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August 12, 1975

No. 1

TO: All Members of VCM/PVC Mailing Lists

Ladies and Gentlemen:

The purpose of this letter, as in the past, is to try to report to you on the latest developments relative to activity at the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA) and, via a separate report, the Environmental Protection Agency (EPA); in addition, we are hereby urging the submission of certain data (described below) to FDA.

We are sure you have noted that, in response to constructive suggestions, the format for our periodic reports to you is changing with this "edition". Specifically, to save space, we have condensed the list of addressees. Further, to help organize your review and filing of these documents, we will number each letter serially with a number located beneath the data, starting with this letter as No. 1.

FDA

Since our July 18, 1975 report to you, a good deal has occurred and we now have some hope (despite what you are reading in the lay press and hearing on the other mass media), although by no means any assurance, that FDA may again modify its thinking in connection with the not-yet-published proposed Regulations dealing with polyvinyl chloride food contact materials. More specifically, we have some reason to feel there is a chance that if manufacturers of compounds for potable water pipe, food contact rigid and semi-rigid articles such as bottles and sheet material, or the same types of finished products, promptly supply the Food and Drug

Administration with information regarding the residual monomer content of their present products, FDA may yet be persuaded to propose to reaffirm the prior sanctioned status of PVC resins and compounds based on the evidence that the characteristics of presently available raw materials will assure that there is no reasonable expectation that vinyl chloride will become a component of foods as a result of the use of polyvinyl chloride food contact articles.

In order to put the extremely hectic activity which has been taking place into some framework, a relatively chronological explanation of what has transpired since our last letter may help. Since that letter was sent to you on July 18, I have had a radio "confrontation" with Dr. Sidney Wolfe of the Health Research Group (HRG) on WOR-AM in New York City, and submitted a letter to FDA in connection with further metabolic studies on vinyl chloride conducted by Dow on its own and in cooperation with the Manufacturing Chemists Association (MCA). Excellent articles covering much of what has been happening have appeared in Food Chemical News. (Its August 4 report concerned our July 18 meeting with the Commissioner, et al. and the August 11 issue mentions, among other things, our August 8 meeting with FDA personnel to discuss the toxicology of vinyl chloride). The Editor of FCN has given us permission to reproduce these articles so copies are enclosed with our fervent suggestion that you review the information contained therein; it is, in our opinion, quite accurate unlike the recent Business Week and August 11 Wall Street Journal stories. Finally, and out of chronology, we will report on some visits made to FDA by individual company representatives and are including herewith samples of letters sent by some companies.

Shortly after the HRG Petition was filed (and you will recall a complete copy of this Petition was included with our July 3 mailing), SPI was contacted by the producer of the McCann program which has been a feature of radio station WOR-AM in New York for at least two generations. We were informed that one day of the program, which is generally directed toward health and nutrition matters, was being set up to have Dr. Wolfe

present the anti-PVC case. This is why we were offered an opportunity to appear to present the pro-PVC case. Although we generally prefer to avoid this kind of situation, we felt it important that the industry not be accused of refusing to appear on the program and that an attempt be made to divert and blunt immediately any unsubstantiated charges by Dr. Wolfe; thus, the invitation for July 22 was accepted by SPI and I was assigned to the debate.

In light of the nature of the forum, it was decided that our best approach would be the reiteration of the facts that (a) even in the past vinyl chloride did not really enter the diet as a result of PVC packaging because any vinyl chloride that might have entered food packaged in old style bottles or otherwise would volatilize rapidly before ingestion could occur, and (b) the new compounds available have such low residual monomer contents that there is no possibility of migration now.

Actually, we had no hope or expectation of convincing Dr. Wolfe of anything. We did hope that the audience might be "de-panicked" and that any unreasonable and unwarranted fears would be forestalled. Another objective was to try to present enough of the industry's view to limit "pickups" from the show by the wire services; I think the issues were left confused enough so this one purpose was achieved. We are enclosing a copy of a transcript of the program so that you can have a record of at least the words. We thought it would be worthwhile to do so simply so you can see what sort of pseudo-rational antagonism is now being faced and is probably influencing FDA public relations concerns. The intensity of Dr. Wolfe's presentation does not come through but, unfortunately, we cannot present the music to go with the words except to those of you who might want to drop by to hear a forty-five minute tape recording.

Turning to more substantive matters, as many of you know, we had planned to meet with FDA toxicologists on August 8 to discuss the protocol for a feeding study being developed by the Ad Hoc PVC Toxicology Committee. Related to this but completely independently, the Manufacturing Chemists Association (MCA) has been sponsoring

an investigation of the metabolic fate of inhaled vinyl chloride which is being conducted by Dow Chemical, U.S.A. In addition, Dow with its own funds extended the study to include the metabolic fate of ingested VCM. These studies tend to confirm the report made during the OSHA hearings to the effect that there seem to be at least two metabolic pathways whereby the body "handles" vinyl chloride. There seems to be a detoxification process whereby harmless metabolites are formed and excreted when low levels of vinyl chloride enter the body, and a second (toxic) route that becomes effective when the low level mechanism is swamped or saturated. Accordingly, it was deemed desirable to notify FDA of these findings as a possible means of providing even more of a scientific foundation for the acceptance of the SPI position vis-a-vis PVC food packaging, as distinguished from the HRG position. A summary of the Dow findings was submitted to the Food and Drug Administration on July 30; we are enclosing a copy of our transmittal letter and the summary.

Current FDA procedures require the preparation of a summary report available to the public whenever FDA personnel meet with those outside the Agency. Accordingly, Sam Fine, Associate Commissioner for Compliance, prepared a memorandum regarding the emergency July 18 meeting which we held with the Commissioner and members of his staff (and which we reported on to you at the time). Food Chemical News for August 4 used Mr. Fine's memorandum as the basis for its lead article which, as noted above, is enclosed herewith. This article indicates that the FDA understanding of our presentation and position appeared to be full and complete.

On August 8, representatives of SPI--Ad Hoc PVC Toxicology Committee met with representatives of the FDA to discuss a draft protocol for a feeding study submitted earlier by SPI. It was the intent of the Group to obtain an FDA critique of the protocol so that the proposed feeding study could be undertaken with the assurance that the results would be acceptable to FDA. In addition, as a result of the MCA-Dow Chemical, U.S.A. work, the meeting was broadened to include a presentation to FDA of the results of the metabolic study to date.

The meeting was unusually well attended by FDA personnel. Included among them were Dr. Howard R. Roberts, Acting Director of the Bureau of Foods; R.E. Shapiro, of the Epidemiology Unit, Bureau of Foods; R. Angelotti, Head of the Office of Compliance, Bureau of Foods; H. Blumenthal, C. J. Kokoski and K. P. Mizra of the Division of Toxicology; A. Holtz, N. Weber, T. Fazio of the Division of Chemistry and Physics and J. J. McAuliffe and G. McCowin of the Division of Food and Color Additives.

Present for SPI and MCA in addition to the undersigned were K. Morgareidge, Food and Drug Research Laboratories, Inc.; C. Spiegel, Continental Can; J. Norris, Dow Chemical; W. Rinehart, Ethyl Corp.; A. Lindquist, Stauffer Chemical; P. Watanabe, Dow Chemical; N. Freifeld, MCA; and D. Dixler, Keller and Heckman.

With respect to the metabolic studies, a presentation was made by Dr. Watanabe which demonstrated that ingested (and inhaled) vinyl chloride forms metabolites with sulfhydril-containing compounds which are then further modified and excreted via the urinary route. When administered at lower concentrations, essentially all the absorbed vinyl chloride is eliminated in this manner. When fed in higher concentrations, there appears to be a significant depletion of the sulfhydril-containing moities in the liver and at the same time large amounts of the vinyl chloride are eliminated by exhalation. Nevertheless, even when fed at high levels, the same detoxifying metabolites are also found in the urine although as a percentage of the administered dose they are significantly lower.

In other words, it appears that the first physiological response to vinyl chloride is to detoxify it by reaction with non-protein sulfhydril groups. When the amount of vinyl chloride becomes too large, however, some of the vinyl chloride is eliminated via the lungs, the quantity depending on how much excess vinyl chloride has been absorbed compared to the sulfhydril reservoir.

During the ensuing discussion, it was pointed out that the work so far does not yet demonstrate that high level ingestion produces any metabolites different from low level exposures; nor is there evidence that high level metabolites are carcinogenic.

With respect to the feeding study protocol submitted by SPI, Dr. Rinehart pointed out that the purpose of the study was to provide data on the dietary effects of vinyl chloride when it was administered in a realistic way, i.e. as a part of the total diet rather than as large daily "slugs" as is the case when it is fed by gavage. Other purposes of the study were to demonstrate the effects of lifetime feeding instead of the one year feeding conducted by Maltoni and to use sufficient animals (100 rats per sex per dose) so as to provide better statistical conclusions. Finally, the study proposed to do extensive pathology whereas Maltoni and his co-workers looked only for tumors.

