloride polymers (Feron et al. study and memorandum dated May 27, 1984, from Cancer Assessment Committee to V. Anand, FDA).

FDA has calculated that the individual lifetime risk of cancer from exposure to vinyl chloride monomer at 25 nanograms per day is less than 1 in 10 million. Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure is expected to be substantially less than 25 nanograms per day. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to vinyl chloride monomer that may result from the use of vinyl chloride polymers in food packaging complying with the vinyl chloride monomer limitations set forth in this document.

These limitations on residual vinyl chloride monomer are necessary to ensure that the present and future exposure to vinyl chloride monomer in the daily diet remains within the limits used to conclude that vinyl chloride polymers may be used safely.

V. Prior sanctions

The agency is proposing to establish a listing of all known prior sanctions for the use of vinyl chloride polymers in packaging materials. These prior sanctions include those listed in the 1975 proposal, as well as additional prior sanctions discovered since publication of that proposal.

As discussed above, the use of a substance is excluded from the definition of "food additive" in section 201(s) of the act if that use is in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment. Section 181.5 of FDA's regulations (21 CFR 181.5) provides that a prior sanction exists only for specific uses of a substance; i.e., at the levels required for the technical effects and in the food categories for which there is explicit approval. As a result, some uses of a substance may be food additive uses while other uses may be prior sanctioned. Indeed, FDA regulations list uses of a number of substances, including vinyl chloride polymers, in each category.

The 1975 proposal listed several prior-sanctioned uses of vinyl chloride polymers and requested that firms holding other valid prior sanctions for these polymers forward them to FDA for inclusion in the final regulation. There were no submissions in response to that request.

Subsequently, FDA reviewed its files on all firms that were known to be manufacturing vinyl chloride polymers for use in food-contact articles before the effective date of the Food Additives Amendment to the act. This review revealed the following additional prior sanctions:

1. Letter to Firestone Plastics Co., Pottstown, PA, dated April 20, 1951, permitting the use of vinyl chloride resins as films for food packaging.

2. Letter to Firestone Plastics Co., Pottstown, PA, dated October 5, 1956, Permitting the use of rigid polyvinyl chloride (homopolymer) sheet for packaging poultry.

3. Letter to Firestone Plastics Co., Pottstown, PA, dated February 21, 1957, permitting the use of vinyl chloride and vinyl chloride-acetate resins for "food wrapping purposes."

4. Letter to Borden Co., Santa Barabara, CA, dated August 15, 1957, Permitting the use of vinyl chloride polymers as tubing for food-contact use.

FDA is proposing to establish § 181.37 to cover those uses of these vinyl chloride polymers for which documentation of the prior sanctions is available. FDA's review of its files for all known pre-1958 manufacturers failed to locate any documentation of a prior sanction for a rigid or semirigid vinyl chloride polymer bottle. The only documented prior sanctions for rigid vinyl chloride polymer that the agency found were for waterpipe and poultry packaging trays.

V. Proposed Regulations

A. Currently Regulated Polymers

In order to provide for the safe use of vinyl chloride polymers currently regulated under Title 21 of the Code of Federal Regulations, FDA is proposing the following:

1. In § 172.210 *Coatings on fresh citrus fruit*, FDA is proposing to delete the use of vinyl chloride-vinylidene chloride copolymer, and the adjuvants used in its production, as components of coatings on fresh citrus fruit. The only known manufacturer of this copolymer reported to FDA that the material has not been used to coat fresh citrus fruit for many years, and that there are no plans to market the product for this use in the future. Deletion of the additive vinyl chloride-vinylidene chloride copolymer in this regulatoin will also result in the deletion of polyethylene glycol, polyvinyl-pyrrolidone, potassium persulfate, propylene glycol alginate, and sodium decylbenzene sulfonate from § 172.210, because the only use of these adjuvants permitted by this regulation is in vinyl chloride-vinylidene chloride coplymers. The deletion of these adjuvants has no effect on their status in other food additive regulations.

2. In § 175.105 *Adhesives*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride homo- or copolymer component of the adhesive.

3. In § 175.300 *Resinous and polymeric coatings*, for the vinyl chloride homo- or copolymer component of the coatings, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight.

4. § 175.320 *Resinous and polymeric coatings for polyolefin films*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride copolymer component of the olefin polymer coating.

5. § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the listed vinyl chloride copolymer components of the paper and paperboard.

