H. R. FLAMMER

READER FILE

MAY, 1988

VPP 623256

PREMIERE POLYMERS

Premiere Polymers
3001 Watterson Trail
Post Office Box 99311
Jeffersontown, Kentucky 40199
502-361-1011

TRANSMISSION FOR FACSIMILE MESSAGES:

DATE: 5/23/88

NO. OF PAGES: 5
INCLUDING THIS ONE.

FROM: SH Saborsky

LOCATION: Premiere

TO: HR Flammer

LOCATION: Houston

IN THE EVENT THAT ANY PAGES ARE MISSING OR UNREADABLE, PLEASE CONTACT US IMMEDIATELY.

MESSAGE: See attached which was sent to HJ Hall

VISTA POLYMERS INC.

MAY 23 1988

PVC BUSINESS AREA

VPP 623257

PREMIERE POLYMERS

Premiere Polymers
3001 Watterson Trail
Post Office Box 99371
Jeffersontown, Kentucky 40199
502-267-1011

TRANSMISSION FOR FACSIMILE MESSAGES:

DATE: 5/23/88

NO. OF PAGES: 4
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FROM: SK Sabosky

LOCATION: Premiere

TO: HJ Hall

LOCATION: Ponca City

cc: (By FAX)
HR Flammer-
Houston

IN THE EVENT THAT ANY PAGES ARE MISSING OR UNREADABLE, PLEASE CONTACT US IMMEDIATELY.

MESSAGE: Thought you would want to see the attached article which is the result of the bus accident which killed 27 people near Louisville.

I called Scott Thurm at the Courier Journal and told him that vinyl chloride is not a product of combustion when vinyl burns. I told him CO and HCl were. His information supposedly came from Bill Martin, Kentucky Fire Marshall. Scott said he would go back to Martin and

clarify his statement and would issue a correction if necessary.

I suggest that you call the VI and fill them in. More erroneous information may come out. Also, someone from VI may want to contact Bill Martin.

Let me know if I can do anything else on this end.

[signature]

The Courier-Journal

EDITION, 76 PAGES. ★★★

FRIDAY MAY 20, 1988 35 CENTS

Seat padding speeds bus fires, tests show

By SCOTT THURM
Staff Writer

582
7194

Three weeks ago, Carlisle Beasley conducted a frightening experiment.

The director of transportation for the metropolitan Nashville, Tenn., school district stuffed seven or eight pieces of newspaper into a paper bag. He placed the bag in the first row of a 1977 school bus and set it afire.

Less than four minutes later, Beasley said, the bus was engulfed in flames.

About the same time, Nashville-area firefighters practiced rescuing passengers trapped in a school bus. But the results of the fire made the rescue drill irrelevant, Beasley said.

"We concluded that the fire department wouldn't be on the scene before the bus was lost."

Beasley's experiment, and others, are receiving scrutiny in light of a collision and fire in Carrollton Saturday night that

See SEAT PADDING
Back page, col. 4, this section

STAFF PHOTO

Seat padding speeds bus fires

Continued from Page One

killed 27 people in a church group returning from Kings Island in an older school bus. The state medical examiner has said all 27 survived the crash but died of smoke inhalation.

A growing number of school officials and experts believe that the foam padding that cushions passengers in collisions also burns rapidly and greatly accelerates a fire's spread.

The padding also emits toxic chemicals when burned, which could make escape from a burning bus more difficult, they say.

"There isn't any question but that in any number of cases, the seats helped spread the fire," said Paul Stewart, a member of the National Safety Council who recently retired as director of school transportation in West Virginia. Stewart reviewed more than a half-dozen fires in an article for the American School Board Journal last November.

Investigators are examining the role of the seats in the fire that consumed the church bus.

"There's no doubt that they did lead to the extension of the fire, and there's no doubt they did emit toxic fumes," Kentucky Fire Marshal Bill Martin said. But he said he couldn't determine how much the seats may have contributed to the spread of the fire or to the deaths.

Carroll County Coroner James Dunn said he is awaiting results of blood tests to see whether toxic fumes played a role in the deaths.

Dr. Frank Miller, a surgeon at Humana Hospital-University of Louisville who is treating some of those burned in the crash, said his patients' lungs and breathing cavities show evidence of being burned by chemicals. He could not say what chemicals.

Martin said he saw foam-rubber padding in the bus when he examined it Sunday. When burned, he said, the foam emits hydrogen cyanide gas, which is very toxic. In addition, he said, vinyl typically used for seats on school buses can emit another toxic gas, vinyl chloride.

The bus that burned Saturday night was a 1977 Superior — a different company from the one that made the bus burned in Nashville. An official of Superior's parent company said yesterday he could not say what the cushions on his company's 1977 models were made of.

However, officials of three other bus makers said polyurethane, or rubber foam, has long been used almost exclusively on school buses.

Federal rules spell out how quick-inches per minute. Ralph Hitchcock of the National Highway Traffic Safety Administration, which sets the rules, said this week the standard is "fairly stringent" and has not been a problem in other accidents.

Indeed, federal safety officials could cite only one other accident in which school-bus passengers died of fire-related injuries. That was the Jan. 21, 1984, collision between a school bus and an empty gasoline tanker truck that killed nine people in West Glacier, Mont.

But Stewart and others cited a long series of close calls, in which children were evacuated from buses shortly before the vehicles were engulfed in flames. And a federal research agency reported problems with similar seat cushions more than 10 years ago.

In a 1975 report, the Center for Fire Research at the National Bureau of Standards in Gaithersburg, Md., said seats on a city bus — with coverings that meet the federal standard — are "the most probable cause of hazard" once a fire begins.

Andrew Fowell, deputy director of the center, said the report noted that thick, heavy smoke can reduce visibility to nothing in less than two minutes and fire can spread from seat to seat — as survivors said Saturday's fire traveled. It recommended reducing the risk by placing a fire-resistant barrier beneath the seat covering.

More than a decade later, several products claim to do just that. Using fire-resistant materials, manufacturers say they can give passengers more time to evacuate.

But officials of several bus companies that are offering the materials say they have found few takers; all said fewer than 1 percent of their orders include requests for the seats, which cost about $30 more each, or about $660 per bus.

