



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 16 1976

OFFICE OF
GENERAL COUNSEL

Mr. Albert J. Beveridge, III
One Farragut Square South
Washington, D.C. 20006

Dear Mr. Beveridge:

In your letter to Mr. Robert Perman of January 13, 1976, you requested on behalf of the Society of the Plastics Industry ("SPI") an extension of time for the public hearing concerning the proposed hazardous emissions standards for vinyl chloride until March 1, 1976. You expressed concern that SPI would not be able to make constructive comments at a public hearing on February 3, 1976, on the basis of "preliminary conclusions or superficial studies", which was all the industry could do since the proposed rule was published on December 24, 1975.

We believe that the hearings should proceed on February 3, 1976, as presently scheduled. The hearing is a rulemaking, rather than an adjudicatory, type hearing and it is our opinion that the approximately one month that the industry has had the documents available to it should be adequate to enable the industry to give an oral presentation of its position at such hearings. It is not our intention that oral testimony should be used for elaborate detailed criticism of EPA's standards and all of the supporting material for those standards. The appropriate method of expressing any detailed criticisms of these standards is in written comments or as a supplement to any testimony that is given at the hearings. The written comment period set forth in the Federal Register notice in which the regulations were proposed states that the comment period is to close on February 23, 1976. If at the time of the hearing on February 3, the industry believes that it will be unable to submit written

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comments by February 23, 1976, you may request that the record of the hearing be held open for an additional period. This is not to indicate, however, that such a request will automatically be granted.

We regret that we can not accommodate your request. However, we think it is important that the Agency move expeditiously to take final action with respect to vinyl chloride emissions.

Sincerely,



Richard J. Denney, Jr.
Assistant General Counsel
Air Quality, Noise and
Radiation Division (A-133)

cc: Jackie Warren, EDF

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CABLE ADDRESS
"INDLAW"

January 19, 1976

Mr. Robert Perman
Office of Air and Waste Management (AW 443)
Room 945 West
Waterside Mall
401 M Street, SW
Washington, DC 20460

Dear Mr. Perman:

On behalf of The Society of the Plastics Industry, Inc. ("SPI"), please be advised that at the present time we intend to make a statement at the hearing to be held on February 3, 1976. We have not yet determined what individual or individuals will appear on behalf of SPI, but will advise you well in advance of the hearing.

The maximum amount of time we believe we will require is two hours. We may be able to shorten the time needed and will advise you at the beginning of the week of January 26.

Sincerely yours,

Albert J. Beveridge, III

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CABLE ADDRESS "KELMAN"

January 26, 1976

No. 14

TO: All Members of PVC/VCM Mailing Lists

Ladies and Gentlemen:

The purpose of this letter is to keep you up to date on the regulatory situation as regards the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).

FDA

In our last letter we advised that we would attempt to bring you information as promptly as we could regarding any further moves towards resolution of the jurisdictional question between FDA and EPA, particularly with reference to PVC pipe. Only after Letter No. 13 went out did we learn so that we can now report that a "first meeting" was held on January 7, 1976 between high level groups from FDA and EPA. Although a number of different subjects were explored, the question of jurisdictional responsibilities for drinking water and water distribution systems was referred to a task force to be headed by Dr. Robert Angelotti of the Food and Drug Administration and Mr. Victor Kimm of EPA.

We are enclosing copies of two different memoranda on this conference, one prepared by Alan Levin of EPA (Enclosure 1), and one prepared by Sam Fine of FDA (Enclosure 2). Although not reflected in either of the memoranda, it is our understanding that Mr. Kimm suggested EPA might be prepared to acquiesce in FDA responsibility for "food additives" that might enter the water supply in light of FDA's greater expertise in this area. This is somewhat disturbing news but all it really means at this stage is that additional exploratory work and discussion is required. Along this line, we are planning to try to follow up on the activities of the newly designated task force as they relate to the jurisdictional

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problem, hopefully so that our views can be more forcefully made known. In any case, we will keep you informed as to any developments.

Not directly related to VCM/PVC matters but nevertheless a matter of some concern, was the Notice published in the Federal Register on January 12, 1976 proposing to withdraw approval of all of the New Animal Drug Applications for diethylstilbestrol (DES). The reason for our concern is that we have been informed by our contacts at the Bureau of Foods that they are worried about the way the Commissioner of Food and Drugs has stated, in the enclosed proposal (Enclosure 3), that, with regard to the sensitivity of an analytical method for DES it "must be both practicable, in the sense that it must be adaptable for use as a regulatory tool, and it must be sufficiently sensitive." As you will see, the Commissioner concluded that any method approved in accordance with Section 512(d)(1)(H) must at least be capable of detecting residues at a level that has been shown to be safe within the meaning of the Act. Then, the Notice states that "Data are lacking to justify the approval of any other analytical method(s) for detection of DES residues because no currently available method is capable of detecting residues at levels that have been shown to be safe within the meaning of the Act." On this basis he has, in effect, concluded that DES must be banned as an animal drug.

The law with respect to new animal drugs is not the same as that with respect to food additives. Nevertheless, the Commissioner has here set as a requirement for an analytical sensitivity for the detection of a carcinogen an assurance that it would detect the substance at a level shown to be safe within the meaning of the Act. Since the Act has sometimes been interpreted to legislate that carcinogenic food additives have no safe level, the application of a similar standard could lead to the adoption of the HRG position, i.e. PVC is made from VCM so some must get in, no level has been proven safe, ergo no data is acceptable to preclude a ban on the basis of the "no migration" concept.

