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No. 7

TO: All Members of VCM/PVC Mailing Lists

Ladies and Gentlemen:

The purpose of this letter is to update you on the latest developments relative to the Food and Drug Administration (FDA) Proposed Rulemaking and to transmit the latest report we have on the Environmental Protection Agency's (EPA) anticipated proposed Standard.

FDA and Related Matters

Following up on our October 8, 1975 letter Number 5 (the subsequent letter dated October 14, 1975 and also numbered 5 should, of course, have been numbered number 6), we are enclosing herewith the Federal Register Notice of Wednesday, October 27, which officially extends the time for filing Comments on the FDA Proposal until December 12, 1975.

As indicated in our October 14 letter, our first rough draft of Comments on the September 3 Proposal was sent to the Lawyers' Committee, the Technical Subcommittee Chairmen, and the Steering Committee of the VCM/PVC Resin Producers Group, on October 15. Having received Comments on the draft from several sources, and although we have been alerted to expect considerable additional input in this respect, we are now in the process of preparing another draft into which we hope to be able to put as much hard data as possible. Towards this end, we are in the process of contacting all the Technical Subcommittee Chairmen for their reports and data, or summaries thereof. Obviously, the next circulation of Comments

will be governed, both as to date and breadth of distribution, by the availability of meaningful data supportive of our draft Comments.

While we await the completion of reports that will provide the data to demonstrate that vinyl chloride cannot reasonably be expected to migrate to food from properly manufactured PVC products, the Food and Drug Administration Staff has not been altogether quiet. As an indication of some of the present activities and thinking at the Bureau of Foods, we are enclosing a copy of a paper presented by Gerad McCowin, Assistant to the Director of the Division of Food and Color Additives, at an SPE/Retec Meeting held in Chicago on October 21-22.

Several things about the paper struck us as being of significance. Perhaps the most important point is the fairly clear statement on page 9 of the reasoning that lead to the FDA Proposal, namely, the fear that the establishment of any limitation would imply the establishment of a tolerance. In other words, in order to avoid setting any numerical level of either residual monomer or migrating vinyl chloride, FDA resolved that the determinative criterion should be that vinyl chloride not be reasonably expected to become a component of food.

Still further, and quite encouragingly we believe, the statement on page 11 dealing with the future for vinyl chloride polymers reaffirms present FDA thinking that those uses presently proposed to be permitted in the September 3, 1975 Notice still are considered to pose no problem. With respect to those uses which the Proposal would prohibit, Mr. McCowin indicated that they could be cleared if data were provided showing a low or non-detectable level of residual vinyl chloride in the food contact articles (with an explanation of the technical changes in production), data showing that vinyl chloride is not reasonably expected to become a component of food under the intended conditions of use, and some theoretical explanation which might demonstrate why the experimental evidence should show no migration.

One point that Mr. McCowin made raised some concern here. He mentioned that FDA's Division of Chemical Technology is developing head space analytical techniques which will provide greater levels of detection sensitivity than the direct injection procedures. These techniques are certainly not yet standardized, let alone considered to be "official," but Mr. McCowin mentioned the fact that the methods are under development in order to make the point that the industry cannot rely upon a particular analytical procedure but rather must rely on the concept of no reasonable expectation of migration. We learned this by talking with him yesterday.

* * *

On an entirely different but related front, the allegation of birth defects and other health hazards from PVC plants has been resurrected again after having been laid to rest once in August of 1974. On October 23, in testimony before the California State Senate Committee on Public Health and Welfare, Dr. Joseph Wagoner, Director of Field Studies for the National Institute of Occupational Safety and Health, stated that babies born in Ashtabula, Painesville and Avon Lake, Ohio, the sites of several PVC plants, have three times the normal level of birth defects. A copy of the Washington Post article reporting this testimony is enclosed.

Dr. Wagoner's statements are apparently based on an update of testimony initially presented to the U.S. House of Representatives' House Interstate and Foreign Commerce Committee in August of 1974 by Dr. Peter Infante of the Ohio State Department of Health. Dr. Infante indicated, at that time, that the rate of birth defects was twice as great in the named communities but stressed that causes unrelated to vinyl chloride may explain the differences.

The current California State activity is a legislative off-season field trip for the State Senate Public Health and Welfare Committee. Although the 1975 legislative session recessed on September 15 until January, 1976, the Committee is holding field hearings (in this case in

Los Angeles) to gather information on some of the bills pending before it. As we reported to you previously, Representative Paul Carpenter did introduce a bill in the California House, A.2493, which would prohibit the manufacture and sale of PVC items that come in contact with human beings and are determined to be a health and safety hazard. The California State Senate hearing, however, was on a broader proposal which seeks to ban the use of all carcinogenic raw materials except by licensed manufacturers where no substitute material is available.

* * *

In another update of old news, nine angiosarcoma deaths now have been confirmed at a Canadian PVC plant owned by B. F. Goodrich Canada, Ltd. Last Year the Canadian plant had reported eight deaths to NIOSH and further research has revealed another new death attributable to angiosarcoma. Another previously unreported angiosarcoma death was registered in Japan for a PVC worker. A copy of the Wall Street Journal article on these deaths is enclosed.

EPA

With nothing new to report relative to the Occupational Safety and Health Administration Standard, we shall now just note that, following our usual practice, we are enclosing a copy of a letter received from our Associate Counsel for Environmental Protection Agency (EPA) activities. Except for one minor point, we believe this report is completely self-explanatory and will serve to bring you up to date in this area. The point we do need to make is that, subsequent to the receipt of this letter, we were informed that, as is discussed at the bottom of page 3 of the attached letter, the proposed Standard did arrive in Washington for final EPA review on Friday, October 24. At the time Mr. Ruckelshaus' letter was sent, this information was not available.

Cordially yours,

Jerome W. Stockman

Enclosures

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