The major FDA criticism from a technical point of view was the absence of what it considered to be a positive control. FDA recommended that some animals be fed by gavage at a level high enough to cause cancer as judged by inhalation and Maltoni feeding study results. The purpose here was to demonstrate that the rats used were susceptible so that if no cancers developed, it could not be stated that the result was due to insensitive animals, i.e. the wrong strain or species.

On a more general level, FDA raised the question as to whether the feeding study would accomplish results commensurate with its cost; since Maltoni has already demonstrated that orally ingested vinyl chloride does cause cancer at some level, a demonstration that it does not cause cancer when administered by a more realistic procedure cannot obliterate his positive findings. Only if the protocol were modified so as to feed the same dose by gavage and by the drinking water route, and the results demonstrated that cancer was induced by gavage and not by PVC in drinking water, could this study negate the evidence already in the record.

FDA did indicate that there might be some limited value to a study that provided enough animals fed at low levels to demonstrate, with good statistical data, that a criterion of no migration with a specified analytical procedure would provide sound assurance of the public health.

Based upon the FDA comments, the Toxicology Working Group of the Ad Hoc Toxicology Committee will meet early in September to consider revising the protocol or other alternatives.

You will recall that we relayed to you a request that residual monomer and migration data be submitted to FDA. This request was reaffirmed in private conversations between FDA and several PVC producers and during the course of the August 8 toxicology meeting reported above. More specifically and urgently, it now appears that there is some hope for inducing FDA to change the direction along which it is presently going toward a proposed Regulation that would place PVC potable water pipe under an Interim Regulation and PVC food contact bottles and sheet under the necessity for clearance by Food Additive Petitions. This hope is that manufacturers of PVC compounds and finished articles in the foregoing classifications can provide evidence that currently sold products have far lower residual monomer contents than those which originally gave rise to the problem. Accordingly, we are requesting data be supplied by individual producers concerning the following:

1. The residual vinyl chloride content of food contact compounds or finished articles (potable water pipe, food packaging sheet and bottles) before the industry became aware of the residual monomer problem.

2. The present levels of residual monomer in the products you are now supplying for these markets.

3. Your residual monomer goals for these products, and when is it anticipated that they will be reached.

It is our hope that with such factual data in its file FDA can be induced to once again consider re-affirming the prior sanction status of PVC for all applications subject to a "no-detectable" monomer migration limit. Such data should be sent to:

Dr. Alexander Schmidt
Commissioner, Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852
(with copies to)

Mr. Sam Fine
Associate Commissioner for Compliance
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852;

Dr. Howard Roberts
Acting Director, Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D. C. 20204;

Dr. Robert Angelotti
Associate Director for Compliance
Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D. C. 20204; and

Mr. Richard J. Ronk
Director, Division of Food and
Color Additives
Food and Drug Administration
200 C Street, S.W.
Washington, D. C. 20204

Again as indicated above, and in connection with company contacts with FDA, we are enclosing a reproduction of the August 11 Food Chemical News article describing a Tenneco visit to FDA. As an example of some of the letters that various producers are sending to the Food and Drug Administration, we are enclosing copies of letters sent by B. F. Goodrich, and by Ethyl Corporation. In addition, residual monomer levels on new type compounds or finished products are being provided by Hooker, Air Products, and others. We urge that all who can do so. Moreover, in the absence of some special reason for not so doing, we would appreciate your supplying us with copies of anything sent to FDA.

OSHA

First of all, the Petition filed by Air Products and Chemicals, Inc. and mentioned in our July 18 letter but inadvertently not attached, is enclosed for your information.

Over the last several weeks (and perhaps we can attribute this in part to the fact that many people are taking July and August vacations this year) virtually no substantive activity related to the Vinyl Chloride Standard has occurred at OSHA. As to the cases where Notices of Contest have been filed, no changes in their status has occurred.

EPA

Following our now usual practice, we are enclosing a copy of a letter received from our Associate Counsel for EPA activities. We believe this report is self-explanatory and will serve to bring you completely up-to-date in this area.

As we have in the past, we shall continue to inform you as fully and promptly as we can with respect to the various phases of the VC/PVC matter. Additionally, we hope that our revised format will make your filing and referencing somewhat easier.

Cordially yours,

Jerome A. Stockman

FOOD CHEMICAL NEWS

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SPI MAKES CASE FOR REAFFIRMATION OF PVC PRIOR SANCTION

The Society for the Plastics Industry has urged the Food and Drug Administration to reaffirm the "prior sanction" for polyvinyl chloride, with a limit on the level of vinyl chloride monomer.

The SPI position was spelled out in a July 18 meeting between FDA Commissioner Schmidt and other FDA-ers and SPI representatives. The SPI position was advanced at the meeting by Jerome H. Heckman, of the Washington law firm of Keller and Heckman. The SPI General Counsel also furnished the FDA-ers with a memo setting forth his position.

The meeting was held on a rush basis after reports that FDA might propose restrictions on some PVC containers (See FOOD CHEMICAL NEWS, July 14, Page 65) led to some industry panic. The memo of the FDA-SPI meeting, written by Associate Commissioner for Compliance Sam D. Fine, said:

> "Word has just reached Mr. Heckman that a customer of one PVC bottle manufacturer, who had been using PVC bottles for packaging salad oil, has cancelled his usual order for such bottles. The cancellation was said to be due to a news report that FDA was changing its views about PVC in contact with food, as a result of evaluation of the petition submitted by the Health Research Group."

Apparently the panic in the industry was caused by FDA thinking in regard to PVC bottles - - which must have been misinterpreted by someone as meaning that there would be an overnight ban on PVC bottles. Action on any FDA proposal will take time.

The latest draft of a PVC proposal is now wending its way through FDA, where there is an urgency inspired by the HRG petition. How soon a proposal will be published depends in part on whether the agency holds up the document until Schmidt returns from his vacation.

The SPI position presented at the meeting, according to Fine's memo, was that industr "has so radically changed the manufacturing procedure for PVC that for all practical purposes there is no problem of the monomer vinyl chloride (VCM) migrating to food." The memo continued:

> "It is the position of SPI that, if by using the most sensitive methodology under exaggerated conditions, the monomer cannot be found, then FDA should recognize there is no problem. SPI believes that the FDA in its forthcoming proposal on PVC for use in food packaging should reaffirm the prior sanction for PVC. Reference was made by the SPI spokesman to the fact that PVC itself has been

> fed extensively to experimental animals (rats) and found safe. It was pointed out that this was the so-called 'old' resin. The studies were made in 1948. It is the belief of SPI that the 1948 resin contained far more of the monomer than does resin manufactured in 1975."

Industry May Fund VCM Feeding Study

Heckman told the FDA-ers that industry has decided to "fund an extensive toxicological study on feeding VCM to rats," the FDA memo said, adding that the protocol for the study has been sent to the agency's Bureau of Foods for approval. The testing is to be conducted by Food and Drug Research Laboratories.

The memo added: "However, it is Mr. Heckman's view that if FDA goes forward with a regulation that does not reaffirm the prior sanction for PVC, industry may well decide to cancel its support for such a study."

In his memo, Heckman urged "that the prior sanction be reaffirmed but that limitations be spelled out for the first time to assure that there will be no vinyl monomer (which is not prior sanctioned) in the food supply." He proposed - -

> ". . . That a prior sanction reaffirmation regulation be proposed and that it (1) indicate that all forms of PVC packaging or processing equipment are considered prior sanctioned and safe provided there is no detectable monomer extractable from them using extraction procedures that reasonably exaggerate intended conditions of use, and (2) that a suitable method for analyzing extractability be set forth in such a reaffirmation regulation."

Such an analytical method "must obviously be one that has been satisfactorily validated and will be reliable for practical day-to-day application," Heckman wrote adding that FDA has developed "such a method which can be incorporated in a reaffirmation proposal."

Noting that any analytical method has a "finite detection limit," Heckman said that, "If the extraction test properly exaggerates any possibility of migration, and with this exaggerated exposure none is detected, one is not relying on the detection sensitivity to assure lack of migration but rather the exaggerated exposure test assures that there is no reasonable expectation of migration under actual intended conditions of use."

The attorney said SPI's proposal would be "responsive" to the HRG petition "in that such action will assure that no vinyl chloride monomer enters the food supply." Heckman said the FDA-proposed limits "would be far more severe than those which have already been imposed by the Occupational Safety and Health Administration in circumstances where exposure to vinyl chloride monomer is not a remote conceptual possibility, but is an absolute certainty."

The OSHA standard permits worker exposure of up to 1 p.p.m. a day, he explained, saying "this is roughly equivalent to permitting 10 p.p.m. of vinyl chloride in the total diet to be ingested daily, if such were possible, which it is obviously not." Heckman added that HRG "participated fully in the OSHA proceedings which led to adoption of its standards."