Even an official of a firm that developed a fire-resistant seat doubts it would have been much help Saturday night.

"No material would stop a fire fed by an outside fuel source, such as petroleum," said Morris Adams, vice president for marketing at Thomas Built Buses in High Point, N.C.

One state — New Mexico — and several large school districts have been using the materials.

"We looked at it as an investment in safety," said John LaRock, superintendent of the Board of Mental Retardation in Greene County, Ohio, which has 11 buses with the highly fire-retardant seats.

Other school officials — including Nashville's Beasley — said they were considering using the new materials but were put off by reports that they are not durable.

The accident has focused attention on a second factor relating to school-bus fires: the choice of fuel.

The bus that burned Saturday night after being hit head-on by a pickup truck was powered by gasoline, which emits flammable vapors at any temperature above 45 degrees below zero. By contrast, vapors from diesel fuel, used in an increasing number of buses, do not become flammable until they reach more than 100 degrees.

With temperatures in the 70s Saturday night, diesel fumes would have needed heat from another source — such as the exhaust system — to become capable of igniting, said Martin, the fire marshal.

Officials of school systems and bus manufacturers said more diesel-powered buses are being bought each year, and that diesel sales probably outnumber gasoline-powered buses. The nation's largest school-bus-chassis manufacturer, Navistar, stopped making gasoline-powered vehicles in 1984.

But safety was not a factor in the shift.

"It made a lot of good economic sense and we did it," said John McDonald, spokesman for Navistar. He said diesel engines last longer and need fewer repairs.

Information for this story was also gathered by Larry Bleiberg.

VPP 623261

H. R. FLAMMER

A

READER FILE

MARCH 1988

VPP 623262

The Vinyl Institute
A Division of The Society of The Plastics Industry, Inc.

Roy T. Gottesman
Executive Director

March 24, 1988

TO: The Vinyl Institute Executive Board

RE: FDA Evaluation of Market Potential For PVC Food Contact Applications

Attached is self-explanatory and for your information and files.

RTG/pmb
cc: B. Luss

Wayne Interchange Plaza II • 155 Route 46 West • Wayne, NJ 07470 • (201) 890-9299

FEB 2 1989

Mr. Richard E. Sanderson, Director
Office of Federal Activities, A-104
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Sanderson:

The purpose of this letter is to request EPA assistance in the environmental review of FDA's proposed rule on vinyl chloride polymers (PVC) (51 FR 4177; February 3, 1986).

In support of the February 3, 1986, PVC proposal, FDA issued an Environmental Assessment/Finding of No Significant Impact (EA/FONSI) to meet its obligations under the National Environmental Policy Act (NEPA). In addition, the proposal requested data bearing on the issues and conclusions contained in the EA/FONSI, including information on 1) the environmental fate and effects of plasticizers used with PVC, and 2) whether PVC contributes to the emission of chlorinated dibenzodioxins (CDD) and chlorinated dibenzofurans (CDF) from municipal solid waste incinerators. The proposal stated that the agency would reexamine its conclusions if new information suggested that the action would have a significant environmental impact.

EPA has previously commented (see letter dated June 2, 1986, appendix A) that it had identified no strong reasons for FDA not to proceed with the proposed action, but that it had concerns with the two areas of potential environmental problems identified by FDA (i.e., fate and effects of plasticizers and potential for CDD and CEF emissions). EPA also expressed concern that the EA did not thoroughly support the FONSI, specifically with respect to 1) the quantity of plasticizers and plastic products affected by the proposal, 2) the extent of discussion of mitigating measures, and 3) the need to clarify the decision against further studies to eliminate the uncertainties.

In response to this comment, the Environmental Impact Section, Center for Food Safety and Applied Nutrition (CFSAN), contacted various scientists and State and municipal authorities to acquire data to further assess the environmental impact of the PVC proposal and to address EPA's comments. As a result of these contacts, the agency has received about 1,400 comments and inquiries. Most of these comments and inquiries have expressed concern about FDA's action on PVC and have requested that FDA prepare an environmental impact statement.

These comments have also raised several additional issues including 1) effect of PVC incineration on municipal incineration plant compliance with State emissions requirements for hydrogen chloride, 2) complications created in recycling programs as a result of the presence of PVC, and 3) the belief

by some State and municipal officials that increasing use of PVC will exacerbate the solid waste management crisis resulting from diminishing landfill capacity. A list of State and local governments and environmental organizations submitting comments is included in appendix B. We have also included in appendix B, a copy of several of these submissions as examples of the concerns raised by State and municipal officials and by environmental organizations. Copies of other submissions are available upon request.

The Society of the Plastics Industry (SPI) and other industry comments claim that FDA's action will not have a significant environmental impact and have urged FDA to promulgate a final rule as quickly as possible. It is our understanding that EPA has received from SPI a copy of SPI's submissions to FDA dated January 13, 1987, April 20, 1987, and October 23, 1987. Copies of other industry comments are also available upon request.

FDA's current understanding and analysis of the principal environmental issues, including consideration of comments received from EPA and others, is described in appendix C.

FDA has not yet decided whether an environmental impact statement is required. To make this decision, we must determine whether the action will cause significant environmental effects. The term "significantly" is defined by CEQ under 40 CFR 1508.27. This definition lists several criteria for judging whether an action is significant, including the degree to which environmental effects are likely to be highly controversial and highly uncertain, and whether an action will threaten a violation of Federal, State, or local laws for the protection of the environment. We are currently evaluating whether one or more of these criteria are met.

Another factor to consider in determining the significance of the impact of this action is the magnitude of the projected increase in PVC market volume. EPA specifically requested in its June 2, 1986, comments that FDA present more clearly the effects of the proposed rule on present and future quantities of plasticizers and plastic products. The magnitude of the projected increase in market volume of PVC remains an area with considerable uncertainty and disagreement. SPI, which in 1983 estimated that an annual increase in the PVC resin market of approximately 350 million pounds would result from FDA's proposed action, recently revised its estimate to reflect changes in market conditions. SPI now estimates that the only increase in the PVC resin market that will result from FDA's proposed action will be the increase that results from the use of PVC in liquor bottles - which it estimates will be 12 million pounds per year. SPI estimates that current uses of PVC in non-liquor bottles will decline by 16 million pounds, resulting in a net decrease in the annual use of PVC bottles of 4 million pounds by 1991. However, CFSAN's Economics Section projects that FDA's action on PVC will result in an increase in the annual use of PVC of 180 million pounds (appendix D).