Since some Staffers in the Bureau of Foods have expressed concern about whether the DES action might have to

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govern treatment of the polyvinyl chloride situation, we thought it would be advisable to bring this matter to your attention. At the same time, we urge you not to overreact on the basis of this information. The fact is that there are important distinctions between the two situations. Indeed, I so indicated last Friday in an informal talk I had with the Staff member most concerned. In so doing, the following distinguishing features were called to his attention:

1. I pointed out with some vigor that it should be more difficult for the Commissioner to go the DES route as regards polyvinyl chloride in light of the willingness of the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) to at least implicitly accede to the existence of a "safe level" by the adoption and proposal, respectively, of their Standards.

2. I reminded him that, while all New Animal Drugs have to be specifically approved to be legally marketed, a potential indirect food additive need not even be cleared if there is no reasonable expectation of migration and the burden of proving reasonable expectation of migration is on the Government.

3. I also reminded him that further toxicological work is being done and there is every reason to believe a no effect level will be shown at perhaps as high as 100 parts per million (As far as we are aware, Maltoni has had no problem with the rats he is feeding 3.3 mg/kg. of VCM), while DES has apparently been proven a carcinogen at a level as low as 6.5 parts per billion.

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4. I further reminded the Staffer that the Commissioner has thus far recognized that there is a whole group of PVC applications where he has conceded the validity of a "no reasonable expectation of migration" posture and no data, or even language, has been filed to contest this view.

5. Finally, I pointed out that the animal drug regulations, like the pesticide provisions, speak in terms of a flat "no residue," rather than in the hard fought for "no reasonable expectation of migration" language of the Food Additives Amendment.

We hope the foregoing list of concepts advanced will have a helpful impact. The only other information I can pass along is that the Staff member involved told me that the Bureau now has a target date of "sometime next spring" for action on the PVC situation. I think I need not tell any of you that there is very little we can do to expedite the process--our having been advised that the data is still under scientific review. The fact that there will be some delay could conceivably be helpful since another Maltoni report is expected soon. This is not to gainsay the fact that we know many of you would like a prompt favorable decision so as to remove the cloud on PVC food contact products. We do have both points of view fully in mind but all we can really promise is that we will try to keep you informed about the shifting tides.

EPA

The VCM/PVC Producers Group met on January 23 and approved plans for an appearance at the Hearing scheduled for February 3, and for the preparation of Comments to be filed in connection with EPA's proposed rulemaking on vinyl chloride emissions. It has been determined that any statements at the

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Hearing should be general in nature. In addition to a discussion of specific points at issue, a recommendation for additional joint research programs sponsored by EPA, industry, and labor will be presented. With respect to the more detailed Comments which must be submitted by February 23, the various technical, legal, health and economic arguments are now being gathered for a timely, comprehensive written filing.

OSHA

In a previous letter we reported that OSHA was interpreting the definition of fabricated product so as to include resins with a residual vinyl chloride level low enough so that employee exposure at or above the action level without regard to the use of engineering controls could not occur. Another recent letter from the Department of Labor addressed to Mr. R. R. (sic) Wheeler, Jr., Union Carbide Corporation, repeats the same opinion, states that there are no plans to amend the vinyl chloride standard, and notes that a revised Program Directive is contemplated. Since the letter refers to other matters which could be of general interest we are, with the permission of Union Carbide Corporation, sending each of you a reproduction of the December 17, 1975 communication from the Department of Labor (Enclosure 4).

General

In previous correspondence we have also made reference to an article in Rolling Stone magazine. The B. F. Goodrich Company has now written to Rolling Stone to correct inaccuracies in the story. Again, as an item we think you will find worth having and reading, we are herewith transmitting a copy of what we feel is a very thorough analysis of major errors in the Rolling Stone story, the same having been sent to the publication by Thomas B. Nantz, Executive Vice President of the B. F. Goodrich Company (Enclosure 5).

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We are somewhat at a loss to know exactly how to characterize the news release issued by the American Chemical Society in connection with a paper published in the January,

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1975 issue of Analytical Chemistry. The paper by D. Hoffman, C. Patrianakos, and K. D. Brunnemann reports that vinyl chloride has been found in tobacco smoke. A copy of the ACS news release and Table II from the paper itself is attached (Enclosure 6).

The fact that ACS issued a general news release about this article and that it was picked up rather widely by the lay press is indicative of the public interest the Society sees in the entire vinyl chloride situation.

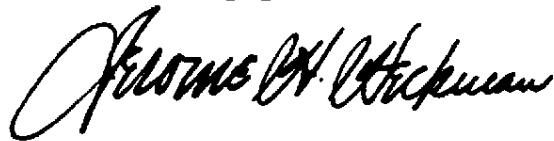
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To end on one bright note, we are pleased to report that the California Assembly's Ways and Means Committee, at its hearings last Friday, January 23, on Assemblyman Carpenter's bill that would have permitted state regulation of PVC food packaging materials, voted 10 to 4 against the bill. In short, the defeat in Committee of this measure, the details of which were described in our last letter (No. 13), brings to an abrupt end another piece of threatening anti-PVC legislation; credit in this instance goes to the whole SPI Public Affairs Committee team, and especially to all those on the scene in California.

* * *

We shall continue to keep you as fully informed as possible on all these matters.

Cordially yours,



Enclosures