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October 1, 1976

NO. 28

To: All Members of VCM/PVC Mailing List

Letter Highlights

1. New extraction data has been presented to the Food and Drug Administration to show that significantly less vinyl chloride may be projected as conjecturally extractable into food and food-simulating solvents than was previously predicted from theoretical models.

2. Recent data regarding Professor Maltoni's inhalation studies have been received and forwarded to the appropriate government agencies.

3. The vinyl chloride EPA emission standard is expected to be promulgated within the next week or so. A pre-publication conference between EPA compliance and enforcement officials and industry representatives has been held to provide guidance as to anticipated government enforcement plans and procedures.

4. Information is being gathered to support a request to OSHA to extend the use of cartridge/canister respirators that are not equipped with end-of-service-life indicators.

Ladies and Gentlemen:

This is to bring you up to date once more regarding the activities of the Food and Drug Administration (FDA),

Environmental Protection Agency (EPA), and the Occupational Safety and Health Administration (OSHA) relative to vinyl chloride monomer (VCM) and polyvinyl chloride (PVC) packaging materials. Among other things, the remainder of this letter deals with (1) a summary of a submission on PVC extraction concepts given FDA this week, (2) the details of some later inhalation data that Professor Cesare Maltoni presented at a recent meeting in Cold Springs Harbor, Long Island (This meeting was sponsored by the National Cancer Institute and billed as a conference on "Origins of Cancer.") and, (3) a progress report regarding efforts to extend OSHA regulatory authority for the use of respirators without end-of-service-life indicators in VCM and PVC plants.

FDA

On September 29, 1976 representatives of Ethyl Corporation and Dr. Daniel Dixler of our office met with Food and Drug Administration personnel to provide a follow-up report on long term extraction studies that had been started more than two years ago. The results obtained show that no detectable VCM (or a questionable vinyl chloride response in some cases) could be found after 27 months storage at room temperature using analytical procedures sensitive to 0.01 ppm.

The samples had been set up as part of a program undertaken to determine the possibility of long term migration of vinyl chloride from a then-available polyvinyl chloride compound. In addition, it was anticipated that the samples would provide an additional "end of shelf life" point to provide an experimental test of the theoretical diffusion model which had been developed.

Analytical sensitivities at the time the bottles were prepared and filled only permitted the determination that the residual monomer (RVCM) level was "less than 1 ppm". Consequently, an effort was made retroactively to determine what the residual monomer level had been at the time of filling so that the prediction model could be more reliably tested. The data submitted to the Food and Drug Administration showed that the RVCM level must have been near 0.9 ppm leading to a predicted VCM level in the contents in the

range of 0.05 ppm at the time the bottles were sampled. Despite this prediction, however, no monomer was detected in the contents using analytical procedures sensitive to approximately 0.01 ppm.

The significance of these findings is not yet clear but it is hoped that they may provide a basis for FDA to adopt a more "reasonable" RVCM level for rigid and semi-rigid PVC products than those mentioned in our last letter.

In this connection, we can report that the Food and Drug Administration's packaging laboratory tested samples of rigid or semi-rigid sheet material which contained approximately 0.3 ppm of residual monomer. This material was then extracted (we do not know how long nor in what solvents) and vinyl chloride monomer was found in the extraction solvents in the range of 3-5 ppb. Although this quantity would represent essentially 100% migration from the sample, a phenomenon generally never observed and considered to be highly unlikely, these results have caused FDA to question SPI's proposed limit of "no detectable residual vinyl chloride monomer using an analytical procedure sensitive to 0.35 ppm" since a material which complied with this limitation was found to yield a measurable level of vinyl chloride to the food-simulating solvent. These same data are, we understand, responsible for the FDA consideration of placing limitations on residual vinyl chloride monomer in packages at "100 ppb, 50 ppb, or lower," as previously reported.

