



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

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OFFICE OF  
EXTERNAL AFFAIRS

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

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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.

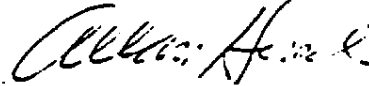
With respect to mitigation measures, FDA states only that it "has not identified any measures it could take to avoid or mitigate potential adverse environmental effects associated with the proposed action (p. 36, EA)." All mitigation measures considered should be presented and dismissed with a discussion 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,

A handwritten signature in cursive script, appearing to read "Allan Hirsch".

Allan Hirsch  
Director  
Office of Federal Activities

Enclosures

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## 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<sub>2</sub> and H<sub>2</sub>O 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-ethylhexyl) 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-ethylhexyl) 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 apparently 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.

## VINYL INSTITUTE HEALTH SAFETY AND ENVIRONMENT COMMITTEE

SPI Conference Room  
1025 Connecticut Avenue, N.W.  
Washington, D.C.

Wednesday  
October 8, 1986  
10:30 a.m.

### Attendees:

|                          |                         |
|--------------------------|-------------------------|
| W. C. Holbrook, Chairman | - BFGoodrich            |
| J. T. Barr               | - Air Products          |
| N. M. Blackman           | - Borden Chemical       |
| Frank E. Borrelli        | - Georgia Gulf          |
| Robert Brager            | - Beveridge & Diamond   |
| Peter de la Cruz         | - Keller and Heckman    |
| C. A. Gellner            | - CertainTeed           |
| Clark S. Graybill        | - PPG Industries        |
| J. Kachtick              | - Occidental Chemical   |
| Joe King                 | - Occidental Chemical   |
| Joe Ledvina              | - Vista Chemical        |
| J.C. Lunn, Jr.           | - Borden Chemical       |
| Robert Luss              | - Occidental Chemical   |
| P. Toner                 | - SPI (part of meeting) |
| H. Waltemate             | - BFGoodrich            |
| M. Scheck                | - Vinyl Institute       |

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### Self-Introductions

Committee Chairman, W. C. Holbrook convened the meeting at 10:30 a.m. and asked for self-introductions of those present.

### Approval of Minutes

Mr. King motioned that the minutes of the July 17-18, 1986 Committee meeting previously distributed to the Committee members be approved. The motion was seconded by Mr. Kachtick. The minutes were approved by voice vote without correction.

### Report On NAPTAC Meeting

Mr. Ledvina reviewed the discussions and presentations made at the September 17, 1986 meeting of the National Air Pollution Techniques Advisory Committee on volatile organics, specifically ethylene dichloride, ethylene oxide, and butadiene. Mr. Ledvina reviewed the substance of the presentations made by industry representatives, and noted the reactions of EPA staff to these industry presentations. Additionally, Mr. Ledvina stated that a hazardous organic NESHAP has been targeted for proposal by the Agency for June 1987, with final promulgation to follow approximately one year later.

Reports On State Regulatory Activity

**California:** Mr. Holbrook noted that the South Coast Air Quality Management Newsletter contained an article noting that it is examining 47 compounds that it has identified as toxic, including EDC. Mr. Holbrook noted that California has an air toxics regulation on vinyl chloride of 10 ppb at the fenceline. Relative to EDC, it was noted that a "Regulatory Needs" will be published in January 1987.

**Texas:** Mr. Kachtick noted that the monitoring program for VC is to be discontinued, and commented that the sampling areas used as part of this program had not included monitoring along the ship canal. As part of a round table discussion, committee members stated that the States of Maryland, Kentucky, Pennsylvania, and Massachusetts are all working on air toxics policies, and that many of these are using the AIHC list of substances.

Vinyl Chloride Standard

Mr. Brager reviewed the contents of his October 7th letter to Mr. de la Cruz dealing with EPA's September 30, 1986 promulgation of amendments to the vinyl chloride standard. The committee discussed at length the issue of whether the Vinyl Institute should consider challenging several portions of the new standard by filing a petition to review. Mr. de la Cruz noted that the 1976 failure to intervene had left the industry in an undesirable position.