Expressing concern about the "uncertainty" regarding the status of PVC, Heckman said any FDA proposal which "adds to the unfavorable climate will undoubtedly cause grossly unjustified damage vis-a-vis the public's sense of security about the food supply."

He wrote that current resins and compounds "differ very significantly from the basic materials that were in the marketplace at the time the HRG referenced extraction data were submitted." Use of the "new materials," Heckman said, "will assure there can be no reasonable expectation that PVC packaging materials will lead to vinyl monomer becoming a component of foods, or will be ingested."

Noting that many firms have advised FDA about changes made in their food packaging materials, Heckman said that, "If more data is needed, . . . we can ask that it be supplied and would urge that the FDA receive the same before it takes any precipitous action that might injure the industry's reputation irreparably."

The SPI attorney urged that, in the preamble to its proposal, FDA "explain carefully that while vinyl monomer may be a carcinogen, and is not the subject of a prior sanction. . . , PVC is an entirely different material in the same way that toxic chlorine gas is not sodium chloride (table salt)." Heckman said PVC is inert and has been shown in testing to be "harmless when ingested. . ."

In a footnote, SPI said that while VCM is a carcinogen when "inhaled in high doses over long periods of time," there is "no conclusive data to indicate that the same is true as regards ingestion of vinyl monomer. . ." Therefore, Heckman said it does not fall under the Delaney anti-cancer clause, since it has not been "found to induce cancer after tests 'appropriate for the evaluation of the safety of food additives.'"

Contending that PVC is exempted from the Food Additive Law under its "prior sanction" so that no action at all is necessary, Heckman said that in view of the concern expressed and the confusion between PVC and VCM "it would appear to us that reaffirmation of the PVC prior sanction would be worthwhile." He added:

> "Industry, therefore, could be counted upon to support such action, rather than contest FDA jurisdiction on this score, providing any limitations imposed in the process of reaffirmation are appropriately designed to make it clear that the presence of vinyl monomer in foods will not be tolerated."

July 21, Page 42) apparently has been resolved informally and amicably. The FDA FOI regulations are being allowed to stand by HEW. An agreement on basic policy regardin FDA's regulation-making authority was reached below the level of HEW Secretary.

Some units in HEW had attacked the FDA regulations, claiming that all HEW agencies should be governed by the HEW FOI regulations. By inference, the powers of FDA to issue regulations on its own were questioned.

Under the agreement, FDA can issue its own regulations, other parts of HEW will be given an opportunity to comment on the draft regulations, and the FDA regulations will be consistent with HEW regulations. This is the policy which will govern FDA's forthcoming proposed regulations to implement the Privacy Act.

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FDA CONSIDERING THREE-TIERED APPROACH TO PVC

The Food and Drug Administration is considering as "one possibility" a three-tiered approach to polyvinyl chloride, under which:

(1) Prior sanctions would be reaffirmed for some products; (2) an interim Food Additive Order would be proposed for pipe manufactured from PVC, pending receipt of additional data; and (3) PVC flexible film, semi-rigid film, and bottles would have to be the subject of submitted Food Additive Petitions which would have to demonstrate lack of vinyl chloride monomer migration to result in clearance under Food Additive Orders.

The three-tiered approach was discussed by Washington Attorney Eugene I. Lambert, of the firm of Covington & Burling, at a July 29 meeting held with FDA-ers. The lawyer said he had learned about the three-tiered approach from the Society of the Plastics Industry, and he asked whether it represents FDA's position.

A memo of the meeting, written by Associate Commissioner for Compliance Sam D. Fine, said Lambert was "told that this was just one possibility, and that no decision has yet been made by the FDA as to its approach on the migration problem."

At the meeting, Lambert and other representatives of Tenneco Chemicals urged that the firm's calendered PVC sheet, which is used for blister packs, not be placed in the category of products for which Food Additive Petitions will be required. They suggested an interim Order instead for calendered sheet, describing recent changes in the manufacturing process.

Meanwhile, SPI's Jerome Heckman, in a July 30 phone call to Fine, advised that he expected within the next two days to receive "new data summarizing feeding studies on the effects of vinyl chloride monomer" (See FOOD CHEMICAL NEWS, Aug. 4, Page 3). In a memo of the phone conversation, Fine wrote:

> "According to Mr. Heckman, there are significant differences in feeding low levels of the monomer vs. high levels. He reported that he has scheduled a meeting of

representatives of the SPI with scientists of the (FDA) Bureau of Foods on Aug. 8, 1975, to evaluate the new data.

"Mr. Heckman said that he hoped the FDA would consider this new data prior to the time it takes any action on PVC as a result of the petition of the Health Research Group. Mr. Fine made no commitment as to when the FDA would be publishing a proposed regulation on PVC."

At the meeting, Lambert explained that Tenneco produces PVC resins and calendered PVC sheet, which is shipped to fabricators for use in preparation of blister packs for the packaging of such products as luncheon meats, jellies, syrups, and cheeses.

Tenneco's Michael F. Saggese said the usual thickness of the sheet for food packagin varies between 0.004 inch and 0.030 inch, with the average food packaging thickness in the range 0.010-0.012 inch, according to Fine's memo of the meeting. The memo continued:

"Mr. Lambert ... emphasized the difference in the manufacturing procedure of bottles and other containers from the procedure for calendered sheet. He said he was not aware that there is a real problem of migration into foods from blister packs made from calendered sheet. He said ... Tenneco Corporation is aware of migration into food simulating solvents under exaggerated test conditions."

Saggese told the FDA-ers that "at present 70% of his firm's production of calendered sheet contains virtually no VCM (at the 0.5 p.p.m. level) and the remainder contains not in excess of 1 p.p.m. VCM," the memo said. FDA-ers asked when Tenneco "achieved the capability of producing calendered sheet with no more than 1 p.p.m. VCM," and Saggese replied "that this capability had been achieved since mid-April, 1975."

Dr. Robert Schaffner, Associate Bureau of Foods Director for Technology, referred to data from FDA laboratories involving extraction of VCM with 50% ethyl alcohol on samples submitted by Tenneco in February, 1975. At Schaffner's suggestion, Saggese agreed with a meeting between Tenneco's technical people and Bureau of Foods scientists to "discuss the techniques utilized for measurement by FDA."

There was reference at the meeting to an Ethyl Corporation method which is sensitive to 10 p.p.m., and to a method to be published in the November issue of the Journal of the Association of Official Analytical Chemists. The memo said, "It was emphasiz however, that the current method being developed in the Bureau of Foods appears to b more sensitive than the one that will be published in November of 1975."

Tenneco submitted to FDA three VCM extraction studies from June and July, 1975.

When Lambert asked what sort of transitional period FDA is contemplating if there is change in the status of PVC food packaging materials, FDA-ers said "FDA was not in position to answer that question at this time."

In addition to Saggese and Lambert, Tenneco was represented at the meeting by Covington & Burling's Richard Kingham. FDA-ers at the meeting, in addition to Fine and Schaffner, were Deputy Commissioner Sherwin Gardner, General Counsel Richard A. Merrill, and Associate Chief Counsel for Food Terry Coleman.

CANDY GMP'S TO BE CHALLENGED IN COURT; FDA REFUSES STAY

The National Confectioners Association has announced its intention of seeking a court injunction against three sections of the Food and Drug Administration's candy an cacao Good Manufacturing Practice regulations (See FOOD CHEMICAL NEWS, June 2, Page 53).

However, FDA has rejected NCA requests for a stay of the effective date of the regula tions. The Association made two such requests. One was based on the planned litiga tion. The other was a request for reconsideration based on FDA consideration of econ mic and environmental impacts (See FOOD CHEMICAL NEWS, July 21, Page 41).

In requesting the stay of the effective dates of the sections relating to record keeping coding, and lot number requirements "pending the determination of an action for decla tory judgment and injunctive relief ...and during all appellate procedures that may be associated therewith," NCA complied with the provision of FDA's stayed procedural regulations (See story, Page 3) governing comments and petitions to FDA from trade associations.

The Association said, "Hershey Foods Corporation, Peter Paul, Inc., M&M/Mars, Inc., The Nestle Company, and Ambrosia Chocolate, Division of W. R. Grace Compa each of which is a member of NCA, have requested that the FDA be advised that they are not participating in and wish to be excluded from this petition."

Hershey Foods' Dr. Ogden Johnson, in an Aug. 1 phone call to FDA Associate Com- missioner for Compliance Sam D. Fine, asked about FDA's decision on the NCA reques for a stay. According to a memo of the conversation written by Fine, Johnson "said he wanted the FDA to know that Hershey Foods had not joined in the action by the NC.

In an Aug. 4 letter to Robert H. Becker, of the Washington law firm of Kleinfeld, Kapl & Becker, Fine rejected the request for a stay of the three provisions of the GMP pen ing judicial review. Fine wrote:

> "The petition asserts that the provisions of the regulation of which you seek a stay relate solely to record-keeping, coding, and lot number requirements, are unrelated to product sanitation, and that an administrative stay of these provi- sions is not outweighed by public health or other public interests. On the contrary, these provisions have an im- portant bearing on the protection of the public health."