6. In § 176.180 *Components of paper and paperboard in contact with dry foods*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride homo- or copolymer component.

7. In § 177.1010 *Acrylic and modified acrylic plastics, semirigid and rigid*, FDA is proposing to establish a limit on residuel vinyl chloride monomer of 5

ppb by weight of the vinyl chloride copolymer component.

8. In § 177.1200 *Cellophane*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride homo- or copolymer components.

9. In § 177.1210 *Closures with sealing gaskets for food containers*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride copolymer component.

10. In § 177.1630 *Polyethylene phthalate polymers*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride copolymer component.

11. In § 177.1850 *Textryls*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride copolymer component.

12. In § 177.1950 *Vinyl chloride-ethylene copolymers*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 10 ppb by weight of the vinyl chloride copolymer component.

13. In § 177.1960 *Vinyl chloride-hexene-1 copolymers*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 10 ppb by weight of the vinyl chloride copolymer component.

14. In § 177.1970 *Vinyl chloride-lauryl vinyl ether copolymers*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 10 ppb by weight of the vinyl chloride copolymer component.

15. In § 177.1980 *Vinyl chloride-propylene copolymers*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 10 ppb by weight of the vinyl chloride copolymer component.

16. In § 177.2250 *Filters, microporous polymeric*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 50 ppb by weight of the vinyl chloride homo- or copolymer component.

17. In § 179.45 *Packaging materials for use during the irradiation of prepackaged foods*, FDA is proposing to establish a limit on residual vinyl chloride monomer of 5 ppb by weight of the vinyl chloride copolymer component.

B. Polymers Not Previously Regulated

In Part 177, FDA is also proposing to establish new § 177.1975 *Vinyl chloride polymer resins, rigid and semirigid*, to provide for the safe use of rigid and semirigid vinyl chloride polymers that have been marketed based on the belief that they are covered for food use by a valid prior sanction. This regulation provides for the use of those vinyl chloride polymers that are not covered by a valid prior sanction or by existing regulations.

This regulation proposes various specifications, including a residual vinyl chloride monomer limit of 10 ppb by weight of the vinyl chloride polymer.

C. Prior-sanctioned Polymers

FDA is proposing new § 181.37 *Vinyl chloride homo- and copolymer resins*, which sets forth all known prior sanctions for vinyl chloride homo- and copolymers and sets forth limits on residual vinyl chloride monomer in these polymers based on what FDA has determined the manufactuers are capable of achieving. The specific proposed limits, expressed by weight of the vinyl chloride homo- or copolymer component, are as follows:

1. In vinyl chloride homo- or copolymer films and coatings, except as noted below, FDA proposes to limit residual vinyl chloride monomer to 5 ppb by weight of the vinyl chloride homo- or copolymer component.

2. In vinyl chloride-vinylidene chloride films, FDA proposes to limit residual vinyl chloride monomer to 50 ppb by weight of the vinyl chloride copolymer component.

3. In vinyl chloride polymer waterpipe, FDA proposes to limit residual vinyl chloride monomer to 50 ppb by weight of the vinyl chloride homopolymer component.

4. In plasticized vinyl chloride for use as flexible tubing and as gaskets and bottle or jar liners, FDA proposes to limit residual vinyl chloride monomer to 5 ppb by weight of the vinyl chloride polymer components.

5. For rigid vinyl chloride polymer sheet, FDA proposes to limit residual vinyl chloride monomer to 10 ppb by weight of the vinyl chloride polymer component.

VI. Conclusions

Based on available toxicity data, the agency's exposure calculations, and its estimates of the risk from the carcinogenic constituent, vinyl chloride monomer, in the polymer when the polymer complies with the specifications that the agency is proposing, FDA tentatively concludes that the use of vinyl chloride polymers as food-contact materials, as described above is safe. The agency is, therefore, proposing to amend the food additive regulations and to adopt new regulations to provide for the safe use of vinyl chloride polymers. The agency is also proposing to delete from the current food additive regulations the use of vinyl chloride-vinylidene chloride copolymers as a component of coatings of fresh citrus fruit.

Following publication of the 1975 proposal, the Environmental Protection Agency (EPA), under authority of the 1974 Safe Drinking Water Act, executed a memorandum of understanding (MOU) with FDA (see 44 FR 42775; July 20, 1979). That MOU established an agreement between EPA and FDA with regard to the control of direct and indirect additives in drinking water. According to that MOU, FDA has the regulatory responsibility with respect to water, and substances in water, used in food and food processing, as well as regulatory responsibility for bottled drinking water under the act. The MOU also gives primary regulatory responsibility to EPA for direct and indirect additives in municipal drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. Therefore, FDA has deferred to EPA to prescribe conditions for the safe use of vinyl chloride polymer pipe in municipal water systems.