At this time, we are requesting EPA assistance as follows:

1. Please review and comment on our analysis of the environmental issues associated with FDA's proposed rule on PVC, the methods that we used in quantifying the relative magnitude of the action, and our preliminary findings (appendix C).

2. Please provide us with any new information that you have that bears on the issues considered in appendix C, particularly information that would eliminate any of the uncertainties that we have identified.

3. We would appreciate it if you would suggest approaches to use to predict environmental exposures to, and environmental effects from, municipal solid waste incinerator emissions associated with the increased use of PVC from FDA's action. We are particularly interested in HCl, CDD, CDF, chlorobenzenes, chlorophenols, organotins, and metallic chlorides.

4. Please tell us whether you think that items 1 and 2 (paragraph 1) contained in EPA's undated letter to FDA are still accurate (appendix E). We are particularly interested in whether these items would be affected by the July 28, 1987, U. S. Court of Appeals decision (NRDC vs. EPA) that directed EPA to revise its vinyl chloride NESHAP and to base the standard solely on risk to health. In addition, we understand that this NESHAP does not cover compounding and fabricating facilities. Please tell us whether you think FDA's action could result in increased vinyl chloride emissions from such facilities and what the potential is for adverse health or environmental effects.

5. Please comment on whether FDA's action will have any effect on industry compliance with the recently established effluent limitations and standards for vinyl chloride (52 FR 42522; November 5, 1987).

6. In light of EPA's intent to regulate incinerator emissions (52 FR 25399; July 7, 1987), please provide us with your view on whether FDA's action on PVC would a) run counter to any regulation promulgated by EPA, b) be mitigated by future EPA regulations, or c) affect (and if so, how) the ability of municipalities to comply with new Federal standards for solid waste incinerators.

We would appreciate your response to this request within 60 days. If you have any questions, please contact Dr. Buzz L. Hoffmann at 485-0276.

Sincerely yours,

Richard J. Ronk
Acting Director
Center for Food Safety
and Applied Nutrition

VPP 623269

APPENDIX A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
EXTERNAL AFFAIRS

MAY 2 1986

Buzz L. Hoffman, Ph.D.
Chief, Environmental Impact Section
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, DC 20240

Dear Dr. Hoffman:

In accordance with our responsibilities under the National Environmental Policy Act (NEPA), and Section 309 of the Clean Air Act, and at the direct request of the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) has reviewed the proposed rule on vinyl chloride polymers (51 FR 4177, 2/3/86) and the associated environmental assessment (EA). Included in our comments are the comments of the five EPA staff members that you specifically suggested review these documents in your letter of February 19, 1986.

In general, EPA feels that the proposed changes are consistent with protecting human health and the environment. The new, proposed restrictions on any residual monomer contents of the products to very low ppm levels should provide adequate protection while also representing economically feasible operational limits to the manufacturing industry. Therefore, based on current evidence, we have identified no strong reasons for not proceeding with the proposed action. Nevertheless, EPA has concerns with the two areas of potential environmental problems identified by FDA. They stem from uncertainty in 1) the environmental fate and effects of di(2-ethylhexyl) phthalate (DEHP), di(2-ethylhexyl) adipate (DEHA) and epoxidized soybean oil, plasticizers used in conjunction with vinyl chloride polymers; and, 2) the extent to which vinyl chloride polymers contribute to the emission of polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) from municipal solid waste incinerators. Because of these uncertainties, we must point out that our present lack of objections does not preclude future EPA action to address the issue if additional information becomes available to warrant such action.

EPA is also concerned that the environmental assessment (EA) for the FDA-proposed action does not thoroughly support the finding of no significant impact (FONSI). We feel that (1) the potential effects of the proposed rule on present and future quantities of plasticizers

VPP 623271

and plastic products to be used and disposed of needs to be more clearly presented; (2) the discussion on mitigation measures needs to be expanded; and, (3) clarifications need to be made for the decision against further studies on eliminating the uncertainties.

Given the carcinogenic potential of the plasticizers, and their uncertain behavior in the environment, and with the uncertainties surrounding the correlation of PCDD and PCDF emissions with plastics incineration, the EA needs to analyze the potential changes in the amounts produced and disposed. This means demonstrating the quantitative impact of the proposed rule on existing use patterns. If it can be shown that the proposed action will not lead to a significant increase in the production, use, and destruction of these materials, relative to present quantities, it might be seen that the impact of the proposed rule will be environmentally insignificant. Therefore, we encourage FDA to make clear the quantities presently being produced, used and incinerated and to compare this to the possible effects associated with the increased use of vinyl chloride polymers permitted under the proposed rule.

With respect to mitigation measures, FDA states only that it "has not identified any measures it could take to avoid or mitigate potential adverse environmental effects associated with the proposed action (p. 36, EA)." All mitigation measures considered should be presented and dismissed with a discussion as to why they are not viable; if, for example, source-separation of plastics, vinyl chloride polymer re-use, or a deposit on PCV products are infeasible or unrealistic, this should be explained.

We believe that the rationale presented to support FDA's decision not to wait for or initiate further study on PCDDs and PCDFs before proceeding with the proposed action are misleading, if not inaccurate. FDA bases its decision on 1) the suggestion that "vinyl chloride polymers are not important in the formation of polychlorinated dibenzo-p-dioxins in municipal incinerator emissions (pp. 36-37 EA)," and 2) the expectation that the U. S. Environmental Protection Agency will "issue guidelines to help limit PCDDs from solid waste incinerators (pp. 36-37, EA)."