The committee discussed the potential impact that specific requirements of the new rule would have on individual companies. Counsel responded to inquiries regarding the probability of a challenge being successful and the potential legal costs associated with such a filing. In his capability as Chairman of the Vinyl Institute Legal Committee, Mr. Luss recommended that the Health, Safety & Environment Committee make a formal recommendation to the Legal Committee, which would be preliminary to consideration by the Executive Board. Then, should the Institute decide to file a challenge, Mr. Luss noted that the members of the Health, Safety & Environment Committee would serve as technical advisors. Mr. Holbrook commented that given this recommended approach, he would then suggest that a special task force be organized to work with Counsel.

In response to questions concerning the appropriateness of an individual company filing, Mr. Brager commented that he believed that the Vinyl Institute should serve as the focus. Mr. Luss stated that there may be others who would be interested in a joint defense.

**Motion:** Mr. Barr moved that the Health, Safety & Environment Committee recommend to the Board that a "petition to review" the September 30, 1986 promulgation of a new vinyl chloride emission standard be filed. The motion was seconded by Mr. King. There being no further discussion, the Committee unanimously approved the motion.

In response to a question dealing with the timing of such a petition and the schedule that would be triggered by such a filing, Mr. Brager noted that following the end of the 60-day limit for filing of a petition to review, EPA would have 45 days to file a certified list of the record; and then the petitioners would have 45 days to file a petitioner's brief.

Mr. Holbrook asked for a Committee discussion on the issue of recommending that a "stay" of the final rule also be filed. Mr. Brager noted that to do this one must prove both irreparable harm and the likelihood of success of a challenge. Mr. Brager recommended that if the industry also wished to pursue this approach that such a filing should be done early in the 60-day period.

Motion: Mr. Kachtick motioned and Mr. Barr seconded a recommendation that the Vinyl Institute file a "motion to stay" the final rule. The motion was unanimously approved.

Following approval of the above two motions, Mr. Holbrook asked for volunteers to serve as part of a technical task force to outline the issues and concerns. Mr. Kachtick agreed to chair such a task force, with the assistance of Messrs. Holbrook, Oubre and Ledvina.

#### Hazardous Waste Identification and Toxicity Characteristic Revisions

To provide an update on industry testing, Mr. Holbrook noted that BFGoodrich now has the appropriate equipment to complete the required tests and stated that the equipment should be set-up by the end of October. Additionally, Mr. Barr noted that Air Products has developed a two-headspace method of testing. Mr. Barr stated that they have shared this method with Occidental; and if anyone else is interested, the contact is Ed Kucher or Steve Peter at Air Products.

Mr. Holbrook asked for a Committee discussion on whether the Vinyl Institute members could join together to perform analytical work on the product (not the wastes). Mr. Luss noted that to avoid any business implications of an industry testing program, there is precedence on how to perform "blind" tests on a confidential basis. Such a program would allow an individual company to know which material was theirs, but would not allow for identification of other companies' products. Mr. de la Cruz noted that if such a project were to go forward, that the results should be filed with USEPA. Following a lengthy discussion of whether and how to conduct such a program, Mr. King volunteered to head up an effort to determine the appropriateness of Mr. Holbrook's suggested industry testing program. Mr. King noted that he will speak with Dr. O'Mara as Chairman of the Vinyl Institute Technical Committee about such a program. Messrs. Blackman, Gellner and Borrelli volunteered to work on the program with Mr. King.

Chairman of the Vinyl Institute Safety Subcommittee

Mr. Holbrook stated that as a result of Mr. Barr's imminent retirement from Air Products that the subcommittee needs a new chairman. Such individual would be responsible for gathering the data for the VI awards programs.

Mr. Borrelli moved that Mr. Oubre of Dow be named as Chairman of the subcommittee. The motion was seconded by Mr. Ledvina and approved unanimously be the Committee. Noting Mr. Oubre's absence from this Committee meeting, Mr. Holbrook stated that he would speak with Mr. Oubre concerning his availability for such an assignment.

Mr. Toner, Technical Director of SPI noted that there was another vacancy to be filled as a result of Mr. Barr's retirement, i.e., the Vinyl Institute "slot" on the SPI Occupational Health and Environmental Issues Committee. There being no suggestion at the meeting, Ms. Scheck stated that she would discuss this item with Dr. Gottesman and would keep Mr. Toner apprised.

