



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.

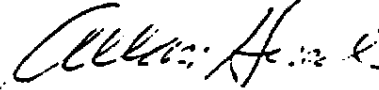
With respect to mitigation measures, FDA states only that it "has not identified any measures it could take to avoid or mitigate potential adverse environmental effects associated with the proposed action (p. 36, EA)." All mitigation measures considered should be presented and dismissed with a discussion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

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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.

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