Asserting that the requirement of the GMP sections would facilitate product recalls, Fine noted that the NCA "petition identifies a number of confectionery manufacturers

WOR-AM: THE McCANNS. "THE VINYL CHLORIDE CONTROVERSY." */

Good morning everyone. This is Patricia McCann. Vinyl chloride is a chemical which goes into making the second most widely used plastic in the U.S. Polyvinyl chloride, that's what the plastic is called, is used to make everything from telephone equipment to food packaging. It's made news because if you recall vinyl chloride was implicated in at least a dozen cases of a rare kind of liver cancer among some industrial workers exposed to it over substantial periods of time.

Just this month, vinyl chloride has been in the news again because the Health Research Group, a Washington-based organization, established by Ralph Nader, requested that FDA ban the use of food packages made from this plastic on the grounds that a residue from the plastic has been found in certain products which we ingest. Dr. Sidney Wolfe from the Health Research Group is with us this morning to discuss the grounds for this group's request to the FDA, and Jerome Heckman is with us too. That's because you are General Counsel for The Society of the Plastics Industry, and you're going to speak on behalf of the industry because, according to the plastics industry, vinyl chloride does not migrate from the package into the foodstuff that the package contains. So we're in for quite a morning on the McCann Show this morning, and I wonder if I've made any mistakes in the introduction, because you know sometimes those of us in the media who get our feet wet like this can exaggerate things, and misinterpret things. So according to you both, so far so good?

HECKMAN: Well I think the one point I might emphasize because I think it's central to the whole issue is that the audience should recognize that vinyl chloride monomer is a gas, as you said. It also evaporates, or as the chemists would say "volatilizes" at 15° below zero centrigrade, so that it's a chemical that moves off at room temperature in effect. And that's an important issue and point that I think will be developed as we discuss the problem.

WOLFE: Yes. I'd like to correct that because it moves off if there is some place for it to move off. For example if you take an empty bottle that's made out of polyvinyl chloride plastic even if there is some small amount of the gas, the vinyl chloride, in it - over a period of time - this gas will move off into the air. If on the other hand the bottle is filled with cooking oil it will move off into the cooking oil. And as Mr. Heckman is aware, a number of studies have shown there are measurable amounts of vinyl chloride in cooking oil sold to people in this country.

HECKMAN: The other point there, if I may just interrupt, is that it should be understood that it will also - when the cooking oil is opened - almost immediately move out of the cooking oil.

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*/ This document is an edited transcript of a program broadcast on radio station WOR in New York City on July 22, 1975.

WOLFE: Like into someone's stomach.

HECKMAN: I think that's a little bit pejorative, but I expect that.

McCANN: Well I tell you what. Now that's an interesting remark because if it could move off, how does it - if there's a cap on the bottle, where does it move off to?

HECKMAN: No. No. I'm talking about after the cap on the bottle is removed. Our position, by the way, basically is that under present conditions particularly, and even in the past, no one has been subjected to vinyl chloride monomer in their diets. That's our position.

McCANN: According to you, according to the industry, none of this substance leaches out to food that is packaged in this type of plastic. Is that what you're saying?

HECKMAN: All right. What's happened is that some of the vinyl monomer has leached out into test extraction solvents.

McCANN: Now we don't know what that means--

HECKMAN: Under very exaggerated conditions.

WOLFE: And things purchased in the market also, which is not under exaggerated conditions.

HECKMAN: Some residual vinyl monomer has also been fc d in things like alcoholic beverages, which I think he is re ing to.

WOLFE: And cooking oil purchased at the market.

McCANN: Well look, we want to get to what evidence there ....

HECKMAN: I think we may be getting diverted now.

McCANN: Well we're going to get back to this, because both of you are making claims one way and the other, and I think what we want to do this morning is to hear what evidence each person has for his own side of this vinyl chloride controversy in terms of the vinyl chloride packaging, plastic packaging of foodstuffs. Because this is where the consumer is involved and concerned.

WOLFE: If I d, I'd just like to give a little background.

McCANN: Would do that Dr. Wolfe as soon as I do some commercials?

McCANN: All right. Patricia McCann here along with our guests this morning. Jerome Heckman, you are General Counsel for The Society of the Plastics Industry, Inc. Could you tell us what that is briefly?

HECKMAN: Well The Society of the Plastics Industry is basically the trade association of those who manufacture machinery, end products, raw materials, and plastic packaging materials, among other things. It's pretty much the trade association of the plastics industry, and I here distinguish between the plastics industry and the chemical industry, because there is to some degree a distinction.

McCANN: All right. Well we don't want to get too deep into distinctions today. And Doctor Sidney Wolfe, you're with us too. You are with Ralph Nader's Public Citizen Health Research Group in Washington, D.C., and I don't know whether that bears explaining. I think you kind of hear the words Ralph Nader, and you know what it's all about. It's getting to be the same way with Dr. Sidney Wolfe too.

WOLFE: Our group does work in several areas. The three main ones are Occupational Health, where we do a lot of work on exposure of workers in factories to chemicals such as lead or mercury, or vinyl chloride. We also do work in the Health Care area. Most recently we've been involved in some studies on unnecessary surgery. We just testified last week on unnecessary surgery which really is a serious problem in this country. And the third area has to do with the Food and Drug Administration where most of what we do is actually in the drug area, but we have on three or four occasions done things on the problems having to do with food additives.

McCANN: What prompted you to get in touch with the FDA Dr. Wolfe, and by the way what kind of a doctor are you?

WOLFE: I'm a medical doctor. Internal medicine is my specialty, plus I have...

McCANN: But you don't have time to practice.

WOLFE: Not very much. Plus I have a background in Bio-Chemistry. I was on the staff at the National Institutes of Health for five years doing research.

McCANN: What prompted your group to go to the FDA and request that poly-vinyl chloride plastic packaging be banned, in terms of food.

WOLFE: Well as I said before a little bit of background, which I think really is why we went to the FDA. The background really has to do with our concern about the problem of cancer, and whether it's cancer in the workplace, or cancer caused by things in the environment; water, air. Or cancer caused by things in the marketplace. Cancer kills about 360,000 or 370,000 a year; about 1,000 people a day in this country die from cancer. And whereas ten years ago or fifteen years ago when I was in medical school, the most popular thoughts as to what caused cancer were viruses and things of that nature, now we've swung over in another direction and the most recent thinking coming from people who work in the cancer area is that the main cause of cancer in this country and elsewhere are chemicals in the environment. In fact, the recent estimates are that 80, 85 or possibly 90% of all cancer is chemically induced. And by chemicals . .

McCANN: Where do these estimates come from?

WOLFE: From the National Cancer Institute which is the Government Cancer Research Center. The chemicals include chemicals in the air, chemicals in the water, chemicals in a concentrated form in the workplace which is where, unfortunately, a lot of information comes from; cancer in food additives, cancer in drugs and the like. But 80-90% of cancer is environmental. Smoking of course is another one. And therefore preventable. So when we learn that a cancer-causing chemical is in the food supply, we get particularly concerned because unlike the workplace where there may be 10,000 or 20,000 workers exposed - and then when it gets into the food supply there may be 100 to 200 million people involved.

McCANN: Are you gentlemen both agreed on the fact that this vinyl chloride is a carcinogenic chemical? Is it definitely proven to be carcinogenic in other words?

HECKMAN: Vinyl chloride as a gas when inhaled has pretty much been demonstrated to be a carcinogen at high levels.

WOLFE: And at low levels also.

HECKMAN: After long-time exposure.

WOLFE: At low levels also, and as Mr. Heckman I'm sure is aware..

HECKMAN: I don't think that's been proven at all.

WOLFE: Well certainly it has. Mr. Heckman is familiar with the studies.

HECKMAN: It depends upon what you mean by high or low of course.

WOLFE: Fifty parts per million for example is a lower kind of level. It's about 1/10th as high as the amount of vinyl chloride in the air when people breathe the air that they have to when they use an aerosol.

McCANN: Just to give us a frame of reference. The workers who are working in a plant that's been cited over and over again in the literature that I've received, how much vinyl chloride gas were they exposed to per day.

HECKMAN: Some of them were exposed to as high as 4,000 parts per million for 10-15 years.

WOLFE: And then there are people who live in the vicinity of plants that produce vinyl chloride that are exposed to much lower levels who also have gotten cancer.

HECKMAN: Now we deny that entirely and will not put up with that kind of assertion for the simple reason that there were two cases, unproven even as yet, and NIOSH's records make it unclear as to whether they were related in any way to vinyl chloride production. That's a sheer guess and conjecture, and we don't believe it's true. In fact we think that it's false.

WOLFE: Now I think that's typical of the attitude of the plastics industry. If there's any possibility, assume that it doesn't cause cancer, which of course is in the best interests of the plastics industry.

HECKMAN: It's obvious that this is an advocacy situation now because there's no question but that Mr. Nader and the Health Research Group is an extremist group...