Environmental Recognition Formula

Ms. Scheck noted that the formula developed at the Committee's July meeting to recognize environmental excellence had been distributed July 29th for final review prior to this committee meeting. There being no further amendments to the formula as distributed, Ms. Scheck noted that it will be presented to the Executive Board at the December meeting for final Institute approval.

OSHA - PVC Update

Mr. de la Cruz reviewed the recent dialogue between the Occupational Safety and Health Administration regarding OSHA's position on the labeling requirements of PVC resins and compounds. Counsel noted the unavailability of Mr. Prendergas of OSHA for a meeting due to a foreign travel schedule. A meeting involving Mr. de la Cruz, Mr. Luss and Dr. Gottesman with Mr. Frank White of OSHA has been scheduled for October 23rd. Counsel noted that an expert in the toxicology/human health field would be a useful addition to this delegation. Mr. King and Mr. Holbrook agreed to search for such an individual and make their recommendations to Mr. Luss or Dr. Gottesman.

CMA Study Update

Mr. Barr reviewed for the Committee discussions that had taken place at a September 8th CMA Meeting of a draft report of an epidemiological study which shows an elevation in brain cancers, emphysema, and two reported deaths from liver and biliary cancer. There was, reportedly, a significant amount of debate that took place at the CMA Meeting about the details of the study and whether its findings are flawed. Mr. Barr noted that the CMA panel took a vote (not unanimous) to favor reporting the findings under TSCA. Mr. Barr stated that the CMA staff person to the panel is Mr. Shah. Counsel was asked to determine whether an 8d had been filed by any company.

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ASL Case Report

Mr. Barr briefed the Committee on the previously reported Pantasote worker ASL case. He noted that a joint defense committee had been established.

"Right-To-Know"

Mr. Borrelli noted that CMA had distributed a review of the Community "Right-To-Know" provisions of the Superfund bill as adopted by the congressional conferees. It was suggested that this information be attached to the minutes of this meeting. Mr. Borrelli also noted that the results of the Community Awareness Survey are to be discussed at the October 9th meeting of the Vinyl Chloride Safety Association. Mr. Borrelli noted that the results of the survey indicated that a variety of dispersion modeling is being done and that there is also a variety of involvement with local communities being undertaken by vinyl-producing companies.

PVC Solid Waste Disposal

Mr. Ledvina noted that the results of the PVC solid waste disposal survey had been compiled by Keller and Heckman and stated that the results would be discussed at the Vinyl Chloride Safety Association Meeting. Ms. Scheck was requested to include these with the minutes when distributed to the Committee members.

OSHA Respirator Standard

Mr. Holbrook stated that the recently published OSHA respirator standard may be of interest to this group. After a brief discussion on the requirements of the standard and their economic effect upon the industry, Mr. Waltemate accepted the assignment of contacting Mr. Oubre and others regarding the impact of this regulation and determining appropriate follow-up.

Review of Vinyl Chloride Clean Air Act Standard

The members of the Committee reviewed a chart prepared by Keller and Heckman outlining the provisions of the new VC NESHAPS in comparison to the 1976 rule and the January 1985 proposed rule. This review is to serve as background for the Kachtick Task Force.

NESHAPS Enforcement

A round table discussion occurred on recent enforcement activities. Specific reference was made to the settlement reached by Air Products; Texas Air Control Board's administrative review of Occidental; TACB's suits against two other producers. It was noted that TACB has greatly increased monetary penalties being levied.

Mr. King reviewed a litigation update as of September 1986, noting the number of cases that have been settled and those that are in the litigation process.

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Next Meeting

Following a brief discussion of the appropriate next meeting date, the Committee recommended that Mrs. Scheck pursue scheduling a meeting for Charleston on December 18, 1986. This is a tentative date, with an earlier meeting a possibility.

Adjournment

There being no further business, Mr. King made a motion to adjourn the meeting. The motion was seconded by Mr. Barr and adopted unanimously at 2:30 p.m.

Respectfully submitted,



Meredith N. Scheck

attachment

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