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April 21, 1976

160.106

No. 20

TO: All Members of PVC/VCM Mailing Lists

Ladies and Gentlemen:

The purpose of this letter is to bring you up to date once again on Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) developments relative to vinyl chloride and polyvinyl chloride. Although nothing substantive has occurred in either of these major regulatory areas, we have received some information from "reliable sources," or have heard rumors which we considered to be well enough founded to share with you.

FDA

We have been reporting regularly that the technical review of the Comments filed with the Food and Drug Administration has not yet been completed. The latest information in this regard is that, while a formal report has not been completed, the scientists in the Bureau of Foods have made an evaluation of the data. Furthermore, we believe that the evaluation, as far as it has gone, has satisfied the Bureau's technical people that the data provided by the industry regarding rigid and semi-rigid packaging materials demonstrates that no vinyl chloride could be detected in food or food-simulating solvents at the claimed limits of detection sensitivity. Hopefully, this will ultimately lead to a consensus that this assures there is no reasonable basis for an expectation that vinyl chloride will become a component of food when rigid and semi-rigid PVC packaging materials have an adequately low level of residual monomer, i.e. in the range of 0.35 ppm.

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As many of you know, we have been cautioning that "political toxicology" may play a significant role in the ultimate regulatory decision. We understand, however, that the report or draft regulation that the Bureau of Foods has been directed to prepare for consideration by the Commissioner's office (which is where image or political considerations can come into play) will be based solely on an objective scientific evaluation. Based on our hope that this will indeed be the case, our general outlook is now cautiously optimistic.

Many of you will recall that the FDA Consumer, the official magazine of the Food and Drug Administration, contained an article on polyvinyl chloride in its December-January issue to which we took immediate and strong objection. The March, 1976 issue reproduces, in its Consumer Forum section, a letter which we wrote voicing some of our objections. We are enclosing a copy of page 3 of the March, 1976 issue since it contains our letter, an FDA response and another letter which objected to other errors in the article.

EPA

Those of you who are directly concerned know that we have been expecting EPA to promulgate its final Vinyl Chloride Emissions Regulation by June 24, 1976. It now appears that because of the volume of technical commentary supplied to EPA staff and the Agency's general work load, it may be unable to complete work on the standard by this date.

Excerpting from a lengthy internal report given us by Bill Ruckelshaus, the following additional information will be of interest to many of you:

"We have advised you before that the vinyl chloride standard does not apply to the industry until 90 days after its promulgation date. During this 90-day period a waiver may be sought which will permit a source up to two years to comply.

Even though the Agency will not meet its own statutory deadline, in our opinion this will not affect the amount of time the companies will have for compliance; therefore the two year and 90-day periods will not start running until the date the final standard is promulgated.

'Legislation

Both the Senate Public Works and House Interstate and Foreign Commerce Committees have reported out bills for consideration by their respective bodies. The House bill is not expected to be printed until the end of April. Forecasts are that the Senate may begin debate as early as next week; it is still unclear when the House will do so. The latest versions of these bills do not change earlier drafts we have reported on as they affect Section 112. We will furnish you with more details as soon as we have had an opportunity to review all final amendments.

'Other

Copies of all comments on the proposed Vinyl Chloride Standard, including those filed after the February EPA hearing, will be available for our review next week. We will advise you of any significant comments after we have had a chance to review them. EPA advises that to date a total of 46 comments have been received."

In addition to Federal standards promulgated by EPA, we understand that the Air Quality Boards of Maryland and Texas are becoming interested in the matter of vinyl chloride emissions. We are enclosing a letter from Gary H. Baise of the Ruckelshaus firm dated April 7, 1976 which discusses

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this development. Generally speaking, if state regulations are promulgated which are more strict than the Federal standard, problems could develop in that it might encourage the press to heighten attacks, both on vinyl chloride and on EPA. Several times in the past states have promulgated unattainable standards stricter than EPA's which made EPA appear to be derelict. Subsequently, industry was unable to meet the state standards and the states' evaluations were exposed as being unrealistic. In the meantime, however, affected industries were caught in an uncomfortable tug-of-war.

In any event, we are "scoping" the developing situations in Texas and Maryland so we will try to keep you posted on whatever we learn, or on any action taken by SPI, if such action becomes necessary.

General

For your general interest we are enclosing a copy of a letter from Ralph L. Harding, Jr. which appeared in the April 12, 1976 issue of Chemical and Engineering News, published by the American Chemical Society. We believe the letter answers very lucidly a charge which has been repeated in many quarters.

