

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES H. MOEHAN
WILLIAM H. DOUGHERTY JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN F. BERCOVICH
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL I. MORRONT
LARRY S. SOLOMON

LAW OFFICES
KELLER AND HECKMAN
450 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE:
202 396-2100
CABLE ADDRESS: KELLMAN

October 1, 1975

Alexander M. Schmidt, M.D.
Commissioner of Food and Drugs
Room 14-71, HF-1
5600 Fishers Lane
Rockville, Maryland 20852

*Received 10/2/75
Janie Peters
Hearing Clerk*

Re: Docket No. 75N-0190--Vinyl
Chloride Polymers in Contact
With Food; Notice of Proposed
Rulemaking, 40 Fed. Reg. 40529,
September 3, 1975

Dear Dr. Schmidt:

On behalf of our client, The Society of the Plastics Industry, Inc. (hereinafter referred to as the "Society" or "SPI") 1/, and Its VCM/PVC Resin Producers Group, Plastic Bottle Institute, Plastic Pipe Institute and Food, Drug and Cosmetic Packaging Materials Committee (all of the four last named entities being essentially semi-autonomous functional divisions of the Society), it is hereby urgently requested that the Food and Drug Administration (FDA) extend by sixty days the time for the filing of Comments in the above-referenced proceeding.

1/ The Petitioner, The Society of the Plastics Industry, Inc. (SPI), is the major national trade association for the plastics industry. The Society is composed of 1400 members and fifty operating units including producers of the plastics raw materials or resins and of the various modifiers and adjuvants used, plastics machinery and mold builders, and those known as processors, converters or fabricators who manufacture plastic resin into finished compounds or products. Among the fifty operating units referred to are the VCM/PVC Resin Producers Group, Plastic Bottle Institute, Plastic Pipe Institute, Food, Drug and Cosmetic Packaging Materials Committee and a number of segments of other units, all of which have a very direct interest in any action affecting the status of polyvinyl chloride food contact materials. The Society's membership represents over 95% of the plastics materials and machinery produced in the United States and about 75% of the processing volume.

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Background Information

The membership of The Society of the Plastics Industry, Inc. includes an estimated 99% of the vinyl chloride monomer (VCM) and polyvinyl chloride resin (PVC) manufacturing capacity in the United States. It also includes an estimated 600 companies which convert PVC resins and compounds into components or end-use products. All of those involved have an obvious and exceptionally vital interest in supplying the Food and Drug Administration with the best possible information obtainable so that any final Regulation adopted will be as scientifically sound as is humanly possible.

From the day on which the instant Proposal was published in the Federal Register, intensive efforts have been made to supplement the extensive data already submitted to the Administration by the industry. The fact that so many divergent interests are involved does make collecting and collating the relevant data a somewhat unusual logistical problem; on the other hand, since almost all interested elements of the industry belong to the Society this will make it possible to provide FDA with the best possible information and latest scientific data, provided the minimal additional time requested by means of this filing is afforded.

To demonstrate that the Society has in every sense been pursuing this matter with the greatest possible diligence, and also to meet one proposed FDA requirement even before the rulemaking has been finalized, the following chronological exposition is pertinent:

1. On September 3, 1975, the day the instant Proposal was published in the Federal Register, a special committee of the Plastic Pipe Institute met in Washington, D.C. to consider what scientific studies it should undertake with respect to the FDA Proposal to cover PVC potable water pipe by an Interim Food Additive Regulation pending the submission of data to support the conclusion that no vinyl chloride monomer will find its way into the water supply from PVC pipe. As a result of this meeting, we have now been instructed to and are hereby advising that

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the Plastic Pipe Institute of SPI may be considered committed to undertaking "adequate and appropriate [studies] to appraise the potential for the presence of vinyl chloride in potable water drawn from a system utilizing water pipe containing vinyl chloride polymers". In other words, the Plastic Pipe Institute is now notifying the Food and Drug Administration of its intent to provide the data proposed to be required by the contemplated new Section 121.4009. It should be understood, however, that this undertaking is made without prejudice to any arguments that may be advanced in the Society's Comments since we believe a serious question exists as to Food and Drug Administration jurisdiction over potable water pipe. Nevertheless, the industry is of the view that relevant concerns about the safety of such pipe should be fully satisfied.

2. Immediately after the Rulemaking Proposal was published on September 3, a reproduction of the 11 volumes of background material in the Hearing Clerk's Office was ordered so that careful attention could be given to any points raised in the existing file. Although the Food and Drug Administration's Staff was completely diligent and cooperative in reproducing the material, we were only able to obtain the 11 volumes of material on September 23. It is obvious that further time will be required to study this material carefully so that all salient scientific and legal questions can be addressed in the Society's Comments.