McCANN: Why do you have to use the word "extremist?"

WOLFE: You're absolutely right. We're "extremely" concerned about cancer.

HECKMAN: I think it's important that they be what they've been, and that it has been necessary for them on occasion in the past to get attention by using the "beat the mule over the head" tactics.

McCANN: All right, now let's get back to - I'm thinking of...

HECKMAN: I think we ought to get back to the facts and forget this other...

McCANN: Jerome Heckman, I am an interviewer on this program, and let's not have any of these tactics here, because we really want to get some clarification across on this show, and I'm thinking of the consumer

who's listening. And she or he would like to know how this chemical, if this chemical, kind of leaches out into his existence, that's what the point is. Now is there any proof today that the foods, mouthwashes, cooking oils are products into which you believe this substance migrates. What evidence is there that - you mean if I go into the supermarket today and I buy a certain kind of mouthwash, are you saying that there is going to be vinyl chloride in that. And how do I know, is it such a minute amount that really we're kind of - splitting hairs here.

WOLFE: Well the FDA has data that really answers that question. Interestingly, some of the data was sent in by the industry itself. And samples of mouthwash taken from the shelves as recently as December of 1974 were brought into a laboratory and analyzed. It was the same thing that millions of people would be buying when they go into the same stores and found to contain significant amounts of vinyl chloride. The question about whether it's a small amount or not, the animal studies that have been done have shown that vinyl chloride as low as levels comparable to fifty parts per million, and as Mr. Heckman said before the first study showing it to cause cancer in workers were as high as 4,000 per million. Levels as low as 50 parts per million can cause cancer in animals. And in some of these food products that have been consumed such as cooking oils for example - levels as high as 6 or 7 parts per million exist. Now what that means is that not as large a percentage of animals or people will get cancer when the level is lower, but a smaller percentage will get it. There is no safe level of any cancer-causing chemical.

McCANN: But actually there's no proof that anybody would get it. I mean there isn't. And even if they did, you could never probably connect it up with "Hey, they were using that mouthwash."

WOLFE: That's precisely why the Food and Drug Law is set up in such a way that the government is required to respond on the basis of animals getting cancer because you obviously can control that much better. The Delaney Amendment which is part of the Food and Drug Law says that no chemical that has been shown to cause cancer in animals is allowed to be added to the food supply. Fortunately it has not been necessary to use that amendment very many times. I say fortunately because with 1,000 people a day dying from cancer, largely chemically-induced, it wouldn't be good to have too many cancer-causing chemicals in the food supply. I think it's been used maybe six times in fifteen years.

McCANN: Jerome Heckman go on. I know you want equal time. You've got it.

HECKMAN: Well I hope to be able to give a little background too. First of all I think I should point out that vinyl chloride has only been demonstrated to cause cancer by means of inhalation studies. And that means when it's breathed in. Feeding studies on vinyl chloride itself are inconclusive as of yet. Polyvinyl chloride, the plastic that is used to wrap food, has been fed over extensive periods of time. The data is in the hands of the Food and Drug Administration. There is no evidence whatsoever that it is unsafe for any application, and it's permitted for all food contact applications for all practical purposes.

McCANN: This plastic has been fed to animals?

HECKMAN: Yes. In the resinous form, not in the gas. Now the feeding studies that are being done with gas are being done by such a very drastic method that we don't really know what they'll prove. But they haven't been completed, so there's no use conjecturing about it. When we start talking about the levels that people will be exposed to, since October 15, 1973, and I make no brief for the Food and Drug Administration on this point by the way, we have been urging the Food and Drug Administration to, in effect, require that no vinyl chloride monomer, detectable by the best methodology that can be developed, be permitted to migrate to foods. And that they adopt a regulation so indicating, and we're still in favor of that. We feel that they should do that and that should take care of the problem perfectly well. There's one other point I do want to make. Dr. Wolfe has talked about parts per million, particularly in connection with the OSHA - with the Occupational Safety and Health Standard, and that sort of thing. Where food packaging is concerned, we're talking in terms of 50 parts per billion as a test method, and I want to tell you what that means.

McCANN: What is the difference between parts per million and parts per billion? When you hear those words used all the time ...

WOLFE: There's a thousand per billion for one part per million.

HECKMAN: And let me express it another way. This is what a member of the public would have to do, assuming that there were some way, and we deny entirely by the way that any part, that any vinyl chloride monomer is finding its way into the diet of human beings.

McCANN: How can you deny it when Dr. Wolfe says there is evidence that some mouthwash bought back in December in 1974 was found to have some of the substance in it. Because that means that a person would ingest it, doesn't it?

HECKMAN: Not in my opinion. I want to clarify the matter of parts per billion first, but Dr. Wolfe continues to want to go on.

WOLFE: You're saying things that aren't true.

HECKMAN: Well I don't have a monopoly on that.

WOLFE: A good thing we don't.

HECKMAN: No.

WOLFE: Your industry doesn't either.

HECKMAN: Well I think I'd like to explain what the parts per billion concept is for the benefit of your listeners, because I think they're being panicked. If you took fifty parts per billion of something in a cup of coffee, and let's assume it's sugar, in order to get a teaspoon full of sugar you would have to drink 150,000 cups of coffee.

WOLFE: What does that prove?

HECKMAN: The only point I'm trying to make is that Pat asked earlier what we're talking about in terms of quantity. And what we're saying to the Food and Drug Administration is use the best method you've got, and bar any vinyl chloride monomer getting into foods. We want you to do that, because we can make polyvinyl chloride, and do, that will lead to no vinyl chloride monomer getting into the diet, because the diet is what counts. Not what's in a bottle of food or anything like that, but what's in the diet is what counts. If it's not in the diet, you're not ingesting it and it's not going to give you cancer.

WOLFE: I'd just like to respond to that. There's a p[illegible]shed article in a journal which you may not have seen, Mr. Hec[illegible], Food & Cosmetic Toxicology which estimates the dietary intake o[illegible] vinyl chloride because it is used in packaging. Now the people who wrote the article, it was published in Feb. '75, estimate that vinyl chloride does get into the diet. So it's interesting that scientists, as opposed to people that are wound up in the plastics industry, do think that vinyl chloride can get into the diet.

McCANN: May I say something at this point? Because I realize I don't think that industry does anything on purpose in terms of when a carcinogenic substance is discovered to be one, it's not that industry intended it that way. It's just that we're all getting so terribly cautious as we're becoming more discreet about our environment. It occurs to me that when you take in a substance like that, if you do enough, it's a small amount and which it seems to be, that the body is capable of metabolizing this, unless the body

is inundated with it. And it seems the body is so inundated when a plant worker in a plastics plant is working there. Of course he'll be inhaling this chemical all the time, and over a period of time I can understand how this could become overwhelmingly toxic to the body. But I tend to see industry's point of view in this case too. What are we talking about here? A substance so minute that the body could probably handle it and metabolize it.

WOLFE: Yes. There are a number of chemicals that cause cancer that are capable of causing it in very small amounts, such as vinyl chloride. There are some that are even more powerful than vinyl chloride, that have caused it in humans in amounts that under a part per million. Parts per billion amounts of certain chemicals have caused cancer.

McCANN: How do you know that? Now Dr. Wolfe, that's an interesting thing to say.

WOLFE: The workers in a chemical plant in Philadelphia, and Mr. Heckman has said they are not part of the chemical industry which I respect, have gotten lung cancer from really tiny, tiny amounts of the chemical which is even more powerful than vinyl chloride. But the point is that we're talking about vinyl chloride being in the air. It's been measured in the air near plants where it's produced, possibly being in the water supply, being in cooking oils, in mouthwashes. In other words, really getting into the general environment so that a given individual might have a number of different sources of exposure. For example , with two billion aerosols having been manufactured with vinyl chloride as the propellant, a large proportion of people in this country have already been exposed to significant amounts of vinyl chloride which they breathed in.

McCANN: Wait a minute. Vinyl chloride is used as a propellant in aerosols?

WOLFE: It was for a period of time and fortunately it has been completely stopped.

HECKMAN: I think I can add to that if Dr. Wolfe will let me. At one time vinyl chloride was believed to be so safe, and you've got to remember that it was industry that blew the whistle on itself on vinyl chloride. No government agency ...

McCANN: You mean industry came to the FDA and said "hey this is..."

HECKMAN: Oh yes. And to NIOSH.

WOLFE: After waiting as long as it could.

HECKMAN: I don't know what to say to a comment like that. Industry came when it had done enough work that it wasn't dealing in the realm of scientific rumor but was satisfied that it was dealing in th realm of scientific fact. And the researchers who did all the work were industry-paid people, not government-paid people; Dr. Maltoni, and before him the other doctors who did the work were industry-paid people, and then industry in effect blew the whistle on itself. So we don't feel that we have to have any kind of a guilty conscience. The one thing that you should know is that at one time vinyl chloride monomer was believed so safe that Dr. Wolfe's medical profession used it as an anesthetic in the operation room. It was not a very satisfactory anesthetic I gather, but it was used that way. So we're not the only ones who make mistakes.