Apparently, FDA relies solely on the work of Karasek et al., (1983) to support the first point. In our view, this is not enough to discount the "hypothesis that vinyl chloride polymer is a primary source of chlorobenzenes, and that consequently, PCDDs are end-products of vinyl chloride polymer waste incineration (p. 14, EA)." In our judgment, current test data are at best, inconclusive (see discussion). On the second point, EPA currently plans to issue an information document on emissions from municipal waste combustion early in 1987. While this report will discuss measures that may reduce the expected level of dioxin emissions, the current state of knowledge does not allow us to presume that those measures are sufficient to render inconsequential the effect of an increase of vinyl chloride in the waste feed. In our view, neither the information currently available, nor the prospect of EPA guidance, supports the decision that no further testing is necessary prior to implementation of the proposed action.

In what follows is a discussion, with references, to assist the FDA in the ongoing effort to assess the potential impacts associated with the proposed rule. If you have any questions on our comments or the enclosed documents, please contact Paul Kaldjian of my staff at 475-8797.

Sincerely,

Allan Hirsch
Director
Office of Federal Activities

Enclosures

VPP 623273

A

Discussion

Plasticizers

DEHP, because of its high production volume and its presence throughout the environment, is currently the most studied plasticizer; at high concentrations, it is a recognized carcinogen, with some evidence of mutagenicity and teratogenicity. In the "Finding of No Significant Impact (FONSI)," FDA states that they can expect "adverse chronic effects to some aquatic organisms to occur from exposure to DEHP before introduction levels from land disposal site leachate are reduced by fate processes." Though FDA expects introduction levels of DEHP to be ultimately reduced through biodegradation, the extent to which this process actually occurs remains unclear. For example, phthalates are readily broken down to CO_2 and H_2O in the aqueous phase, and when they partition from the water column to sediment they concentrate and remain persistent. Concentrations of DEHP measured in parts per billion are found throughout the environment. But where there is sorption and accumulation onto sediment, concentrations may increase to parts per million, a concentration sufficient to cause noticeable adverse effects on the benthic community. Enclosed is a paper addressing this issue, "Environmental Assessment of a Phthalate Ester, Di(2-ethylhexy Phthalate (DEHP), Derived from a Marine Microcosm, (Perez, et al., 1984)." It should be of some assistance.

In addition to the Perez, et al. paper, we have included excerpts from one by the National Research Council of Canada, a list of tests received by EPA from the Chemical Manufacturers Association testing program for phthalate esters, Federal Register notices describing the testing program, a draft summary of "EPA and other Agency Activities on DEHP," and a chemical hazard information profile (CHIP) on di(2-ethylehexyl) adipate. We hope they will be of assistance in developing guidelines for the use of plasticizers.

PCDDs and PCDFs

The current EPA view is that emissions of PCDDs and PCDFs from properly designed and operated municipal waste combustors (MWCs) is not a cause for concern given present, available technologies. However, the increased use of vinyl chloride products will result in an increase in vinyl chloride waste streams and, as the number and capacities of incinerators increase, greater amounts of plastics will be burned. The extent to which these might cause or contribute to PCDD/PCDF emissions from MWCs is not clear. Investigators such as Christopher Rappe and Otto Hutzinger have published results and theoretical arguments that suggest that chlorinated plastics, including PVC, can contribute to the emission of PCDDs and PCDFs from the combustion of municipal wastes. (Perhaps FDA can begin by following up a paper by Rappe, "PCDDs and PCDFs from Various Incinerators," presented at the Dioxin 85 conference held in Bayreuth, West Germany, and soon to be published in Chemosphere.) Further, there are, undoubtedly, MWCs that do not operate up to state-of-the-art incineration levels. EPA is aware of control technologies which apparetly reduce emissions of PCDDs/PCDFs significantly, based on the limited testing that has been done to date.

Karasek et al., (1983), speculate that synthesis of the adsorbed PCDDs on fly ash may be more dependent on incinerator conditions than the presence of vinyl chloride polymers and suggest a detailed, systematic study of incinerator conditions. A study similar to the one proposed is currently being carried out in Pittsfield, Massachusetts by the New York State Energy Research and Development Authority. Enclosed is a page from Public Works describing the study; with it is the name and address of a contact person. EPA encourages FDA to follow the study and to use the results in their decision-making. For your information, we have also enclosed EPA's "National Dioxin Study Tier 4-Combustion Sources" project plan.

VPP 623275

APPENDIX B

APPENDIX B. COMMENTS RECEIVED IN RESPONSE TO FDA'S PROPOSED RULE ON PVC

Among the 1,400 comments and inquiries received by FDA in response to its environmental assessment (EA) and finding of no significant impact (FONSI) prepared in support of the proposed rule on PVC, a number of environmental organizations and State and local governments submitted comments. These groups are identified below. Comments marked with an asterisk have been attached. Also attached is a comment from the Coalition on Resource Recovery and the Environment.

Environmental Organizations

Alabama	Alabama Conservancy Shoals Chapter
	Birmingham Audubon Society
	Fowl River Protective Association, Inc.
California	Californians Against Waste
	Ecology Center of Southern California
	Sierra Club Southern Calif. Regional Conservation Committee
	The Planning and Conservation League
Connecticut	Connecticut Fund for the Environment, Inc.
	Don't Dump On Us
District of Columbia	Audubon Naturalist Society
	*Environmental Task Force
	Fund for Renewable Energy and the Environment
	Greenpeace
	Institute for Local Self Reliance
Florida	Environ. Information Serv. of Friends of the Everglades
Illinois	Center for Neighborhood Technology
	Coalition for Appropriate Waste Disposal
	McHenry County Defenders
	People for Community Recovery
Indiana	Northwest Indiana Coalition for the Environment
Massachusetts	Coalition for Household Hazardous Waste
	Conservation Law Foundation of New England, Inc.
	Quabog Bird Sanctuary
Maryland	Audubon Naturalist Society of the Central Atlantic States
Michigan	Michigan United Conservation Clubs
	Western Michigan Environmental Action Council
Minnesota	Earth Protection, Inc.
	Minnesota Herbicide Coalition
	St. Cloud Area Environmental Council
New Jersey	Colts Neck Environmental Commission
New York	Council on the Environment of New York City
	*Environmental Action Coalition
	*Environmental Defense Fund
	Environmental Planning Lobby
	Hudson River Sloop Clearwater, Inc.
	Hudson Valley Green
	Malverne Environmental Council, Inc.
	Udalls Cove Preservation Committee, Inc.
Pennsylvania	Clean Air Council
	Governor Pinchot Chapter, Sierra Club
	Green Valleys Association

Environmental Organizations (Cont.)

