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December 23, 1975

No. 10

TO: All Members of VCM/PVC Mailing List

Ladies and Gentlemen:

Firstly, please accept my apologies for doing a little "over-writing" in the past few days. Unfortunately, we have just learned that we were guilty of omitting a document referred to in our December 19, 1975 letter (No. 8) and have received sufficient calls on the matter so that we thought it would be best to take care of this problem with all of you. At the same time, mention of a few other items of interest can be made.

To correct the December 19 omission, enclosed herewith is a copy of the set of Comments the Environmental Protection Agency filed with the Food and Drug Administration. If you check your files, you will note that we made mention of the EPA statement on page 4 of our earlier communication.

Following up on the information conveyed on page 5 of letter No. 8, John Lawrence of the Staff of the Society of the Plastics Industry, Inc. has now advised us that he has arranged for duplication of the complete set of our SPI Comments. We gather that copies will be available by next week and that the charge for the same will be \$75 to non-members of the Society. The charge to members will be \$45.

As another "straw in the wind" bit of information, we have also been informed that, in response to an official inquiry by a foreign government, the Food and Drug Administration has advised that it expects to take final action of some type on the PVC rulemaking proposal in "three to six months." Obviously, this conflicts with earlier indications

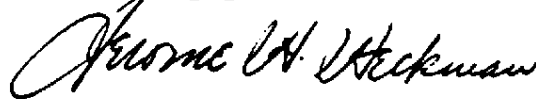
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by some FDA Staffers who predicted action within 30 days. However, as those of you who are familiar with FDA procedures will realize, we put very little credence in the 30 day prediction and would not be shocked if the three to six month projection proves wholly inaccurate, one way or another.

Finally, this is to let you know that, on the basis of a personal check I made this morning, neither the Health Research Group nor any other organized consumer interest entity has yet filed substantive Comments in Docket No. 75 N-0190. We definitely do anticipate such filings so we will be watching carefully for them and will keep you posted on whatever we learn.

Cordially yours,

A handwritten signature in cursive script, appearing to read "Jerome H. Heckman".

Enclosure

SPI-24603

DEC 14 1975

Hearing Clerk
Food and Drug Administration
Room 4-65
5000 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

The Environmental Protection Agency, Office of Water Supply is pleased to comment on the proposed regulations titled Vinyl Chloride Polymers in Contact with Food, 21 CFR Part 121, Pocket No. 75N-0100.

In response to concerns about the possibility of vinyl chloride leaching from PVC pipe into drinking water, EPA's Water Supply Research Division in Cincinnati has developed methods of analysis for vinyl chloride in water. These methods allow differentiation of vinyl chloride from cyanogen chloride, which in some cases has been shown to interfere with the analytical determinations. These methods provide a limit of detection in the range of 0.02 ng/l, which is several orders of magnitude more sensitive than the methods applied to VC detection in other media, such as in food simulating solvents (20 ppb), and in polyvinyl chloride (350 ppb), 21 CFR Part 121, p10531.

To date only preliminary data have been obtained on the occurrence of vinyl chloride in water contacting in-use PVC pipe, as reported below. These sites were selected because of known locations and ages of installed PVC pipe and ambient water temperature variations.

We note that in each case except for Jonah Water Supply Corp., Williams County, Texas, where the pipe is rather new, little or no difference was found between the VC concentration in the source water versus water that had traversed the PVC pipe and even in that case the resulting concentration was low (1.2 ppb). In other cases where VC was found, levels were well below 1 ppb. Those levels of vinyl

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<u>Site</u>	<u>Age of Pipe</u>	<u>Length and size</u>	<u>Water Temperature</u>	<u>Vinyl Chloride Concentration in Water</u> (Detection limit 0.03 ug/l)	
				<u>Influent Water</u>	<u>End of Pipe</u>
Coolidge, Arizona	11 years	5280' of 3" + 3640' of 2"	20 8-22-75 9-22-75	0.3 ug/l none	0.3 ug/l none
Pioneer, Cal.	9 years	4.7 mi of 6" + 2.3 mi of 4"	24-25 9-16-75	none treatment plant	0.06 ug/l
Jonah Water Sup. Corp. Williamson County, Tex.	8 months	3 mi of 6" & 8" + 9.5 mi of 4-5"	22-25 10-10-75 10-28-75	none none	1.4 ug/l 1.2 ug/l
Salado, Texas Well #1	7 years	0.11 mi of 8" 0.30 mi of 6" 0.11 mi of 2"	21-23 10-10-75 10-28-75	none none	none none
Roseburg, Oregon	4-9 years	3.0 mi of 3" 0.4 mi of 2"	14 10-12-75	none end of asbestos cement feed line	0.03 ug/l

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chloride that have been detected in water from transmission pipe in actual use are well below the levels which have been associated with adverse effects in experimental animals.

Recent limited simulation studies have been conducted in our laboratories using two loops consisting of 100 feet of 3/4 inch PVC pipe. One of the systems consisted of non-NSF approved C-PVC pipe with 110 mg/kg residual monomer, while the other system was NSF approved C-PVC pipe with 3 mg/kg residual monomer content. Samples were taken during periods of flow at 6 ml/min and also after water flow had been stopped for several days. In the first example (110 mg/kg pipe) VC water concentration ranged from a low of 0.5 ug/l during flow periods to a high of 52 ug/l, 22 days after flow was stopped. In the second example, (3 mg/kg pipe), after the initial period, values of about 4 ug/l were obtained 7 days after flow was stopped.

Our preliminary conclusions are that the concentrations of vinyl chloride in water in contact with PVC pipe tend to increase as the monomer content of the pipe, temperature and contact time increase. Indications are that pipe that has been manufactured for water use more recently (within the past 6 months) seems to have a lower free vinyl chloride content than pipe manufactured earlier. However, additional data, especially in existing installations, will be required before final conclusions can be reached.

As part of EPA's forthcoming National Monitoring Study of Chemicals in Drinking Water, vinyl chloride will be among a number of specific chemicals that will be analyzed for in approximately 100 major water supply systems across the country. This study will be commencing shortly and will be completed by September 1970. I understand that a large scale monitoring effort is to be conducted by PVC pipe manufacturers. We believe that future studies should include sampling both in distribution systems and at the tap of home plumbing systems containing PVC pipe of various ages and types so that an assessment of actual exposure from those sources can be made.

Sincerely yours,

Victor J. Kimini
Deputy Assistant Administrator
for Water Supply (WH-550)

JAC:evr:mc:12-12-75

SPI-24606