McCANN: Gentlemen, I am going to do some commercials and we will be back to you in only moments. The topic is Vinyl Chloride - Can Plastic Food Packaging be Harmful to your Health. And we're trying to air the issue and it's not easy. But I'm wondering - this is something that we can discuss afterwards - if any attempts are being made. I know there is one very popular vegetable oil that changed its packaging from plastic back to glass. And if they did, it's kind of like "why doesn't everybody else if there's any doubt in anybody's mind."

All right gentlemen, we have a question from a listener, why do you need vinyl chloride? That is the question from a listener.

HECKMAN: Well I'd be glad to start off on that subject. I'm not sure that you need vinyl chloride other than to make polyvinyl chloride. So let's change the question to "Why do you need polyvinyl chlorid ", because I think that's the real issue. And I think we need polyvinyl chloride because it has a number of properties that no other packaging material that we have available today has. For example, I suspect that the people of this country would probably be required to stand in meat lines, much like the gasoline lines, if polyvinyl chloride film - if it were not possible to use that film to prepackage the meat that you buy in the chain stores. The whole production system has been geared to that and that's only one use. There are many other food packaging uses of that type, and I can assure you, and I think the Food and Drug Administration would assure you if it were here, that there is no danger at all from that type of packaging. And there is no chance that any vinyl monomer, the chemical, is getting into the meat supply. There's no reason to change away from it.

McCANN: I mean what is there to say? One of you is saying it gets into food, and the other is saying it doesn't.

HECKMAN: That's correct. That's where the controversy is and our position is very simple. If you can't find it there, then as far as we're concerned it's not there.

McCANN: What about the mouthwash, just taking that one instance?

HECKMAN: In the first place, Dr. Wolfe is talking about old data. And since this problem came to light, the industry and even in the last six months has made fantastic strides toward its reducing the potential monomer content of all of the resins to the point where we really feel the problem no longer exists.

McCANN: Although I did read in some of the literature that your office sent me that they don't see in the foreseeable future where they would ever be able to assure - that there would be no technology in the foreseeable future to assure that there would be no residue left in the packaging. That it really would require great strides.

HECKMAN: That was part of a quote in Modern Plastics magazine, May, 1975. That's right. And that is true as regards what might be in the basic raw material that comes out of the plant, but not in the packages - nothing will get into the diet or the food supply as a result of that. If you've got less than a part per billion or a part per million really in a raw material, and then you make that raw material into a bottle and apply heat to that and thereby drive off more of that monomer, you're getting down to where you just can't be talking about much of anything. Then when you test the material under conditions that grossly exaggerate any condition that the food will be subjected to . . .

McCANN: What are you referring to when you say that?

HECKMAN: Well you test in solvents that grossly exaggerate the capability of food to pull anything out of the bottle or the package.

McCANN: Are there certain kinds of foods that are more likely to pull out whatever residue is left?

HECKMAN: Alcohol.

WOLFE: I think what Mr. Heckman is referring to which is correct is that vinyl chloride is more soluble in certain kinds of substances.

McCANN: Which one?

WOLFE: Well in alcohol for example - fat - it's very, very fat soluble, which is why it gets into cooking oil that's been put into bottles.

McCANN: What about the cooking oil that's so popular that did change its packaging a few years back from plastic. Wesson oil?

HECKMAN: That's not a fair statement, because what Wesson oil did, and they made a statement to this effect to the Food and Drug Administration so it is a matter of record. What Wesson did, according to their statement, is conduct a market test with polyvinyl chloride and then at that time decided not to use it for economic reasons of its own.

McCANN: Not for safety?

HECKMAN: According to their own statement, that's what they said to the Food and Drug Administration, and I think we have to accept what they say.

WOLFE: They did stop using it though, that's the main thing.

HECKMAN: And they said that they never really changed from glass. Now we'd like to know from Dr. Wolfe at some point what he would suggest we use instead.

McCANN: What would you suggest Dr. Wolfe?

WOLFE: Well as you just stated Mr. Heckman, one obvious alternative is glass, and Wesson and other companies did switch back to glass after trying out as you pointed out on an experimental basis, but the subjects of the experiment were millions of people in this country who bought and ingested Wesson oil that was contained in polyvinyl chloride. So one alternative is glass. Other alternatives are cellophane, but I think the important point is are the other alternatives safe. And we just discussed that a minute ago, and it would be kind of unfortunate to get an alternative for polyvinyl chloride that is just as dangerous or even more dangerous than polyvinyl chloride. So I think that whatever food packaging wrappings we use in the future, they should be tested in advance, so that we don't have more surprises as we did with vinyl chloride.

McCANN: You're not saying stop using polyvinyl chloride in the rest of industry. You're saying just when it comes to food packaging, let's try another type of plastic.

HECKMAN: Well we're saying polyvinyl chloride is <u>the</u> most tested, safest packaging material to use right now.

McCANN: Patricia McCann right here and we have just about time to cordially say good-bye to our guests this morning, and they've been very cordial to each other for the last four minutes I've noticed.

That's kind of nice. The vinyl chloride controversy was the subject of this morning's program. We may not have solved anything, but I think you two people said a lot and people are just going to have to make up their own minds and keep their eyes peeled for newspaper articles. And I have to thank you both, Jerome Heckman and you too, Dr. Sidney Wolfe for coming on and airing both sides of the vinyl chloride controversy here on WOR, New York.

# # #

about any aspect of this matter, please do not hesitate to contact us.

Cordially yours,

Enclosures

cc: Mr. Sam Fine
Mr. Sherwin Gardner
Mr. Richard Merrill
Mr. John Walden

bcc: Mr. Richard Ronk
Mr. Gerad McCowin
bbcc: SPI-PAC-VCM/PVC Resin Producers Committee

JHH:DSD:ds

July 30, 1975

Dr. Alexander Schmidt
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, Maryland 20852

Re: Vinyl Chloride Toxicology

Dear Dr. Schmidt:

In accordance with my promise to Mr. Fine yesterday, and on behalf of The Society of the Plastics Industry, Inc. and the Manufacturing Chemists Association, we are enclosing three copies of a summary report entitled "Studies on the Metabolism and Pharmacokinetics of Vinyl Chloride in Rats" by Watanabe, Hefner, McGowan and Gehring of Dow Chemical Company. The full report on these studies will be presented to your FDA toxicologists at a meeting scheduled to be held on August 8 to review a protocol for a vinyl chloride feeding study.

It is our belief that these studies provide important confirmation of preliminary indications that the metabolic fate of vinyl chloride is dose related and that this information deserves careful consideration before the Food and Drug Administration proposes any new Food Additive Regulations in connection with the use of polyvinyl chloride plastics.

We expect that the report which will be presented next week will be sufficiently complete with respect to the technical content to permit full toxicological evaluation. Until then, however, if you have any questions

STUDIES ON THE METABOLISM AND PHARMACOKINETICS OF VINYL CHLORIDE IN RATS

Watanabe, P. G., Hofner, R. E. Jr.,
McGowan, G. R. and Gehring, P. J.

Studies on the fate of ^{14}C labeled vinyl chloride (VC) after single oral administration in rats at dose levels of 0.05, 1, and 100 mg/kg body weight have been completed. Following 0.05 and 1 mg/kg, the proportions of the administered dose excreted in the urine, feces, expired as CO_2 and expired as VC were similar. However, following 100 mg/kg a greater proportion of the administered dose was expired by the lungs as VC. Therefore the fate of VC following a single oral dose between 1 and 100 mg/kg was clearly dose dependent. The observation that the metabolism of VC appears to be a saturable process is consistent with our previous studies on the fate of VC following inhalation exposure in rats.

Dose dependent effects are of prime importance in toxicology. As increasing doses of chemicals begin to overwhelm or saturate normal detoxification processes, it may be expected that there will be a disproportionate increase in toxicity. Therefore the toxicity incurred with large doses of a chemical

must be interpreted with caution and judgement. An important aspect of this judgement is whether the dose dependent effects are functioning over a range of doses extending from those that do not cause toxicity into those that cause toxicity. It is noteworthy that current carcinogenesis bioassays in rats given oral doses of VC have shown, to date, induction of angiosarcomas at 50, and 16.6 mg/kg/day, 5 days/week, but no tumors at 3.3 mg/kg/day (Maltoni, 1975). It appears that a correlation exists between doses of VC that cause tumors and those that saturate metabolic or detoxifying pathways.

The effect of VC on the hepatic non-protein sulfhydryl content was studied by exposing rats to atmospheres containing 1000, 250, 50 or 10 ppm VC for 1-7 hours. Exposure to 250 and 1000 ppm VC caused a progressive depression of the hepatic non-protein sulfhydryl content which reached a plateau of 35-40% between 5 and 7 hours. At 50 ppm the apparent maximum depression of about 40% was achieved only after 7 hours of exposure. No depression of hepatic non-protein sulfhydryl content occurred following exposure to 10 ppm VC for 7 hours. Thus, the depression of hepatic non-protein sulfhydryl content appears to correlate with induction of hepatic angiosarcomas in rats exposed by inhalation (Maltoni, 1975). The data

indicates that the detoxification pathway for VC involves conjugation of VC or its reactive metabolites with non-protein sulfhydryl groups. Therefore, it seems reasonable to postulate that as the non-protein sulfhydryl groups are depleted, reactive metabolites may be free to react with other macromolecules (DNA, RNA, protein, lipids) resulting in toxicity and perhaps carcinogenicity. It is highly significant that exposure to 10 ppm VC for 7 hours caused no depression of hepatic non-protein sulfhydryl content. This indicates that there is a threshold of exposure in rats where the ability to replace sulfhydryl groups is not overwhelmed and physiologic defense mechanisms remain operative. Furthermore, this suggests that thresholds may exist for other toxic effects.

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B.F.Goodrich Chemical Company

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EDWARD B OSBORNE
DIVISION V CE PRESIDENT, MARKETING

August 7, 1975

Dr. Alexander Schmidt, Commissioner
Food and Drug Administration (FDA)
5600 Fishers Lane - Room 14-71
Rockville, Maryland 20852

Dear Dr. Schmidt:

During the past 2 years B.F.Goodrich Chemical Company has been cooperating through The Society Of The Plastics Industry, Inc. (SPI) with FDA in the development of information required to enable the Bureau of Foods to develop a rational regulation on the use of products containing PVC in contact with food. In my letter of 2/3/75 to Dr. Schaffner (copy attached) we endorsed the concept to permit the use of PVC products in food contact applications, providing there is no detectable migration of vinyl chloride to the food, using a test method sensitive to 50 parts per billion in a food simulating solvent under exaggerated exposure conditions. We reaffirm this endorsement and urge its prompt adoption.

We are disturbed to learn through SPI that there may have been a substantial change in the thinking concerning the proposed regulation. We understand that this change would, in effect, ban the use of some PVC products for any food contact if vinyl chloride monomer (VCM) in any amount, however minute and insignificant, could be released by any procedure, however exotic. We are concerned that this change may be the result of a petition submitted by the Health Research Group. We object to such a change! We are firmly convinced that scientific facts support the regulation that we endorse and suspect that the Health Research Group's petition is founded on nothing more than unreasonable speculation.

The issuance of the type of regulation that we endorse will provide industry with the guidelines it needs, and we urge its immediate publication. However, in view of the controversial nature of the subject and the existence of a number of ongoing technical programs on air, food and water ingestion of VCM and its migration from PVC, perhaps a technical symposium should be called in the public interest. The current status of these various studies could be presented and discussed. We believe there was rational progress made by a similar symposium called 2 years ago by National Institute of Environmental Health Sciences on phthalate esters. We believe the actions which we have suggested are in the interest of public health and safety. The industry has made drastic reductions in residual VCM in its resins and compounds during the past 2 years, especially in materials destined for products to come in contact with food and potable water.

ETHYL CORPORATION

C. M. NEHER
SENIOR VICE PRESIDENT

August 4, 1975

Dr. Alexander Schmidt, Commissioner
Food and Drug Administration
200 "C" Street, S.W.
Washington, D. C. 20204

Dear Dr. Schmidt:

In the absence of our President, this letter is forwarded to advise concern over the information coming out of Washington of a change in the attitude at FDA with respect to Vinyl Chloride Monomer in food packaging and related items. On November 20, 1974, our President wrote to Director Richard Ronk expressing concern over then published information, and in a subsequent meeting supplied a position paper (letter and position paper attached).

Mr. Ronk and his people proved to be courteous, considerate, and competent, and in the discussions we were able to identify an area of concern at FDA which we at Ethyl were subsequently able to satisfy with data.

Frankly our experience with the Bureau of Foods demonstrated that Government, Science and Industry working together can achieve the goals the Nation sets.

HOWEVER,

in the past two weeks there appears to be action afoot which negates this elementary proposition. We are now told that there is a possibility that the regulations proposed by the Bureau of Foods (which Science in Government had developed, supported by data from Science in Industry) may be changed without supporting data and possibly for Public Relations reasons. You can see why we are concerned. If our national goals are to be achieved, it will be by Government, Science, and Industry working together, not in an adversary relationship.

ETHYL TOWER / 451 FLORIDA / BATON ROUGE, LOUISIANA 70801

Incidentally, we would like to call your attention to long term animal feeding studies conducted many years ago for FDA registration of GEON® 202 resin by the Harvard School of Public Health (copy attached). Based on recent analyses of this resin powder, made by the original process, that material must have contained several hundred parts per million of both vinyl chloride monomer and vinylidene chloride co-monomer.

We appreciate your consideration of our recommendations.

Very truly yours,

E. B. Oxtoby

EBO/BMGZ:ksc

Copies
Dr. Sherwin Gardner, Deputy Commissioner
Dr. Sam Fine, Associate Commissioner
Mr. Richard Merrill, Chief Counsel
Mr. John F. Walden, Assistant Commissioner for Public Affairs
Mr. Richard Ronk, Director, Bureau of Foods
Mr. A. Vittone, President, B.F.Goodrich Chemical Company
Mr. T. B. Nantz, Executive Vice President, The B.F.Goodrich Company
bcc: [redacted]
Mr. Ralph L. Harding, Jr. - SPI, New York City

Air Products and Chemicals INC

CHEMICALS GROUP

Five Executive Mall, Swedesford Road, Wayne, Pa. 19087

June 30, 1975

RECEIVED

JUL 8 1975

A. ROSS ADAMS

Honorable John Stender
U.S. Department of Labor
Occupational Safety and
Health Administration
1726 M Street N.W.
Washington, D.C. 20210

Re: Petition for Amendment of
29 CRF Section 1910.1017

Dear Mr. Stender:

Pursuant to 29 CFR Section 1905.3, Air Products and Chemicals, Inc. ("APCI") hereby petitions for an amendment to the definition of "fabricated product" as set forth at 29 CFR Section 1910.1017(b)6. Other petitions for an amendment to the definition of "fabricated product" have been submitted by Dow Chemical U.S.A. and Union Carbide Corporation. The purpose of this proposed amendment is to expand the scope of the fabricated products exemption as it applies to certain resins and compounds (homopolymers or copolymers of vinyl chloride) which contain residual vinyl chloride monomer at levels so low that fabricator and transportation employees working with such low residual level product would not be exposed to concentrations of vinyl chloride in excess of the action level of .5 ppm 8-hour TWA.

Proposed Amendment

It is specifically requested that 29 CFR Section 1910.1017 (b) 6 be amended to read as follows:

"(6) 'Fabricated product' means a product made wholly or partly from polyvinyl chloride

(i) which does not require further processing at temperatures, and for times sufficient to cause

Dr. Alexander Schmidt, Commissioner August 4, 1975

Our people will be seeking audience with your people in the days ahead to discuss this issue. Your review of the facts with them would be appreciated.

Best regards,

C. M. Neher

CMN:pw

cc: Dr. Sherwin Gardner, Deputy Commissioner
Dr. Sam Fine, Associate Commissioner
Mr. Richard Merrill, Chief Counsel
Mr. John F. Walden, Assistant Commissioner for Public Affairs
Mr. Richard Ronk, Director, Bureau of Foods
Mr. Bruce C. Gottwald, President, Ethyl Corporation

Air Products and Chemicals, Inc.

mass melting of the polyvinyl chloride resulting in the release of vinyl chloride to the workplace atmosphere in excess of the action level; or

(ii) which does not contain more than .0050 weight percent (50 ppm) of residual vinyl chloride

Rational for the Proposed Amendment

The vinyl chloride standard (29 CFR Section 1910.1017) is complex, difficult to administer, and contains many burdensome requirements on employers. It requires the use of sophisticated and expensive monitoring and analytical equipment. These burdens are particularly oppressive to small businesses which manufacture fabricated products from polyvinyl chloride.

Subsection (d) of the existing standard requires each establishment to carry out a program of initial monitoring and measurement to determine if employee exposure to vinyl chloride monomer ("VCM") is in excess of the "action level." As shown in the attached exhibits covering a wide range of materials and a large variety of fabricating establishments, the residual vinyl chloride content of the polyvinyl chloride being processed can be well above 50 ppm without there being any employee exposure in excess of the action level.

Currently, if a fabricator is processing material containing less than 50 ppm residual VCM, he must nevertheless carry out the program of initial monitoring. Although this is a needless and burdensome exercise at this residual level, the burden is not thereafter lifted. Further monitoring is required "whenever there has been a production, process or control change, or the employer has any other reason to suspect that any employee may be exposed in excess of the action level."

Accordingly, a fabricator might have to remonitor whenever it changes its supplier of resin, the grade of

resin, the time or temperature of melting, its ventilating equipment etc.

It is submitted that so long as the residual level of VCM in the resin is less than 50 ppm (this could be certified by the resin producer) neither the initial nor the subsequent program of monitoring is necessary or appropriate. Accordingly, fabricators processing material containing less than 50 ppm residual VCM exclusively would be relieved of the burdens of the standard.

The requested redefinition of "fabricated product" would also serve to simplify the transportation and export of resins and compounds falling within the new definition. Petitioner is currently encountering resistance on the part of foreign purchasers of its PVC resins and compounds because of the warning lables required by 29 CFR Section 1910.1017(l)4. It is submitted that such labels are unnecessary for polyvinyl chloride containing low residual levels of VCM. Government regulations in such foreign countries generally do require such labelling, and foreign purchasers in such countries are alarmed. Although it is clear that OSHA has no authority to require such labels on contaners of PVC after they have left the United States, OSHA does have the authority to require such labels so long as the product is in the United States and subject to handling by United States workers. It is impractical to remove the warning labels after the product has left the United States. The proposed amendment to the definition of "fabricated product" would serve to obviate the necessity of warning labels on containers of polyvinyl chloride containing low residual VCM.

In addition to granting relief as aforesaid, the redefinition of "fabricated product" would serve as an incentive to polyvinyl chloride producers to manufacture product containing less than 50 ppm residual VCM.

Data in Support of the Proposed Amendment

The data in the attached table provide the basis for this Petition. These data represent those monitoring

results taken at fabricators' plants in recent months where the residual VCM level of the raw materials was known. Petitioner has many other monitoring results in which the residual VCM level of the material was not measured (but which from operating experience we believe to be in the same range) that confirm these findings.

All results below 0.01 ppm for the 8-hour TWA have been reported as N.D. (Not Detectable) because of the demonstrated sensitivity of the carbon absorption method published by NIOSH. Differences in reported results in this range are not significant.

We believe that these data justify the requested amendment to the definition of "fabricated product," and solicit your serious consideration. We will be glad to discuss this further with your staff if you so desire.

Very truly yours,

AIR PRODUCTS AND CHEMICALS, INC.

Raymond H. Schenck
Attorney

RHS*swc

bcc: A. R. Adams ✓
J. T. Barr
R. Fleming
J. V. Heider/file

FABRICATORS EMPLOYEES EXPOSURE TO VINYL CHLORIDE

8-Hour TWA By The Suggested NIOSH Method

Date	Type of Operation	Material Used	VCM Content - PPM	Job Function	8-Hr TWA
Apr. 28, 1975	Film Extrusion	Compound	1.5	Extruder Operator	ND
Apr. 20, 1975	Injection Molding	Compound	2.3	Molding Operator	ND
Apr. 13, 1975	Pipe Extrusion	Resin	221	Inspector	0.03
				Mixer Operator	0.49
				Extruder Operator - A	0.02
				Foreman	ND
				Extruder Operator - B	0.04
				Extruder Operator - C	0.02
				Extruder Operator - D	0.05
				Extruder Operator - E	0.01
Apr. 10, 1975	Record Pressing	Compound	85	Mold Operator - A	ND
				Mold Operator - B	ND
				Mold Operator - C	ND
				Flexible Film Operator	0.02
				Scrap Grinder	0.19
Apr. 8, 1975	Film Manufacture	Compound	18.0	Extruder Operator	ND
				Vacuum Forming	ND
Mar. 20, 1975	Extruder	Compound	29.3	Extruder Operator - A	ND
				Extruder Operator - B	ND
				Scrap Grinder	0.03
		Resin	20.2	Blender	ND
Mar. 11, 1975	Injection Molding	Compound	66	Operator	0.01
Mar. 6, 1975	Injection Molding	Compound	157	Operator	0.01

FABRICATORS EMPLOYEES EXPOSURE TO VINYL CHLORIDE

Date	Type of Operation	Material Used	VCM Content - PPM	Job Function	8-Hr TWA
Feb. 25, 1975	Film Extrusion	Compound	27	Extruder Operator	ND
				Winder Packer	ND
Feb. 5, 1975	Record Molding	Compound	36	Mold Operator - A	ND
				Mold Operator - B	ND
				Flexible Disk Operator	0.03
				Scrap Grinder	0.08
Feb. 4, 1975	Injection Molding	Compound	8.7	Molding Operator	ND
Feb. 3, 1975	Film Extrusion	Compound	7.9	Extruder Operator - A	ND
				Extruder Operator - B	ND
Jan. 23, 1975	Cove Molding	Resin	12.8	Compounder - A	ND
				Compounder - B	ND
				Compounder - C	ND
				Extruder Operator	ND
				Inspector	ND
Jan. 22, 1975	Flexible Profile	Resin	18.9	Hopper Loader	0.04
				Extruder Operator - A	ND
				Extruder Operator - B	ND
				Mixer Operator - A	0.09
				Mixer Operator - B	0.10
Jan. 15-17, 1975	Shoe Soles	Resin	14.9	Blend Conveyor Operator	ND
				Mixer Operator - A	0.15
				Molding Operator - A	ND
				Molding Operator - B	ND
				Mixer Operator - B	0.34
				Molding Operator - A	ND
				Molding Operator - B	0.29
				Grinder Operator	0.14

FABRICATORS EMPLOYEES EXPOSURE TO VINYL CHLORIDE

Date	Type of Operation	Material Used	VCM Content - PPM	Job Function	8-Hr TWA
Jan. 15-17, 1975 (cont'd)				Mold Operator - C	ND
				Mold Operator - D	ND
				Weigh Man - A	0.46
				Mixer Operator - C	0.01
				Mold Operator - E	0.03
				Weigh Man - B	ND
				Mold Operator - F	0.01
				Mold Operator - G	ND
Jan. 13, 21, 1975	Flexible Compound	Resin	5.7	Foreman	0.01
				Mixer	0.04
				Bagger	0.02
				Extruder	0.02
				Helper	0.01
Jan. 10-16, 1975	Flexible Profile Extrusion	Resin	2.2	Extrude Operator - A	0.02
				Extruder Operator - B	ND
				Mixer Operator	0.41
				Hopper Operator	0.05
				Extruder Operator - C	0.02
				Extruder Operator - D	0.02
				Fuser Operator	0.04
Jan. 10, 1975	Injection Molding	Compound	36.8	Molding Operator	ND
Jan. 7, 1975	Injection Molding	Compound	54	Operator	ND
				Helper	ND
Dec. 17, 1974	Citation	Compound	103	Operator - A	ND
				Operator - B	ND
				Operator - C	ND
				Operator - D	ND
				Operator - E	ND

LAW OFFICES
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CARL EARDLEY
LEONARD GARMENT
OF COUNSEL

CABLE ADDRESS
"INDLAW"

August 8, 1975

Jerome H. Heckman, Esquire
Keller & Heckman
1150 17th Street, N.W.
Washington, D.C. 20036

Dear Jerry:

This letter will update you as to the latest developments regarding EPA's action concerning the vinyl chloride standard.

Schedule

The proposed vinyl chloride standard was reviewed by EPA Administrator Russell E. Train on Friday, August 1, 1975. The result of his review was to forward it to other interested Federal Agencies for review and comment. EPA suggests this be done within thirty (30) days. As you may recall, the original schedule provided for the standard to clear EPA by June 17, 1975. Copies of the standard may be secured from John Lawrence or this office. We sent copies to the members of the VC-PVC Steering Committee on Tuesday and Wednesday.

Legislative

The House Interstate and Foreign Commerce Subcommittee on Health and Environment and the Senate Public Works Subcommittee on Environmental Pollution adjourned for the August recess without taking any action to amend regulations applicable to alleged hazardous pollutants. The Subcommittees have not yet acted on Administrator Train's request that he be given authority to set "process" standards under Section 112 of the Clean Air Act rather than emissions limitations. It is anticipated that the Subcommittees will complete their work on the Clean Air Act amendments during September, with full Committee consideration in October. To date both Houses have been running considerably behind their schedules.

Airlie House Conference on Environmental Disease and National Health Policy

On August 6-8 the Society for Occupational and Environmental Health and the Blue Cross Association co-sponsored a conference for the labor, medical, scientific, and insurance communities to examine the risks to health posed by occupational hazards and the current availability of, and prospects for, effective health planning and care. Among the participants were Dr. Irving J. Selicoff, who discussed to some extent the state of medical knowledge about asbestos and vinyl chloride, Dr. Theodore Cooper, Assistant Secretary of Health, HEW, Dr. Leslie Boden, Harvard School of Public Health, Dr. George Melcher, Group Health, Inc., Sheldon Samuels, AFL-CIO, and Anthony Mazzocci, Oil, Chemical and Atomic Workers. Because some of the subject matters discussed were of particular relevance to the Society, we will forward to you a separate report on the Conference.

Sincerely yours,

W. D. Ruckelshaus

WDR/ap