3. On September 10, 1975, after a broadside invitation was extended to all members of the Society believed to have an interest in the instant proceeding, a meeting was convened in Washington. At this meeting, working Subcommittees were appointed to collect existing material and develop new

data of direct relevance to the issues presented by the FDA Proposal. Meetings of these working groups have been taking place on an accelerated basis since September 10. As a result, all of the scientific Subcommittees have their work plans fully developed and new testing is underway. As will be pointed out hereinafter, the additional testing has been made necessary, at least in major part, by certain requirements detailed for the first time in the Food and Drug Administration Rulemaking Proposal.

Justification for Extension of Time

The primary reason for the instant request is that the Society's scientific working committees now functioning with a full sense of urgency have advised that some of the data they are preparing will necessarily require new extraction studies and a review of the new analytical procedures proposed. Therefore, their reports may not be completed in most instances until late November. For example, scientists primarily interested in the plastic bottle industry have studies underway which involve exposing materials to food simulating solvents for a minimum of 28 days. Analysis of the extraction solvents and preparation of proper scientific reports will obviously require an additional two to four weeks.

Essentially the same circumstances are applicable to new testing of plastic sheet or "blister-pack" type materials.

It should thus be apparent that collection and collation of all of these data, and the careful preparation of comprehensive Comments on issues as critical as those presented in this proceeding warrant the sixty day extension requested. Without this additional time, it is respectfully submitted that FDA may be forced into making decisions based on seriously outmoded information and, therefore, would likely be compelled to reach conclusions inconsonant with the public interest.

In requesting this extension, the Society is mindful of the importance of responsible Food and Drug Administration action to protect the public in every way. It is respectfully

submitted, however, that the interests of the public will best be served by granting the extension for the following reasons:

1. It is entirely clear from the Administration's Proposal and the data already in the Food and Drug Administration's files that there is no immediate hazard to the public health. The Commissioner may be even more assured that there is no hazard at this point in time because the industry has now progressed in its technology so that PVC resins, compounds and fabricated products currently being marketed for food contact applications contain extremely low or no residual monomer. Indeed, it is anticipated that in its Comments the Society will urge the Commissioner to adopt a Regulation which will severely limit permitted monomer content in food contact articles. The point here is that if there ever were a hazard, there certainly is none which would justify precipitous action now.

2. In addition, FDA specifically requested Comments and information which would help it determine all safe categories of food contact articles that may exist. (40 Fed. Reg. 40534) To this end, the Food and Drug Administration set forth in its proposal essentially three criteria which, if met, would satisfy the Commissioner of the safety of PVC food contact articles, i.e. low or no residual monomer in PVC food contact articles, no detectable extraction of VCM into food simulating solvents, and a sound theoretical basis for predicting no migration below the detectable level.

The industry, as previously noted, had been anticipating the need for reducing residual monomer in all PVC resins and compounds so the first criterion is one on which data can be collected with reasonable rapidity even though it may be delayed somewhat by the need to re-test with the new FDA test method to determine current residual monomer levels.

Likewise, we have been advised that companies in the industry have been conducting extraction studies in food simulating solvents with the so-called "new compounds" containing less than one part per million residual monomer. Thus, it would appear that these data can also be collected relatively soon.

On the other hand, we now recognize from the Proposal, and for the first time, that there is a very important need for a data base upon which to develop theoretical calculations to demonstrate for plastic bottles and sheet the soundness of the conclusion that vinyl monomer may not reasonably be expected to become a component of food "below the detectable level". This already has led to the institution of additional extraction work presently underway. It is this work which we are informed should be completed and reported upon by approximately the end of November or the beginning of December. Thereafter, we anticipate that all of the data can be prepared for submission, along with comprehensive Comments designed to develop all of the important scientific and legal issues presented in this proceeding.

Among other things, for example, it is presently contemplated that the new data, including possibly some additional toxicological information, will assure the Food and Drug Administration of the existence of built-in safety factors as regards all PVC food contact products made with the polymers and copolymers now being marketed for such use.

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On these bases, we urge favorable consideration of this extension request and respectfully submit that the granting of the additional sixty days for Comments will benefit the public and the Food and Drug Administration

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in that it will make possible final regulations that are based on the most current and sound scientific information available.

We would appreciate your prompt and careful attention to this matter.

Very truly yours,

cc: Mr. Sam D. Fine
Richard Merrill, Esquire

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