

SHELL CHEMICAL COMPANY

*Feed
Vinyl
Chloride*

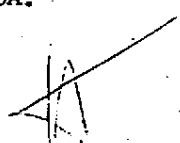
DATE JUNE 3, 1975

TO SAN RAMON COMPLEX - MANAGER
ANIMAL HEALTH

FROM WASHINGTON REPRESENTATIVE -
WASHINGTON, D. C.

SUBJECT VINYL CHLORIDE

Attached for your information is correspondence from the office of Keller and Heckman, Esq., concerning OSHA, FDA and EPA's latest activities with respect to prospective or anticipated rulemaking in regard to Standards for Occupational Exposure to Vinyl Chloride. Please note page 4 of this letter and the attached article, "FDA Regulation of the Use of Polyvinyl Chloride for Foods," by C. F. Jelinek, Director, Division of Chemical Technology, Bureau of Foods, FDA.


E. L. Hobson, Ph.D.

Attachment

cc w/att.: San Ramon Complex - Information Services ✓
Animal Health - Mr. C. M. Reider
Manager Toxicology and Applied Pharmacology

MAY 19 1975

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May 13, 1975

TO: All Members of:

SPI Food, Drug and Cosmetic Packaging
Materials Committee;
General Polyvinyl Chloride Interest
Mailing List;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
Plastic Bottle Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee;
VCM and PVC Producers Committee.

Ladies and Gentlemen:

The purpose of this letter is to try to update you once again on developments relative to the Occupational Safety and Health Administration (OSHA) Standard for Occupational Exposure to Vinyl Chloride and to inform you about the latest activity with respect to prospective or anticipated rulemaking by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA).

OSHA

Late last week we received the Solicitor General's "Memorandum for the Respondents in Opposition" to the Petition for a Writ of Certiorari now pending before the Supreme Court of the United States.

The Solicitor General's Memorandum, a typically short and pointed response by the government to a Petition for Writ of Certiorari, set forth the positions that the Standard for Occupational Exposure to Vinyl Chloride is

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feasible; the Secretary of Labor acted within his discretion in setting the Standard; and the United States Court of Appeals for the Second Circuit applied the proper standard of review in upholding the Secretary of Labor's Standard and reasoning; and that, for these reasons, the Writ of Certiorari should not be issued.

With this Memorandum on file, it is expected that the Clerk will forward the Petition package to the Court by sometime late this week. This "package" will also include a "Petitioners' Reply to Opposition of Respondents" which has been drafted for submission today or tomorrow. Counsel for Petitioners, Firestone and Union Carbide have coordinated their draft of the Reply with us, and our comments were provided promptly so the "Reply" will be a joint filing.

Since the Justices ordinarily rule on Petitions within about 30 days, we would expect that the Court's decision as to whether it will take the case will be made by the end of the first half of June. If the Petition is granted, Petitioners will have to file Briefs as early as the first of August in preparation for Oral Argument midway through the October, 1975 Term of the Court, that is, sometime around the first of the year, 1976.

With regard to the OSHA Standard itself, we have received a number of calls and letters concerning the labeling and related matters discussed in our May 5, 1975 letter. At this juncture, we can only reiterate that information, bolstered somewhat by comments in the nature of confirming statements made by Grover Wrenn of OSHA during a talk he gave at The Society of Plastics Engineer's ANTEC session on vinyl chloride last week.

Bearing in mind that the basic intent of the OSHA Standard is to insure against undue occupational exposure of employees to vinyl chloride monomer, OSHA has been stating for some time that certain operations involving PVC, such as blister packaging, fall within the definition of "fabricated product" because employees involved in these operations are not exposed to vinyl chloride above the action level. Indeed, OSHA has provided Advisory

Opinions that some resins could also be considered fabricated products because they contain such low levels of residual monomer that further processing could not or did not result in the release of vinyl chloride above the action level. Furthermore, some companies have proceeded to treat their low residual monomer resin products as fabricated products without formal Advisory Opinion clearance by OSHA.

Now, however, primarily because of internal disagreement as to the practical application of the term "fabricated product", the OSHA Staff is reevaluating its position on its Advisory Opinions vis-a-vis the intent of the Standard. Realizing that some difficulty of interpretation exists, not only have interested persons sought further information about exemption of specific products as "fabricated", but OSHA is known to be looking at a possible amendment of the Standard which would tie the definition of fabricated product more clearly and closely to exposure above the action level.

Specifically, we believe a Petition or Petitions for amendment of the Standard will be filed seeking, in essence, to add the phrase "...above the action level" at the end of the "fabricated product" definition. If such an amendment is ultimately made, it would have the effect of excluding materials such as some PVC pellets from the scope of the Regulation.

In the meantime, the amendment process being a time consuming matter, we are informed that OSHA is trying to develop something in the nature of a "fabricated product" policy statement for guidance of both its enforcement staff and industry. This statement would be an interim device to serve during the time necessary for amendment of the Standard.

While the situation remains very much up in the air, we expect further indication soon as to how OSHA intends to resolve this matter of practical application.

Of course, where specific evidence would support an exemption, Advisory Opinions may still be requested and

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granted for particular products. The only problem remaining, pending the new policy statement, is whether enforcement officials in the field will honor the exemption but we would assume that the great majority of them will since we feel reasonably certain that the courts would give them great weight.

FDA

The Food and Drug Administration continues to work on proposed Regulations with respect to the use of polyvinyl chloride as a packaging material for foods, drugs and cosmetics, but no indication has been received as to the time when the forthcoming proposals will appear in the Federal Register.

As to the ultimate nature of the FDA proposals, however, the attached paper (the underlining therein is ours) given just last week by Dr. Jelinek, Director of FDA's Division of Chemical Technology, points out, as we have repeatedly, that because vinyl chloride is probably a carcinogen when ingested it will be necessary for industry, in order to escape the effects of the Delaney Clause, to prove to FDA that PVC food-contact articles are not food additives and, therefore, not subject to the Food Additives Amendment; as you know this is precisely what we have been about for more than a year now. One of Dr. Jelinek's suggestions is that the industry concentrate on reducing residual VCM to such a low level that there will be no detectable migration from the packaging material.

EPA

In connection with the status of all EPA activities, we are attaching herewith a copy of a report we have just received from Associate Counsel handling these matters. We believe you will find this report quite complete and self-explanatory.

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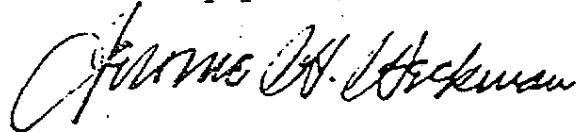
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As in the past, please be assured that we shall continue to make every effort to keep you fully and promptly informed about any matter of significance in the VC/PVC area.

Cordially yours,

A handwritten signature in cursive script, appearing to read "James H. Hickman". The signature is written in dark ink and is positioned below the typed name "James H. Hickman".

Enclosure