EPA

On September 24, SPI, through the courtesy of the Council of European Chemical Industry Federations (CEFIC), received a copy of a report prepared by Professor Maltoni concerning interim results on some of his experiments in which rats have been exposed to vinyl chloride (VCM) via the inhalation route. In accordance with its usual policy and at the request of CEFIC, the Society promptly informed various concerned government agencies about the data. Copies of the report were supplied even though many government representatives were in attendance at a National Cancer Institute-sponsored conference held in Cold Springs Harbor, Long Island,

where Professor Maltoni originally presented this information. Apparently, Professor Maltoni's Cold Springs Harbor presentation, which included a discussion of his latest inhalation data was not readily assimilated or widely publicized, possibly because the conference included a great many presentations and was rather vaguely billed as designed to cover "Origins of Cancer."

We are enclosing a copy of the report, the statement of the CEFIC Main Committee for the Toxicity of Vinyl Chloride, and a copy of Ralph Harding's transmittal letter to Mr. Roger Strelow of EPA, so that your files will be complete. Letters worded in precisely the same way were also delivered to Dr. Louis B. Thomas of the National Cancer Institute, Wilson Tally of EPA, and Richard Ronk of FDA.

With respect to the anticipated national emission standard for vinyl chloride which is expected to be promulgated within the next week or so, satisfactory and enlightening conferences have been held among and between representatives of the Vinyl Chloride/Polyvinyl Chloride Producers Group Technical Committee and the representatives of EPA who will be concerned with enforcement and compliance. The purpose of the meetings was to provide members of the affected sections of the industry with information regarding EPA's anticipated compliance demands and enforcement procedures.

OSHA

In our last letter we requested instructions from those of you who might be affected regarding possible action to extend the use of vinyl chloride canister/cartridge respirators without end-of-service-life indicators. At a recent meeting of the Steering Committee of the Vinyl Chloride/Polyvinyl Chloride Producers Group, steps were taken to obtain information from the manufacturers of respirators that, hopefully, will permit us to bring this question into focus with OSHA. In this connection we might mention that OSHA representatives have informally indicated that they would entertain such requests provided they represented an industry-wide, rather than an individual company approach.

General Information

Since there may be some of you who do not regularly receive and read Food Chemical News, essentially the "bible" on food additives and many other Food and Drug Administration regulatory reporting, with the permission of the publisher we are attaching hereto reproductions of pages 3 and 6 of the September 20 edition. The first article included provides a little more information about the Cold Springs Harbor meeting although it does not mention Professor Maltoni's presentation at all. The second article beginning on page 5 reports on a paper given by Dr. Morris F. Cranmer, Director of the National Center for Toxicological Research which points up the need for a quantitative estimate of risk in dealing with carcinogens. Although he recommended the use of a linear model as being even more conservative than the Mantel-Bryan approach, he recognized certain advantages inherent in the Mantel-Bryan method. As we see it, Dr. Cranmer is joining the growing group within the scientific community who are seeking to establish a rational basis for dealing with the "cancer scare", and one of its most abhorrent manifestations, the Delaney Clause.

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We shall, of course, continue to follow the various aspects of the vinyl chloride/polyvinyl chloride matter and will continue to keep you fully informed.

Cordially yours,

George A. Hitchman

Enclosures

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Ralph L. Harding, Jr.
President

September 28, 1976

Mr. Roger Strelow
Assistant Administrator
Air and Waste Management
U.S. Environmental Protection Agency
4th and M Street, S.W.
Washington, D.C. 20460

Dear Mr. Strelow:

We have just received a further interim report on the ongoing VCM inhalation studies of Professor Maltoni at Bologna. While we understand that some of the data may have been presented by him at the recent Cold Springs Harbor meeting with a number of government experts present, we want to make sure that you have this report without delay.

Along with the Maltoni report, we are also enclosing a "Statement of the CEFIC Main Committee for the Toxicity of Vinyl Chloride" which was given to us today. This committee, representing all of the VCM and PVC producers in the European Common Market, including Maltoni's sponsors, has concluded that "a quantitative evaluation for rats could not be drawn at the moment." We plan to follow closely, and if possible, participate in their interpretive analysis of Maltoni's work, as well as their further efforts to assess human exposures.

This information is also being sent to:

Mr. Wilson Talley - EPA
Mr. Louis Thomas - NIH
Mr. Richard Ronk - FDA

Cordially,

RLH:sms

SPI-24364