Texas	Ecology Action
	Outdoor Nature Club of Houston
Vermont	Conservation Society of Southern Vermont
	Otter Creek Audubon Society
Washington	Sierra Club Hazardous Materials Committee
	Washington Citizens for Recycling
Wisconsin	Citizens Natural Resources Association of Wisconsin

State Governments

Illinois Department of Energy and Natural Resources
Illinois General Assembly
*Massachusetts Bureau of Solid Waste
*Minnesota Pollution Control Agency
New Hampshire House of Representatives
New Jersey Department of Environmental Protection
*New York State Department of Environmental Conservation
*New York State Legislative Commission on Solid Waste Management
*Pennsylvania Department of Environmental Resources
Vermont Governor's Office

Local Governments

California	San Diego
	Santa Cruz County
Connecticut	New Haven
Illinois	Champaign County (Regional Planning Commission)
	Champaign
	Urbana
Maine	Buckfield
New Jersey	*Essex County
	Evesham Township
	Hardwick Township
	Hunterdon County
	Mullica Township
	Newark
	Rahway
	Somerset County
	West Windsor Township
New York	*New York City (Department of Sanitation)
	New York City (City Council)
	New York City (Comptroller's Office)
Wisconsin	Eau Claire County (Landfill)
	Waukesha County (Solid Waste Management Board)

APPENDIX D

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: June 1, 1987

From: Patricia M. Lasonde, Ph.D.
Economics Section (HFF-303)

Subject: Market Potential for PVC for Food-Contact Uses

To: Buzz Hoffmann, Ph.D.
Chief, Environmental Impact Section (HFF-304)
Through: Chief, Economics Section (HFF-303) RJL

This memo provides comments regarding the validity of the market volume estimates for food-contact uses of vinyl chloride polymers submitted by Keller and Heckman (for the Society of the Plastics Industry, Inc. (SPI)).

This analysis is necessitated by the uncertainty surrounding the market volume forecasts for PVC provided by SPI in four separate submissions: August 17, 1983, November 7, 1986, January 13, 1987, and April 20, 1987. The most significant difference between the estimates contained in these submissions is the reduction in the expected use of PVC resin in rigid and semi-rigid container applications resulting from the promulgation of a final rule regarding the use of PVC in food-contact applications. SPI, which originally forecast an increase in the use of PVC resin in rigid and semi-rigid containers from 31 to 291 million pounds (1983 - 1988) now predicts a net decrease in the use of PVC resin for such applications from 66 to 62 million pounds (1986 - 1991).

SPI has indicated that their current estimates of the potential growth of PVC containers (and other PVC food packaging in general) are substantially lower than their original estimates because: (a) the PVC resin forecasts for 1988 provided in the 1983 submission were overly optimistic based on market conditions existing at that time; and, (b) certain market conditions have changed which would reduce the penetration rate of PVC into certain food-contact applications.

At a February 27, 1987 meeting, FDA explained to industry representatives and members of the Keller and Heckman law firm that information supporting the lower market projections were needed in order to evaluate the revised estimates. (See attached memorandum for details of that meeting). Consequently, Keller and Heckman submitted additional market projections for PVC for FDA review (April 20, 1987).

My comments, which will address the four Keller and Heckman submissions, are presented in three sections. The first section addresses the market potential for vinyl chloride polymers (PVC) in alcoholic beverage containers resulting from a final regulation for PVC. Keller and Heckman argue that PVC is currently approved for use in all food-contact applications for which it is currently technically and economically feasible (1/13/87 and 4/20/87 submissions). Consequently, they contend that the only major new use resulting from FDA's promulgation of a PVC regulation in 1987

would be the use of PVC in rigid liquor containers. Based on supporting information (discussed below), a reduction in SPI's previous estimate of 43.3 million pounds to 12 million pounds of PVC resin associated with liquor containers is reasonable.

The second section discusses the effect of a PVC regulation on food-contact uses other than liquor containers (e.g., juices, bottled water, beer and wine). SPI estimates now indicate that the use of PVC containers will be limited to the liquor and, presumably, edible oils markets. Although Keller and Heckman show that there is some shifting from PVC to polyethylene terephthalate (PET) in the edible oil market which would explain the lower estimate for this application, they do not explain what will prevent PVC containers from competing in other food-contact applications. As FDA indicated in the February meeting with industry representatives, FDA cannot evaluate the validity of the new estimates without supporting evidence. Consequently, this section reviews SPI's original 1983 estimates for PVC use in rigid and semi-rigid containers in light of the existing trade literature concerning the potential uses of PVC in food-contact applications.

The third section provides FDA projections of the usage of PVC in food-contact applications based on the estimates provided by SPI and other PVC market information available in trade journals.

1. PVC Liquor Containers

The following table provides a summary of the estimates of the current and potential use of PVC in all alcoholic beverage bottles submitted by Keller and Heckman on August 17, 1983.

TABLE 1: PVC Resin use in Alcoholic Beverage Containers (millions of pounds)

Beverage	1983	1988
Liquor		
rigid/semi-rigid containers	0.0	43.3
Wine		
rigid/semi-rigid containers	1.0	22.0
plastisols and organosols	2.0	3.0
Beer		
rigid/semi-rigid containers	0.0	10.0
coatings	3.5	3.5
plastisols and organosols	12.0	15.0
TOTAL	18.5	96.8

These estimates indicate that the amount of PVC resin expected to enter the market from rigid containers for all alcoholic beverage containers (liquor, wine and beer) to be approximately 75.3 million pounds in 1988. The remaining PVC resin, 21.5 million pounds, would be consumed in plastisols and coatings.

Keller and Heckman's most recent submission (April 20, 1987) provides the following estimates from industry representatives as well as PVC penetration estimates from various journals.