In connection with the general discussions going on concerning environmental carcinogens, we are enclosing two articles from the New York Times, one from the April 10 issue, the other from the April 13 issue.

We also want to direct your attention to the W. O. Atwater Memorial Lecture delivered by Dr. Emil M. Mrak at the American Chemical Society's Centennial Meeting in New York. The entire talk was, we felt, quite cogent; the report of the lecture in Food Chemical News for April 19, 1976 provides an excellent summary. For this reason, with the permission of the publisher we are enclosing a copy of page 3 of Food Chemical News which includes some of the important points Dr. Mrak made.

We want to call to your attention the fact that the Bureau of Explosives at the Association of American Railroads has requested assistance from SPI in setting up

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a mutual aid response system for incidents in transportation involving vinyl chloride. This has been turned over to the VC/PVC Producers Group for prompt attention.

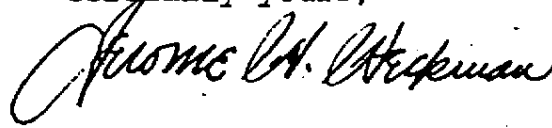
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We shall continue to monitor the various aspects of the vinyl chloride/polyvinyl chloride matter and report to you as fully and promptly as we can.

Cordially yours,



Enclosures

Consumer Forum

A Question of Timing

While we certainly have no quarrel with your printing an article which recites the chronology and rationale for FDA action on polyvinyl chloride, we strongly question the timing and content of *Polyvinyl Chloride: Why FDA Acted* which appeared in the December/January issue of FDA CONSUMER.

Should the official magazine of FDA publish an article on the vinyl chloride regulations prior to the completion of that process? We think not. In fact, we believe that the published article could suggest that FDA has prejudged the case and decided to ban several important types of polyvinyl chloride packaging prior to reviewing new industry data which shows that these products present no hazard to public health.

We also find it difficult to understand why author Wayne Pines' otherwise excellent chronology fails to mention:

- Commissioner Schmidt's finding that polyvinyl chloride packaging presents no immediate hazard.
- The December 19 filing of 900 pages of comment by The Society of the Plastics Industry documenting industry's contention that there is no reasonable expectation of vinyl chloride monomer migration from any polyvinyl chloride product.
- The December 19 recommendation of the Office of Wage and Price Stabilization urging FDA to delay its polyvinyl chloride regulations until it has evaluated more current data on the presence of polyvinyl chloride in food.

Since the article states that "December 12" was the final date for filing comments on the FDA proposal, we believe it was written substantially ahead of important new factual developments in the chronology of this regulation. Therefore, we believe that FDA CONSUMER will want to set the record straight with an article that presents all the facts in the vinyl chloride regulation, including industry's arguments as well as the final action by the Agency.

Jerome H. Heckman
General Counsel
The Society of the Plastics Industry
Washington, D.C.

FDA CONSUMER often carries articles on proposed regulations because consumers should know

what regulatory actions FDA is considering, and why. Publication of the article on polyvinyl chloride in no way indicates FDA has prejudged the case. FDA will carefully review all the comments submitted on the proposal and make its judgment on the basis of the evidence. When final action is taken, it will be reported in FDA CONSUMER.

The FDA CONSUMER article did point out that the public health hazard from polyvinyl chloride food packaging material was not of a nature that warranted either an immediate ban on use of the material or recall of food products packaged in it. The comments on FDA's proposal filed by the Society of the Plastics Industry and the recommendation of the Office of Wage and Price Stabilization occurred substantially after the FDA CONSUMER article was written and prepared for publication.

Not Polyvinyl Chloride

The December 75-January 76 issue of the FDA CONSUMER contained an article on polyvinyl chloride, accompanied by a picture of several containers which the article stated "may be" made from polyvinyl chloride.

While no labels were visible in the picture, one of the containers was, nevertheless, readily identifiable as our RJR Foods Vermont Maid Syrup, because the distinctive container, made from private molds, is only available to us. RJR Foods adopted the plastic container for syrup several years ago as a convenience to the consumer because of its light weight and freedom from hazard of glass breakage.

Since "may be" was included in the caption alongside the picture and since we do not want consumers to be misled, we wish to state for the record that this package does not contain polyvinyl chloride nor has it ever.

David L. Meggison
Vice President, Technical Services
RJR Foods
Winston-Salem, North Carolina

Consumer Forum is an opportunity for the readers of FDA CONSUMER to express their views. Short, to-the-point letters are most acceptable for publication. Please address letters to Consumer Forum, FDA CONSUMER, HFI-20, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.