

Before The
Department of the Treasury
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS
Washington, D.C.

On Behalf of
THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

Petition for Generic Approval of
Polyvinyl Chloride as a Suitable
Material to Package Distilled Spirits

INTRODUCTION

In accordance with the Bureau of Alcohol, Tobacco and Firearms procedure, as set forth in Industry Circular No. 76-18, dated August 25, 1976, The Society of the Plastics Industry, Inc. (hereinafter referred to as SPI), respectfully requests that the Bureau of Alcohol, Tobacco and Firearms (hereinafter referred to as BATF) reinstate generic approval, on a permanent basis, of polyvinyl chloride (PVC) as a suitable material to package distilled spirits.

It is our intent that this Petition serve as a formal written application to the Director of the type required under Bureau procedure. To this end, preliminary statements delineating the particular interest of SPI, and specific relief sought are contained in Parts I and II; the underlying bases

SPI-16284

of the Petition including relevant technical data and an historical summary are treated in Parts III and IV, and the enumerated "conditions and considerations" required by Circular No. 76-18 are addressed in Part V.

I. SPI IS AN APPROPRIATE PARTY TO
PETITION BATE TO REINSTATE
APPROVAL FOR PVC LIQUOR BOTTLES

A. SPI Has a Direct, Immediate and
Substantial Interest in the
Approval of PVC Liquor Bottles

SPI is a New York Not-for-Profit Corporation, with its primary office in New York, New York. It is the principal trade association for the plastics industry in the United States, representing approximately 1,400 members which collectively account for 95% of the plastics materials and machinery produced. Approximately 75% of the total dollar volume sales of plastics in the United States is attributable to SPI member companies.

SPI also represents the majority of companies, industry-wide, which would be involved in the various stages of production of PVC liquor bottles. Its membership includes companies which are presently in the business of supplying PVC resin, processing and manufacturing plastics products (including bottles) composed of PVC compounds, engineering or constructing molds and similar necessary accessory equipment, and manufacturing machinery used to make PVC plastics products.

It is thus very apparent that SPI's membership has a direct, immediate, and substantial interest in the approval of PVC liquor bottles. In the case of resin suppliers, approval would, quite simply, increase existing demand for PVC resins. Approval would also directly benefit molders, many of which have either existing or reserve capacity to produce PVC liquor bottles with a minimal amount of lead time, for example, to meet the soon to be effective metric standards of fill.

The virtual "on line" capacity of SPI member companies to produce PVC liquor containers stems from the plastics industry's extensive experience with such bottles. As is discussed more fully below, in response to FDA assurances that the necessary resins were prior sanctioned for all food-contact uses, BATF authorized experimental usage of PVC liquor bottles from 1969 to 1973. The PVC liquor bottle established a favorable track record during this three and one-half year period, enjoying overwhelming industry and consumer approval. The bottle scored equally well from an environmental standpoint, and approval was recommended in the Bureau's 1973 Environmental Impact Statement (EIS) assessing PVC liquor bottles.

At approximately the same time at which the 1973 EIS was issued, to everyone's surprise, for the first time it was demonstrated that residual vinyl chloride monomer in bottles as made then was a potential trace migrant.

FDA raised questions as to safety, and in response, BATF revoked experimental authority until such time as health and safety issues could be resolved.

During the three and one-half year period of experimental use, participants in the program, many of which are members of The Society, developed the capacity, technology and expertise to produce lightweight PVC bottles for use with distilled spirits. More importantly, however, over the intervening six plus years, the health and safety problems have been resolved. Consequently, the industry is now fully able to produce a liquor bottle which offers considerable advantages over presently approved containers.

B. SPI is an Appropriate Party to Petition
BATF on Behalf of its Members

The proper time for such action having come, as shall be shown below, SPI is an appropriate party to petition BATF, on behalf of its membership, to reinstate Bureau approval, on a permanent basis, for PVC liquor bottles. The propriety of The Society's present appearance before the Bureau is reinforced by the fact that SPI represented its membership in the identical capacity throughout the period of experimental usage of the PVC liquor bottle. Nearly all aspects of the experimental program were conducted on a "generic basis," beginning with the blanket approval of suitable PVC compound and terminating with the withdrawal that applied across the board to all PVC liquor bottles. Prior experience thus

SPI-16287

establishes that insofar as restoration of generic approval is sought, SPI is particularly well-suited to represent the industry-at-large.

II. STATEMENT OF WHY PETITIONER IS
ENTITLED TO RELIEF SOUGHT

Petitioner respectfully requests that BATF restore generic approval, on a permanent basis, of PVC as a suitable material for use as a container for distilled spirits for sale for beverage purposes. Approval would, of course, be conditioned upon Food and Drug Administration (FDA) concurrence in the existence of PVC compound meeting all applicable FDA requirements for alcoholic beverage packaging. Thsu, generic approval would clear PVC as a suitable material, subject to any conditions imposed by either FDA or BATF.

Petitioner wishes to emphasize that a reinstatement of generic approval would not, in any way, interfere with the Bureau's normal regulatory practices. Clearance on a "distiller-by-distiller" and "bottler-by-bottler" basis, as required under BATF regulations, would still be necessary. Thus, generic approval would operate as it did during the period of experimental usage, with specific BATF approval extending only to suitable PVC compounds.

The basis for Petitioner's request for restoration of generic approval can be stated quite simply: The problem

SPI-16288

of migration of residual vinyl chloride monomer (RVCM), which resulted in BATF revocation in 1973 of experimental use of PVC, has been resolved. In the six and one-half years that have since elapsed, continuous refinements in production techniques have reduced the level of RVCM in the bottle wall by a factor of nearly a million.

Supporting data demonstrate that when present PVC bottles are tested under conditions which exaggerate the intended conditions of use herein applied for, e.g., filled with 50% alcohol and stored at 120°F for periods up to six weeks, no migration from the bottle to the contents could be observed under the best present instrumental analytical procedures. Furthermore, experimental evidence demonstrates that there is no reasonable expectation of migration of RVCM.

A review of the entire history of the PVC liquor bottle reveals that the toxicological problem posed by migration of RVCM was the only factor barring approval by BATF. During the experimental program, BATF conducted a comprehensive and thorough evaluation, concluding that PVC liquor bottles had to be viewed favorably from environmental impact and usage standpoints, when compared to glass containers. The final pronouncement on the matter, contained in the 1973 EIS statement, squarely recommended approval of the PVC liquor bottle.

The relief requested by Petitioner must be considered in the specific context of the existing status of PVC for

rigid and semi-rigid applications. As the Bureau is undoubtedly aware, PVC, for all uses, including rigid and semi-rigid applications, enjoys prior-sanctioned status under the Federal Food, Drug and Cosmetic Act (FD&C) Act. Although FDA proposed to change such status for the application requested here, in 1973, and again in 1975, these proposals were never acted on.^{1/} Accordingly, under the Administrative Procedure Act, 5 U.S.C. § 551, et seq., the withdrawal of prior-sanctioned status was never effected. Thus, for the applications contemplated in this Petition, rigid and semi-rigid PVC resins in articles for use in contact with alcoholic foods (as well as other uses) retain prior-sanctioned status.

Furthermore, "the distinctions between plasticized and rigid PVC have become irrelevant based on new manufacturing techniques, and the uses should be treated similarly," according to a July 27, 1979 memorandum from the Division of Chemistry and Physics, Food Additive and Animal Drug Chemistry, Evaluation Branch, Bureau of Foods, FDA. Accordingly, in addition to the fact that the proposal was never

^{1/} The 1973 proposal would have withdrawn the prior-sanctioned status of rigid and semi-rigid PVC resins in articles for use with "alcoholic foods." During the time following the proposal, FDA learned that VCM could migrate from rigid and semi-rigid articles in all food-contact applications. Consequently, in September of 1975, the Agency reformulated its proposal to withdraw prior-sanctioned status for all rigid and semi-rigid food-contact applications. At the same time, finding no reasonable expectation of migration, the proposal would have reaffirmed the prior-sanctioned status of flexible PVC.

completed, the basis upon which certain PVC applications would be affirmed as prior-sanctioned, while other applications would be denied such status is no longer valid. All categories of PVC resin, e.g., rigid, semi-rigid and flexible PVC have actually remained and are now legally and otherwise suitable for food-contact applications.

By the terms of FDA's own proposal, "the safety of a substance used in food-contact articles may be reevaluated at any time." 40 Fed. Reg. 40529, 40533 (1975). The proposal also clearly enunciated the FDA policy that prior-sanctioned uses would continue to be approved where there is no reasonable expectation of migration:

"The Commissioner interprets Section 402(a) of the Act, which prohibits use of food-contact articles that may render food injurious to health, as requiring a showing of both possible migration and possible harm. The Commissioner concludes that the criterion of migration in Section 201(s) of the act is appropriately used in applying Section 402(a) of the act. Consequently, a poisonous or deleterious component of the prior-sanctioned food-contact article comes within the terms of Section 402(a) of the act if it may reasonably be expected to become a component of food. Since the carcinogenic potential of vinyl chloride upon ingestion is already sufficiently well-documented to warrant a determination that it may, if present, render food injurious to health, the only prior-sanctioned uses of vinyl chloride polymers that may continue to be authorized are those where there is no reasonable expectation of migration." (Emphasis added.) 40 Fed. Reg. 40533 (1975).

Petitioner is confident that, upon request, FDA will reaffirm the prior-sanctioned status of vinyl chloride polymers in semirigid and rigid articles, such as bottles for use with distilled spirits. Indeed, the prior-sanctioned status of PVC has been "approved" in the press, and a finding of "no migration" within the statutory meaning of the word, affirmed. As stated by former Commissioner Donald Kennedy prior to leaving the Agency, "as far as tests have been able to prove--they show monomer presence of 3 ppb--there's no monomer migration where vinyl chloride is concerned."^{2/} FDA statements made by other Agency officials, although informal, confirm that prior-sanctioned status will, in fact, be reaffirmed.^{3/}

The only factor which could conceivably interfere with a reinstatement of generic approval would be a substantial change in the facts assessed by BATF in its 1973 EIS recommending approval of PVC liquor bottles. However, an evaluation of the Statement in the context of 1979 manufacturing techniques and environmental concerns fully substantiates that the conclusions reached therein have, in fact, been further validated with time. Judicial as well as administrative findings continue to affirm that, in the comparative context of other packaging materials, plastics containers emerge as superior alternatives, from an environmental standpoint, to their more traditional counterparts.

^{2/} Modern Packaging interview, February, 1979, attached at Appendix A.

^{3/} See Food Chemical News, FDA May Not Ban Rigid/Semi-Rigid Use of Polyvinyl Chloride, October 9, 1978, at 7, attached at Appendix B.

From the standpoint of public policy, it is in the interest of the public that alternative packaging materials be made available to distillers. The reduced shipping and storage costs associated with the lighter weight PVC liquor bottle may well result in substantial savings to the consumer. Furthermore, the availability of an entirely new packaging material to distillers may have a "pro-competitive" effect on the price to distillers of competing containers. Although interbrand competition exists, bottle manufacturers currently enjoy a relatively inelastic demand for their products, given the general lack of approved alternative materials. Upon approval, such manufacturers will have to compete not only among themselves, but with PVC bottle suppliers as well.

III. HISTORY OF THE POLYVINYL CHLORIDE LIQUOR BOTTLE

The history of the PVC liquor bottle, in terms of both BATF regulation and FDA proposed action, is instructive on two points which are of the utmost relevance to Petitioner's request for reinstatement of approval. Firstly, the three and one-half year period during which the PVC liquor bottle was on the market under experimental authority afforded more than adequate time to assess the functionality and overall desirability of the PVC liquor container. Indeed, as is evident from the history, BATF's extension of experimental authority was predicated upon satisfactory usage and favorable feedback

from both consumers and the industry, coupled by the objective of the Bureau to thoroughly and comprehensively evaluate the liquor bottle prior to approval.

Secondly, an examination of that period will reveal the industry's sustained and ultimately successful efforts in refining production technique during stripping and compounding to reduce dramatically RVCN concentrations. The "six plus" years which have elapsed since marketing was terminated are marked by constructive and successful industry/FDA cooperation to produce a PVC liquor bottle which has no potential harm to the public.

A. The BATF Experimental Program
For PVC Liquor Bottles

As the Petitioners have indicated, BATF, for a period of almost four years which began in 1968, and terminated in 1973, permitted the experimental use of PVC containers for distilled spirits, provided that the formulations used complied with the applicable requirements of the FD&C Act, and Regulations promulgated thereto. From its inception, the experimental packaging program was responsive to the liquor industry's interest in a plastic bottle.

The packaging program was initiated by the Treasury's Alcohol, Tobacco and Firearms Division, or ATFD as it was then called, in July of 1968, when it issued Circular 68-21 which requested industry views concerning the possible use of plastics

for manufacturing liquor bottles. In response to favorable responses and the results of preliminary laboratory tests which were run by the Division, approval of experimental use for PVC liquor bottles was granted on November 21, 1968. By its terms, experimental use was approved for calendar year 1969 for bottles in less than one-half pint and in one-half gallon sizes. The rationale for restricting the experimental bottling to these two sizes was to keep the number of plastic liquor bottles released to trade channels within reasonable bounds, yet at the same time, to provide sufficient distribution to reveal any unforeseen practical or technological problems inherent in their use under actual bottling or marketing conditions.

Experimental use was extended through calendar year 1970 for experimental bottling of distilled spirits in PVC plastic bottles because many bottlers were not prepared to start operations until late 1969. The experimental program during 1968 did not provide sufficient time to accumulate necessary data relevant to the actual marketing conditions of PVC containers to determine their suitability for unrestricted use. In response to a survey of participating bottlers of distilled spirits using PVC bottles, experimental use was extended through calendar year 1971. According to the survey, the majority of participants were favorably impressed with PVC, although some reservations with respect to certain characteristics of the bottles were reported. To examine these

reservations, the extension of experimental authority through 1971 was also expanded to include pint-size bottles.

The program was broadened on November 18, 1970, by way of Industry Circular No. 70-34. Each participating bottler was given the option of using any one of the other standard sizes in addition to the less than one-half pint and one-half gallon sizes. Final comments from participants concerning the experimental bottling of distilled spirits and PVC bottles were requested by the Agency on September 17, 1971, in Industry Circular 71-20. Additionally, November 15, 1971, was set as the tentative date for the decision on the acceptability of PVC plastic bottles. Shortly thereafter, on November 12, 1971, the Bureau announced that it would follow the Environmental Protection Agency (EPA) recommendation to assess the environmental impact of PVC liquor bottles under the National Environmental Policy Act of 1969 (NEPA). Experimental authority was extended to June 30, 1972 to coordinate with the time involved in preparing a Draft EIS.

Following up on EPA's recommendation, on January 28, 1972, ATFD released its "Approval of Polyvinyl Chloride Liquor Bottles Draft Environmental Impact Statement." The Draft Statement proposed approval of PVC containers as a suitable material for the manufacture of liquor bottles on the conditions that (1) PVC contain only those additives which meet the requirements of FDA for packaging alcoholic beverages for human consumption, and (2) the bottles be rigid or semi-rigid.

The Draft EIS conclusion that PVC plastics are a suitable material for use in the manufacturing of liquor bottles was made "[O]n the basis of the overwhelming acceptance of PVC bottles by the liquor industry, the favorable recommendation from the ATF National Office Laboratory, and favorable comments from ATF regional offices."^{4/}

Responsive comments to the Draft Statement were filed by EPA, the Department of Agriculture (USDA), the Department of Commerce (DOC), the Department of Health, Education and Welfare (HEW), the Department of Interior (DOI), the City of New York, Representative John D. Dingell, Concern, Inc. (an environmental group) and the Glass Containers Manufacturers Institute, Inc. EPA's comments generally summarized the concerns of those persons and groups, raising issues regarding alternative plastics containers, waste generation, open dumping, sanitary landfill, controlled and uncontrolled incineration, litter and irreversible commitment of resources. For the purposes of addressing the concerns of EPA and others, on January 8, 1973, SPI filed, with what had since become BATF, additional data addressing specific points raised.

On October 13, 1972, BATF contracted with Bailie Associates, an independent research group affiliated with the University of West Virginia to provide an independent

4/ Internal Revenue Service, Approval of Polyvinyl Chloride Liquor Bottles, Draft Environmental Impact Statement, January 28, 1972, at 7.

and objective review of the findings in its Draft EIS, and to evaluate the concerns raised by EPA and others. To resolve the factual controversies surrounding the use of PVC, Bailie Associates examined a plurality of factors.^{5/} In view of the

^{5/} Factors which were examined by Bailie Associates included:

- (a) the possibility of utilizing other plastic compounds in manufacturing liquor bottles and the environmental consequences of such materials;
- (b) a comparison of glass versus PVC plastic in regard to their respective uses of natural resources for a specific number of lifesize containers;
- (c) the possibility of setting a precedent for other beverage industries to change to PVC plastics containers and the environmental consequences of such transition;
- (d) the food additive question concerning the suitability of reusing PVC liquor bottles for other applications such as food packaging, either commercially or in the home;
- (e) contributions of the PVC liquor bottle to the problems of solid waste disposal;
- (f) contributions of the PVC liquor bottle with respect to disposing of PVC plastic in open dumps, sanitary landfills and by composting;
- (g) evaluation of materials available and the alleged corrosive effects of PVC plastic in incinerators and the contribution of PVC plastic to air pollution when incinerated or when burned in uncontrolled, accidental fires;
- (h) the feasibility of reusing PVC liquor bottles and the problems or advantages inherent to recycling PVC plastics as compared to glass; and
- (i) the impact of PVC liquor bottles on liquor, consumer safety and accidental fires as assessed from the standpoint of published information and available expertise.

ongoing environmental assessment of the PVC liquor bottles, the experimental program was extended until June 30, 1973 and that date was specified as the final time limit for the program.

Bailie Associates determined, after an extensive examination that, overall, PVC liquor containers were less harmful to the environment than glass liquor containers. The Bailie Report was attached to the Bureau's Final EIS, issued on March 9, 1973, and the Bailie conclusion was adopted by BATF. Accordingly, the Final Environmental Impact Statement proposed approval of PVC as a suitable container material for use with distilled spirits.

In support of its proposed action, the EIS summarized the results of the experimental program of packaging distilled spirits in PVC. According to the comments of the 21 participants, the majority of industry members found PVC plastic bottles to offer numerous advantages including "lighter weight, resistance to breakage, shape and color versatility, space saving and consumer acceptance."^{6/} The PVC bottle also scored well on product considerations. It was reported to be "comparable to glass in such areas as taste transfer, permeability and durability."^{7/} Other findings based on

^{6/} Bureau of Alcohol, Tobacco and Firearms Polyvinyl Chloride Liquor Bottles, Final Environmental Impact Statement, March 9, 1973 at 5.

^{7/} Id. at 6.

experimental usage included the potential for substantial savings in shipping and storage costs. Given the weight differential between glass and plastic liquor bottles (glass one-half gallon bottles are approximately eight times as heavy as PVC bottles of the same size), the EIS observed that shippers using one-half gallon PVC bottles reported 50% more cases could be placed on a truck of a given weight load capacity or limitation.^{8/}

The Final EIS reiterated the conclusions reached in the Draft Statement; it approved the use of PVC plastic as a suitable material for use in the manufacture of liquor bottles, citing the "overwhelming acceptance" by industry members participating in the program, and the favorable recommendations from the ATF laboratory, ATF regional offices, as well as the results of the Bailie Associates Report. In reaching this conclusion, BATF performed the requisite analysis under NEPA, carefully weighing the relevant factors. Importantly, the Statement observed that "the alternative of not approving polyvinyl chloride plastic as a suitable material for the manufacture of liquor bottles would constrain the liquor industry to continue to use bottles of glass, earthenware, and other currently approved materials which include aluminum, tinfree steel and similar metals."

^{8/} Id. at 9-11.

Permanent authorization was, of course, made contingent on PVC compound satisfying FDA criteria for food safety. It was in this area that problems arose. At approximately the same time that BATF was finalizing its assessment of PVC liquor bottles, representatives of Schenley Distillers, Inc., Cincinnati, Ohio, were finding trace amounts of vinyl chloride migrating from PVC bottles into distilled alcoholic beverages, such as vodka and gin. FDA subsequently confirmed the findings of the Schenley migration study and communicated such findings to BATF by way of a letter dated May 3, 1973. FDA's letter advised the Bureau that FDA would be issuing a proposed regulation which, if finalized, would disallow the packaging of alcoholic beverages in PVC bottles.

BATF's reaction was immediate. On May 11, 1973, the Bureau issued Industry Circular No. 73-110 which terminated, on a generic basis, experimental packaging of distilled spirits in PVC containers, effective midnight of the same day. The Circular referenced FDA's letter which stated that the proposed withdrawal was based on "recently received data that indicated that the vinyl chloride monomer would leak into the packaged distilled spirits at levels which may be of toxicological concern." Thus, on May 11, use of PVC liquor bottles came to an abrupt halt. In the six and one-half years which have since lapsed, not a single alternative packaging material which can compete effectively with existing containers has been authorized by the Bureau.

B. FDA Proposals Regarding PVC
For Food-Contact Applications

FDA's proposed regulation was published in the Federal Register on May 17, 1973, 38 Fed. Reg. 1291 (1973).

As written, it would have precluded use of PVC resin in articles for use in contact with "alcoholic foods." The basis of the proposal was twofold: (1) the finding that residual vinyl chloride in PVC bottles was being extracted by bottled distilled spirits and wine,^{9/} and (2) the fact that no available animal feeding studies established a safe level of consumption when vinyl chloride was extracted from containers into food.

The plastics industry reacted immediately. Action was taken among suppliers of PVC compounds to confirm and eliminate the possibility of unexpected migration. Containers in use during the experimental period were believed to have had RVCM contents in the range of 500 ppm. Industry efforts to reduce vinyl chloride monomer continued and in November, 1974, Ethyl Corporation advised FDA that a less than 1 ppm of RVCM specification for food-grade bottle compound could be met by January, 1975.

^{9/} Schenley Distillers had reported levels of vinyl chloride as high as 20 parts per million (ppm) in vodka and 25 ppm in gin; FDA confirmatory work showed levels of 11 ppm vinyl chloride in vodka and 12 ppm in gin.

The May 17, 1973, FDA proposal was never adopted or made effective in any way. When the same types of PVC bottles used for distilled spirits were used for aqueous and oily foods, RVCN was observed to migrate to these foods as it had the alcoholic foods. Accordingly, on September 3, 1975, in a subsequent Notice of Proposed Rule Making entitled "Vinyl Chloride Polymers in Contact With Food," Docket No. 75N-0190, 40 Fed. Reg. 40529 (1975), FDA proposed to prohibit all uses of semi-rigid and rigid vinyl chloride polymers in food-contact articles, such as bottles and sheets because in such applications, vinyl chloride might reasonably be expected to become a component of food. Additionally, the proposal sought to reaffirm the prior-sanctioned status of flexible PVC because data reviewed by FDA at the time established that there was no reasonable expectation of migration.

In the years following the 1975 proposal, Ethyl Corporation, a member company of SPI, launched a comprehensive research program to determine whether there was a residual monomer level for rigids and semi-rigids below which there would be no reasonable expectation of migration, or whether migration would continue at all levels of residual monomer.

The positive results of this program are the "driving force" behind this Petition. Firstly, Ethyl's research demonstrates that RVCN cannot, realistically, be further stripped from rigid PVC products when the level has been reduced to the low ppb range. Secondly, no change in RVCN

levels in the wall of the container can be measured when 50% ethanol, edible oil and water are stored in such containers for extended time periods, even at elevated temperatures.

These two important findings have been confirmed at FDA's packaging laboratory and show that there is no reasonable expectation of vinyl chloride migration to food, even though there is a finite measurable level of RVCM in the container wall. The data have been reported to FDA and are attached at Appendix C.

IV. SUMMARY OF DATA WHICH ESTABLISH THAT
PVC COMPOUND POSES NO REASONABLE
EXPECTATION OF MIGRATION TO DISTILLED
ALCOHOLIC BEVERAGES OR OTHER FOODS

Even before publication of FDA's 1973 Notice regarding the use of PVC polymers in contact with alcoholic foods, The Society of the Plastics Industry, Inc. (SPI) provided FDA with updated information regarding the newly discovered phenomenon of migration of RVCM from PVC containers into alcoholic beverages. Since that time, SPI and some of its member companies have provided a continuous flow of information on the subject.

Of particular relevance here was that within the range of observed data (RVCM levels of 1 ppb and above), it had been demonstrated that conventional diffusion equations would reliably predict diffusion/migration from PVC resin and rigid PVC containers. According to these equations,

diffusion/migration is a linear function of the RVCM concentration. As such, the equations developed based upon relatively high levels of RVCM predicted that there would always be migration, however, small, as long as there is any level of RVCM. By 1975, however evidence had been presented by Dr. Gilbert of Rutgers University that when the RVCM level was sufficiently low, i.e., at some level below 1 ppm, the monomer appeared to be "trapped" or immobilized and, hence, that diffusion/migration was not a linear function of RVCM concentration.

Ethyl Corporation launched a comprehensive research program to try to produce PVC bottles from which there would be no migration. The investigation was evolutionary in that results obtained at one stage of the investigation guided the research goals established for a subsequent step; and with improvements in analytical detection capabilities, questions that could not be answered at one time became subject to resolution later.

The most important phase of the Ethyl investigations began when FDA developed an analytical procedure capable of measuring RVCM at levels in the range of a few (e.g. 1 to 2) parts per billion (ppb)^{10/}. Utilizing this analytical pro-

10/ It is important to recognize that the lower detection limit (sensitivity) for an analytical procedure is rarely a precise value. Rather, it is an estimate of a value that can generally be achieved; but at any given time a particular analyst in a particular laboratory may fail to reach, or may exceed, the lower detection limit claimed for a procedure.

cedure, Ethyl undertook to determine:

(1) During the removal of RVCN from PVC resin (i.e. during the "stripping" operation), does the RVCN concentration drop to some finite value below which the monomer can not be removed?

(2) Can bottles be fabricated from such resin; will the RVCN level in bottles fabricated from such resin be further reduced?

(3) If bottles fabricated from such resin were used to store beverages, including 50% ethanol solutions, at elevated temperatures for extended periods of time, would the traces of RVCN migrate to the contents?

Protocols for these studies were designed in collaboration with the Bureau of Foods' scientists, and samples of resins, compounds and bottles^{11/} at various stages of the experiments were given to the Bureau of Foods so that the analytical results obtained by Ethyl could be independently confirmed. As a result of the work conducted, the following results were obtained:

(1) When PVC resin in powdered form was heated, it rapidly and steadily lost residual

^{11/} Resin is the polymer as it is produced. The resin is blended with technologically necessary substances (adjuvants) such as thermal stabilizers and impact modifier to produce a molding compound. By the application of heat and pressure the compound is softened sufficiently so that it can be shaped and fused (molded) into a finished plastic product such as a bottle.

monomer until a level in the low ppb was reached. Additional heating resulted in no further reduction in the residual monomer level. Thus, it appeared that the RVCN content of PVC resin as produced existed in two forms:

(a) monomer that was mobile and which would rapidly migrate from the resin especially when the resin was heated, and

(b) monomer which was so firmly bound or trapped that it would not migrate even though elevated temperatures were employed.

(2) Bottles could be manufactured from PVC resin or compound with similar very low RVCN levels. Compounding a low RVCN resin did not result in further RVCN reduction.

(3) When these low RVCN bottles were filled with 50% alcohol, edible oil, water, or nitrogen, and stored at 120°F^{12/} for periods

^{12/} For packaging applications FDA generally considers that tests conducted at 120°F for five days are sufficient to establish the maximum migration of a packaging component into foods. For PVC in particular, temperatures much higher than 150°F result in distortion of the container; thus rigid PVC containers are technologically unsuited for use at higher packaging or storage temperatures.

up to six weeks, the RVCM level remained unchanged. Thus, the phenomenon observed in the resin also was observed in the fabricated articles; i.e., the the residual monomer was trapped or immobilized so that it would not migrate at even unusually long times at elevated test temperature conditions.

It should be made clear that when samples of PVC bottles are being analyzed at these very low levels of RVCM, replicate analyses show some variability. Thus, it would not be unusual for individual samples from a series of bottles made from one batch of compound to show values ranging from less than 1 ppb to as high as 5 ppb. Likewise, replicate batches made in exactly the same way, might show average values differing by several ppb.

Because of the inherent variability of both the analytical method and molded bottles, the results obtained by Ethyl show some scatter. However, if the linear diffusion model which was applicable at higher RVCM concentrations was still applicable to these very low RVCM bottles, the difference in residual monomer content before and after exposure would have been clearly measurable. In fact, no difference could be measured.

One further point should be mentioned. In most migration studies, the concentration of the migrant is measured in

the solvents used. RVCM was not sought in the solvents in this case because no analytical procedures are available with lower detection limits adequate to the task. For example, if all the RVCM in a bottle that contained 2 ppb RVCM in its walls were to completely migrate to the contents of the container, the concentration of vinyl chloride monomer (VCM) in the contents would be somewhat less than 90 parts per trillion (ppt). Since, at most, only half the residual monomer level would be expected to migrate into the contents, the other half diffusing outward, the maximum vinyl chloride concentration in the solvent could not exceed 45 ppt. These levels are far below present analytical capabilities. Nevertheless, the analysis of the RVCM content of the container walls showed that the hypothesis that all the monomer migrates is completely false since no migration at all could be measured.

The data leading to the foregoing conclusions were reported to FDA as they were developed, the final report being submitted early in 1978.^{13/} FDA scientists who had confirmed

^{13/} The following data document Ethyl's progress and its subsequent reporting to FDA:

(1) December 2, 1977, letter from Ethyl Corporation to Dr. Gerard L. McCowin, FDA, attaching protocol for Proposed Experimental Program to Evaluate a Non-Linear Diffusion Response for VCM in PVC bottles.

(2) Revised Protocol (in response to FDA request for amplification) "Proposed Experimental Program for Determination of Vinyl Chloride Monomer (VCM) Diffusion in PVC."

(continued on next page)

some of the analytical measurements have raised no technical objections since that time either to the results or to the major conclusion that flowed from it: when the residual monomer level of PVC is in the low ppb range, there is no reasonable expectation that vinyl chloride will become a component of food.^{14/}

(Footnote 13 continued)

(3) June 29, 1978, letter from Ethyl Corporation to Dr. Robert Livingston, FDA, reporting "Results of Experimental program for Determination of Vinyl Chloride Monomer Diffusion in Polyvinyl Chloride."

(4) Minutes of Ethyl Corporation's August 25, 1978, meeting with FDA, attaching various progress reports to FDA.

(5) September 5, 1978, letter from Ethyl Corporation to Dr. Robert Livingston, FDA, attaching "Additional Proposed Experimental Program for Determination of Vinyl Chloride Monomer (VCM) Diffusion in PVC."

(6) October 19, 1978, letter from Arthur Lipman, Ph.D., FDA, to Ethyl advising that the September 5, 1978, protocol was satisfactory with additional experimental work.

(7) February 21, 1979, letter from Ethyl Corporation to Dr. Robert Livingston, FDA, reporting data in accordance with Ethyl's proposed program of September 5, 1978.

^{14/} The FDA memorandum of July 27, 1978 is said to provide a comprehensive review of the analytical data. It is reported to agree that in any meaningful or realistic sense there is no vinyl chloride migration from the low RVCM containers. It states, however, that in an absolute, molecular sense, "zero" migration is a scientific absurdity -- and that it is impossible to prove or disprove.

V. SATISFACTION OF PROCEDURAL GUIDELINES
CONTAINED IN INDUSTRY CIRCULAR
NO. 76-19 "MANUFACTURE AND
USE OF PLASTICS CONTAINERS"

Procedural Guidelines which set forth the contents appropriate to a Petition for approval of plastics compounds for bottling of distilled spirits are contained in Industry Circular No. 76-19, which was issued on August 25, 1976. In accordance with § 3 of the Industry Circular, Petitioner hereby addresses the following "conditions and considerations" which are to be assessed by the Bureau prior to acting upon an application for the use of plastic liquor bottles.

1. Bottle Specifications

(a) Petitioner seeks only generic approval of rigid or semirigid PVC liquor bottles. Accordingly, all liquor bottles produced by individual molders for specific distillers will have a molded shape or design which cannot be permanently altered by pressure without damage to the bottle. Petitioner respectfully requests the Bureau to take notice that all PVC bottles on the market in the years 1968 through 1973 under experimental authority met this criterion.

(b) Under the FD&C Act, and the Regulations promulgated under it, PVC compound, provided there is no reasonable expectation of VCM migration, is acceptable for use in containers for packaging alcoholic beverage products for human consumption. Insofar as specific written verification

to this effect is required under the Bureau's procedures, Petitioner has submitted a request for such verification to Mr. Richard J. Ronk, Director, Division of Food and Color Additives, at FDA. A copy of this request is attached at Appendix D. In view of the supporting data which confirm that PVC bottle compound can be manufactured to ensure that there is no reasonable expectation of RVCM migration, Petitioner believes that written verification from FDA will be forthcoming.

(c) Insofar as Petitioner's request is limited to Bureau approval of PVC as a suitable material to package distilled spirits, the condition in subparagraph c that bottles must be manufactured "only in approved sizes" is not applicable.

2. Laboratory Tests

Petitioner respectfully refers the Bureau to the test results obtained by the ATF laboratory during its experimental assessment of PVC liquor bottles. These tests have evaluated the requisite factors, i.e., proof gain or loss, volume reduction and other pertinent parameters. The refinements that have since occurred in the manufacture of PVC do not affect the accuracy of these laboratory results.

3. Environmental Assessments

An Environmental Impact Statement has already been prepared by the Bureau assessing the environmental impact of the polyvinyl chloride liquor bottle. Bureau acknowledgment that this requirement has in fact been satisfied for

SPI-16312

PVC is evident in the Industry Circular which states that: "[I]n addition to the EIS which was issued regarding the proposed PVC liquor bottles, there will be a need for further studies into the environmental aspects of other plastics prior to our taking any action regarding their proposed use in the manufacture of liquor bottles." Accordingly, Petitioner respectfully submits in satisfaction of the requirement of environmental assessment the 1973 final EIS, by reference, which recommended approval of PVC liquor bottles.

Although the assessment was performed over six years ago, recent environmental evaluations of plastics materials, on the administrative as well as the judicial level, confirm the current validity of the 1973 statement. Specifically, in 1976, FDA released a Final EIS entitled "Plastic Bottles for Carbonated Beverages and Beer," which recommended approval of plastic beer and soda bottles. This Statement focused specifically on containers composed of acrylonitrile (AN) and polyethylene terephthalate (PET) resins, yet made general findings in the areas of manufacture and use, disposal, litter, safety and cost/benefit analysis which are applicable to the PVC bottle. As such, the 1976 assessment affirms the recommendation of the 1973 EIS to approve PVC bottles.

Examples of how the 1976 EIS, the two court decisions and various regulatory measures affirm the specific findings in the 1973 EIS are discussed in Appendix G.

4. BUREAU PROCEDURE

.01 Preliminary Testing Program

Petitioner respectfully requests that data obtained through the prior experimental program on shelf testing, organoleptic research and other applicable tests be considered in conjunction with this Petition.

.02 Application for Approval

This Petition shall serve as formal application to the Director requesting generic approval of the PVC liquor bottle for use with distilled spirits. Extraction data in support thereof are attached to this Petition as Appendix C and have been attached to Petitioner's request to FDA for verification that the PVC compound in question meets all application FDA requirements for alcoholic beverage packaging.

.03 Samples

Petitioner respectfully requests that the submission of plastic container requirement be waived insofar as this Petition seeks "generic" relief, and further since BATF is thoroughly acquainted with the properties of the PVC liquor bottle.

CONCLUSION

For the reasons stated herein, Petitioner respectfully requests that BATF reinstate approval of polyvinyl chloride as a suitable material to package distilled spirits.

Respectfully submitted,

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SPI-16315