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because, based upon new scientific and legal developments, FDA has decided that the actions outlined in the proposal no longer represent the appropriate course of regulatory action.

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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

nal 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