TABLE 2: PVC Resin use in PVC Alcoholic Beverage Containers
(millions of pounds)

Beverage		1985	1995
Liquor			
	SPI estimate	0	12.0
	Market Search	0	8.2
Wine			
	SPI estimate	0	0
	Market Search	0	11.8
Beer			
	SPI estimate	0	0
	Market Search	NA	NA

It is important to note that Keller and Heckman's submission provides PVC resin estimates for liquor only. They state that some industry analysts have expressed doubt that PVC will have a significant impact on the wine packaging market. There is no mention of any impact on the beer packaging market. It is assumed that SPI currently believes that PVC rigid containers will not capture any of the beer packaging market.

The Market Search, Inc. estimate of 8.2 million pounds of PVC resin for liquor bottles in 1995 is consistent with SPI's reduced estimate. The estimated figures provided by SPI and Market Research are also consistent with the liquor bottle data provided by DISCUS (Distilled Spirits Council of America).

DISCUS estimates the number of 1.75-liter liquor bottles as approximately 231.5 million in 1984.[1] A trend estimate based on 1980-1984 DISCUS figures indicates the expected 1991 production of 1.75-liter liquor bottles to be approximately 277 million.

Because the apparent consumption of liquor is presently decreasing (a trend expected to continue because of higher liquor taxes, an increase in the legal drinking age, changes in consumer preferences[2]), this 1991 figure for the 1.75-liter liquor bottle market is considered an upper-bound estimate.

Assuming:

1. approximately 277 million 1.75-liter liquor bottles in 1995;
2. a 1.75-liter PVC bottle weight of 110 grams (.243 lbs)[3];
3. that PVC resin constitutes approximately 83% of PVC bottle compound[4];
4. that approximately 65% of 1.75-liter liquor bottles have handles[5]; and
5. a PVC market penetration into the 1.75-liter handled bottle market of 25% [6];

implies that approximately 9.3 million pounds of PVC resin will be used in liquor applications in 1991. Consequently, SPI's estimate of 12 million pounds of PVC resin for liquor applications seems reasonable based on existing market conditions.

2. Other Food Contact Applications

The 1983 projection of the 1988 usage of PVC resin in rigid and semi-rigid containers for food classes other than alcoholic beverages was estimated to be 216 million pounds. Although industry representatives emphasized at the February 27th meeting that the original estimates for PVC penetration into these food-contact applications are also overstated (and for some food product categories, unrealistic), the most recent industry submission does not explicitly discuss the reduction in the SPI forecast for most of these applications. The 1987 projection of the 1991 usage of PVC resin in rigid and semi-rigid containers for food classes other than alcoholic beverages is 50 million pounds. (It is interesting to note that the SPI's 1983 projection of 1988 PVC usage in rigid containers for edible oils is 69 million pounds. SPI's April 20, 1987 estimate for current PVC usage in bottle applications (presumably all edible oil containers) is 66.4 million pounds. The proximity of these two estimates indicates that the original estimates may not have been unreasonable for some food products).

There are two explanations for the reduction in SPI's estimate for PVC usage in other food-contact applications. One, SPI now predicts that PVC will not be used in any future food-contact application other than in liquor bottles and edible oils. Two,

Keller and Heckman are arguing that PVC usage for all other current or future food-contact applications (other than for liquor containers) is already approved by FDA and should not be considered in the environmental impact estimates.

In response to the first explanation, Keller and Heckman have not provided any direct evidence that PVC cannot effectively compete with PET, polyethylene or polypropylene in other food-contact applications. Keller and Heckman do indicate that "the markets once anticipated for PVC because of distinct advantages over other packaging materials are not now available because of strong competition from these other plastics, principally PET" (Keller and Heckman, 4/20/87, p. 6). However, it is expected that PVC's potential share of these markets will be reduced to some positive number greater than zero as is the case for liquor bottles and edible oils.[7]

In addition, there is no indication in any trade journal that rigid bottle PVC applications will be limited to the 1.75 liter, liquor bottle market. On the contrary, various trade journals indicate that the potential market for PVC bottle applications is strong for bottling water, juices, and wine.[8] Research is currently underway for PVC and other plastics which may increase the applicability of these substances in other food product markets. For example, it is noted that market penetration by PVC bottles will be accelerated once the resin's heat-distortion temperature is raised above the temperature required for hot-filling. This would allow jams, jellies, and puddings to be packaged in rigid PVC containers.[9]

Reason two can perhaps be explained by the January 13, 1987 submission. Keller and Heckman argue that FDA's promulgation of a final rule on PVC will have little impact on overall PVC production because PVC is prior-sanctioned for use in all food contact applications. They further argue that any barriers to PVC's entry into food-contact markets are technical or economic rather than legal (p. 63). However, it is FDA's determination that PVC is not prior-sanctioned for all food contact applications. In fact, there is no regulation or prior sanction for PVC's use in rigid and semirigid containers.

Consequently, since there is no substantive evidence to the contrary, it is assumed that there will be an increase in the use of PVC in food-contact applications other than in the liquor container market and that this increase should be evaluated in the environmental impact estimates.

Although Keller and Heckman contend that SPI's August 17, 1983 estimates are overstated, these data represent the most detailed

forecasts currently available to the FDA. The survey results for food-contact uses other than for liquor bottles are presented below.

Table 3: Estimates of PVC Usage in Rigid Containers
(millions of pounds)

Food Class	1983	1988
Fluid Milk	0	10
Processed Milk Products	0	20
Cream	0	5
Ice Cream	0	10
Meat, Fresh	0.8	1
Canned Meats and Fish	3	7
Oil	17	69
Butter	1	4
Shortening	0	2
Non-Alcoholic Beverages	0.2	2.6
Fruits and Vegetables (in cans or jars)	5	8.6
Nuts, Shelled	0	2.6
Powdered Dry Food	0.5	7
Tea, Coffee, Cocoa	0	4.6
Desserts	0	2
Preserves	0.2	23
All Other Frozen Meals	1	10
Spices, Seasonings, Condiments	1	21
Water	0.25	6.5
TOTAL	29.95	216.0

Although FDA has no other direct information from SPI to assess the accuracy of these estimates, the following market projections for plastic rigid packaging provides indirect evidence regarding the potential use of PVC in food-contact applications.

The table presented below, provides projections for 1991 of the consumption of plastics for rigid packaging that incorporate extrudable high barrier resins for various food product categories. The first column contains projections of plastic rigid container usage in various food-contact applications for the year 1991 (Plastics Engineering, 1986). The second column contains estimates of the consumption of PVC compound based on hypothetical PVC penetration rates of 1%, 2.5%, and 5%. Since PVC compound typically consists of 83% resin, total PVC resin consumption for each penetration rate is calculated by multiplying total PVC compound consumption by .83 (SPI estimate, 4/20/87).

Total PVC resin consumption is also computed net baby food and infant formula.

Table 4: Estimate of PVC Usage by Food Category
(millions of pounds)

Food Type	Consumption of All Plastics	Consumption of PVC Compound Assuming Various PVC Penetration Rates		
		(1%)	(2.5%)	(5%)
Low Acid				
Vegetables	336	3	8	17
Puddings	379	4	9	19
Baby Food	622	6	16	31
Infant Formula	746	7	19	37
Soup	1,185	12	30	59
Other	2,000	20	50	100
High Acid				
Baby Food	383	4	10	19
Jams, Jellies, Desserts	439	4	11	22
Vegetables	547	5	14	27
Peanut Butter	588	6	15	29
Dressings	1,280	13	32	64
Juice, Juice Drinks	2,247	22	56	112
Sauces	3,116	31	78	156
Fruits and Vegetables	4,910	49	123	246
TOTAL:	18,770	188	469	939
ALL FOOD TYPES AFFECTED:				
PVC Compound Consumption:		188	469	939
PVC Resin Consumption: (83% of PVC compound)		156	389	779
ALL FOOD TYPES EXCLUDING BABY FOOD AND INFANT FORMULA AFFECTED:				
PVC Compound Consumption:		170	426	851
PVC Resin Consumption: (83% of PVC compound)		141	353	706

Source: "Barrier Resins Hold Key to Plastics Food Packaging", Plastics Engineering, 1986.

Based on these forecasts for all plastics, if PVC were to capture between 1% to 5% of the rigid plastic market (excluding baby food and infant formula), PVC resin consumption would total 141 to 706 million pounds in 1991 for rigid container applications. FDA realizes that these estimates are rough and that the penetration rates will vary widely across food-contact applications. However, these estimates do demonstrate that if PVC is able to compete with other plastics and capture even a small portion of the rigid container market, the future usage of PVC will be significant. In addition, these estimates provide indirect evidence supporting the plausibility of SPI's original estimates for rigid and semi-rigid PVC packaging.

3. FDA Estimates of PVC Resin Use in Food-Contact Applications

FDA projections of PVC resin usage in food-contact application for 1991 are contained in the following table.

Table 5: FDA Estimates of Current and Future PVC Resin Use in Food Contact Applications (millions of pounds)

	1986	1991- NO FDA ACTION	1991- FDA PROMULGATION OF PVC RULE IN 1987
Bottles, Nonalcoholic			
edible oil	66	37	50
other	0	0	147 (a)
Bottles, Alcoholic			
liquor	0	0	12
wine	0	0	7 (b)
Film	105	106	106
Plastisols	50	55	55
Sheet	15	25	25
TOTAL (bottles and other packaging):	236	223	402
Compounded Growth Rate (1986-1991):		-1%	11%

(a) SPI's 1983 projection for 1988 for other foods excluding edible oils (216 million pounds - 69 million pounds).
(b) Based on Market Search Inc. estimates for PVC usage in wine.

The most striking difference between FDA's estimates and the estimates provided by SPI in the April 20, 1987 submission is the market projection for nonalcoholc bottles other than edible oil and high-alcohol liquor bottles. (SPI's 4/20/87 estimates are provided in the Appendix.) FDA has received no direct information to indicate that PVC rigid container bottles will be limited to either edible oil or high alcohol liquor containers if the agency promulgates a final PVC regulation. Consequently, SPI's 1983 projection of PVC resin consumption in other nonalcoholic bottles for 1988 is substituted for SPI's current estimate of zero.

Based on SPI's 1983 projections along with SPI's revised estimates for liquor bottles and presumably edible oil, FDA estimates that the effect of this regulation is an increase in the use of PVC of 179 (or approximately 180) million pounds. As can be seen in Table 6 below, this increase arises from an increase in the projected use of PVC bottles. SPI estimates that with no PVC regulation, the use of PVC bottles will drop to 37 million pounds in 1991. However, if FDA prmulgates a PVC regulation, FDA estimates an increase in the use of PVC in bottle applications to 216 million pounds. The difference between these two estimates represents the effect of the regulation.

Since PVC applications for film, plastisols and sheet are currently approved for all food-contact applications, a PVC regulation is not expected to dramatically affect these uses. Although, this regulation may have an indirect effect for some products (e.g., any increase in the use of PVC film, plastisol, or sheet associated with the expansion of PVC bottles into new markets), this indirect affect is expected to be small.[10] SPI current estimates project an annual growth rate for these applications of approximately 2%.

Table 6: FDA Estimates - Bottles and Film/Sheet/Plastisol

	1986	1991- NO FDA ACTION	1991- FDA PROMULGATION OF PVC RULE IN 1987
Bottles	66	37	216
Film/Sheet/Plastisols	170	186	186
TOTAL	236	223	402

FDA's estimates imply a 27% compounded growth rate for PVC use in rigid and semi-rigid bottles for 1986-1991, about half of the 54% compounded growth rate implied by SPI's 1983 projection for 1983-1988, although substantially higher than the -1% compounded growth rate implied by SPI's 1987 projection for 1986-1991. SPI PVC bottle estimates for 1975-1986 for food and non-food applications indicate a 12.8% compounded rate of growth. Keller and Heckman have indicated that a 10-15 year trend of PVC food packaging could not be assembled. Consequently a more sophisticated trend analysis could not be performed. It should be noted that the growth rates for PVC usage in food-contact applications implied by FDA estimates (27% for bottle applications and 11% for all PVC food-contact uses) are expected to eventually decline as the market for new PVC applications matures.

As indicated above, the growth rate implied by SPI's current estimates of the use of PVC in film, sheet and plastisols between 1986 and 1991 is 2%. This rate is lower than the 7% compounded growth rate for film, sheet, film, coatings, plastisols, and organosols reported by Keller and Heckman in the 1983 submission for 1983-1988. Keller and Heckman do not provide an explanation for the decrease in the growth rate estimate although they do provide estimates of the use of PVC in film (1975, 1981, and 1986) and plastisols (1975 and 1986) for food use only which support the lower growth rate projections. Of course, it would be useful to obtain estimates for the intervening years (i.e., 1976-1980 and 1982-1985) in order to evaluate the stability of this trend estimate.

In considering these estimates for PVC, it is important to note that SPI figures represent PVC resin used in domestically produced containers. These figures do not take into consideration the finished products which may be imported in PVC containers and will eventually be disposed of in the U.S. (e.g., bottled water) nor do they account for finished products which may be exported. Unfortunately, any estimate of the net effect of international trade on the amount of PVC entering the U.S. disposal stream would be purely a conjecture.

Patricia M. Lasonde

Patricia M. Lasonde, Ph.D.

APPENDIX

Estimated of Current and Future PVC Resin Use in Food-Contact Applications

SPI ESTIMATES
(millions of pounds)

	1986	1991- NO FDA ACTION	1991- FDA PROMULGATION OF PVC RULE IN 1987
Bottles, Nonalcoholic	66	37	50
Bottles, Alcoholic (liquor)	0	0	12
Film	105	106	106
Plastisols	50	55	55
Sheet	15	25	25
TOTAL	236	223	248

MARKET SEARCH ESTIMATES
(millions of pounds)

	1985	1995
Food Packaging	161.45	283.24
Liquor Packaging	0	8.2
Wine Packaging	0	11.8

FOOTNOTES

[1] PVC bottles, unlike PET bottles, can be marufactured with hollow handles. Most sources agree that this may important in the 1.75 liter bottle market. 1984 1.75 liter bottle estimate: Annual Statistical Review 1984/85, Table 23, DISCUS, Economics and Statistics Division, 1985.

[2] Between 1983 and 1984, U.S. bottling of distilled spirits decreased 2.7%. Jobson's Liquor Handbook, 1986, p.11.

[3] Correspondence between Ron McHugh and Ethyl Corporation, July 6, 1983. Submission, Keller and Heckman, Attachment 5: "Pet to Dominate Plastics for Liquor Packaging", Plastics World, October 1985.

[4] Submission, Keller and Heckman, April 20, 1987, Attachment 2.

[5] "The Plastic Invasion Continues: PET for Liquor", Food Engineering, August 1983.

[6] Submission, Keller and Heckman, Attachment 5.

[7] In fact, Keller and Heckman do not explain the decrease in the use of PVC in food classes other than edible oils which reportedly used PVC in rigid containers in 1983 (e.g., fruits and vegetables in cans or jars used 5 million pounds of PVC in rigid containers in 1983).

[8] "PVC Bottles Coming On Strong", Plastics Engineering, August 1986, "Polyvinyl Chloride" , Modern Plastics, January 1987.

[9] Ibid

[10] The compounded growth rates provided by SPI (4/30/87 submission, attachment 3) for film and plastisols for food-contact use only for 1975-1986 are 1.4% and 2.0%, respectively. However, the data indicates that the growth of film has declined to less than 1% between 1981 and 1986. Keller and Heckman do not provide data for past PVC sheet use.

APPENDIX E

A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

RECEIVED
2
OFFICE OF
EXTERNAL AFFAIRS

Buzz L. Hoffman, Ph.D
Chief, Environmental Impact Section,
Bureau of Foods
Food and Drug Administration
Washington, D.C. 20240

Dear Dr. Hoffman:

This letter responds to your November 18, 1983 request for information concerning the environmental effects associated with the use of polyvinyl chloride (PVC) as a food container. My office sought comments from a variety of sources within EPA in an effort to provide specific answers to your questions.

1. The proposed action should not impact the vinyl chloride NESHAP. Producers of ethylene dichloride, vinyl chloride, and polyvinyl chloride resins are already subject to provisions of the vinyl chloride NESHAP. Should this action result in new plant construction, those plants would be regulated as well.

2. The Society of the Plastics Industry (SPI) has estimated that there would be an approximate increase of 350 million pounds per year of PVC in food contact applications if present restrictions were removed. The capacity of U.S. PVC producers is estimated to be 8.2 to 8.3 billion pounds per year with a demand of 6.6 to 6.9 billion pounds per year (1984 projections). An increase of 350 million pounds would represent about 4% of the current industry capacity. Since the industry is operating at about 80% of capacity, increased demand for PVC would probably be accomodated by existing PVC capacity.

   Further, reviewers were concerned that PVC incineration may result in the formation of toxic chlorinated aromatic pollutants, e.g., chlorinated dibenzofurans and chlorinated dibenzodioxins (CDF's and CDD's). Recent monitoring of municipal incinerators has shown that CDD's are produced at low levels. Although chlorinated aromatics (PCB's, chlorobenzyenes, and chlorophenols) are considered the most

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likely precursors, some reports have suggested the possibility that PVC's could also contribute to the formation of CDD's and CDF's. More information on this point should be sought from the appropriate experts in incineration at EPA, other agencies, and the scientific community. Also, FDA should review the potential litter problem resulting from a manifold increase in the use of disposable containers (like soda bottles).

3. EPA does not anticipate any actions that would cause hydrogen chlorides to be regulated by NESHAP, NAAQS, or NSPS and feels it unlikely that the proposed action would precipitate consequent regulation.

4. Regarding possible groundwater contamination, our reviewers feel that problems arising from land disposal of PVC might be significant, noting that vinyl chloride had been found in groundwater near landfills (e.g., Lee Lanes landfill in West Virginia).

I have enclosed copies of five documents that our reviewers believed would assist you in preparing the environmental assessment. In addition, they recommended the following studies:

1. "Chlorine and Hydrogen Chloride," National Research Council, National Academy of Sciences, NAS Press (1976) and;

2. Environmental Health Criteria - 21, Hydrogen Chloride - ICPS International Programme on Chemical Safety, World Health Organization, Geneva 1982.

If we can be of further assistance, please contact David Parker (382-5046).

Sincerely,

David G. Hanna, Deputy Director
for Allan Hirsch
Director
Office of Federal Activities

Enclosure

VPP 623294