The agency has carefully considered the potential envoronmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25) that was published in the Federal Register of April 26, 1985 (50 FR 16636, effective July 25, 1985).

FDA welcomes the submission of any data bearing on the issues and conclusions contained in the finding of no significant impact and the environmental assessment. FDA would particularly like any additional information on the environmental fate (e.g., persistence) of di(2-ethylhexyl) phthalate, di(2-ethylhexyl) adipate, and expoxidized soybean oil in terrestrial and benthic environments, and any additional information on the effects (acute, subacute, and chronic) of these chemicals on representative organisms from those environments. FDA would also like additional information on whether vinyl chloride polymers contribute to the emission of polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans from

municipal solid waste incinerators. FDA will reexamine its conclusions if new information becomes available suggesting that this action will have significant environmental impact.

The agency has prepared an assessment concerning the economic impact of the proposed rule. The cost expected to arise from any final rule based on this proposed rule is the cost of reducing residual vinyl chloride monomer to acceptable levels in food-contact articles containing vinyl chloride. FDA has found that since 1975, most vinyl chloride polymer resin manufacturers and manufacturers of food-contact articles containing vinyl chloride have made the changes in their manfuacturing processes that are necessary to produce vinyl chloride polymers that comply with this regulation. Therefore, this regulation should not produce any new developmental costs for manufacturers. The agency notes, however, that the improved methods of manufacturing vinyl chloride polymers are more expensive than those that were in use before 1975. The agency estimates that these new methods cost about $2.9 million more annually than their predecessors.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will result from this action. A copy of the assessment supporting these determinations may be seen in the Dockets Management Branch (address above).

Interested persons may, on or before April 4, 1986, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 172

Food additives.

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Part 176

Food additives, Food packaging.

21 CFR Part 177

Food additives, Food packaging.

21 CFR Part 179

Food additives, Food packaging, Radiation protection.

21 CFR Part 181

Food ingredients, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Parts 172, 175, 176, 177, 179, and 181 be amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10.

2. In § 172.210 by removing and reserving paragraph (b)(3) and by revising the introductory text of paragraph (b)(4) to read as follows:

§ 172.210 Coatings on fresh citrus fruit.

* * * * *

(b) * * *

(3) [Reserved]

(4) In lieu of the components listed in paragraph (b)(2) of this section, the following rosin derivatives and either or both of the listed adjuvants:

* * * * *

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

3. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10.

4. In § 175.105 (c) (5) by revising the item "Vinyl chloride" to read as follows:

§ 175.105

Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Polymers.	
Homopolymers and copolymers of the following monomers:	
* * * * *	
Vinyl chloride.....	Residual vinyl chloride monomer content determined in the finished adhesives, using the method described in § 177.1975(c) of this chapter, shall not exceed 5 parts per billion by weight of the vinyl chloride homo- or copolymer component.
* * * * *	

* * * * *

5. In § 175.300 by adding new paragraph (i) to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(i) Residual vinyl chloride monomer content determined in the finished coatings, using the method described in § 177.1975(c) of this chapter, shall not exceed 5 parts per billion by weight of the vinyl chloride home- or copolymer component.

6. In § 175.320 by redesignating paragraph (c) as paragraph (c)(1) and by adding new paragraph (c)(2) to read as follows:

§ 175.320 Resinous and polymeric coastings for polyolefin films.

* * * * *

(c) * * *

(2) For coatings formulated with a vinyl chloride homo- or copolymer listed in paragraph (b)(3) of this section, residual vinyl chloride monomer content, determined in the finished coatings, using the method described in § 177.1975(c) of this chapter, shall not exceed 5 parts per billion by weight of the vinyl chloride copolymer component.

* * * * *

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

7. The authority citation for 21 CFR Part 176 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10.

8. In § 176.170(b)(2) in the table by adding limitations to the items "vinyl chloride copolymers." "Vinyl chloride-vinyl acetate hydroxyl-modified copolymers." "Vinyl chloride-vinyl acetate hydroxyl-modified copolymers reacted with trimeliitic anhydride," and "Vinylidene chloride copolymers" to read as follows: