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SEP 11 1974

September 9, 1974

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:

This latest addition to our set of reports on governmental and related activities covers the period since our rather massive letter of August 26, 1974. We have up-dates on matters concerning the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

Our present information is, of course, that the Occupational Safety and Health Administration is still aiming at a Federal Register publication of the vinyl chloride occupational standard on or about October 5, 1974. In connection with the Standard, OSHA has received a draft of an economic impact study prepared for it by Foster D. Snell Incorporated. Although still in draft stage, copies are available to interested parties through OSHA; the final statement is due to be completed this week. The Hearing

record has been held open for this document, and one company has filed a motion to reopen the Hearing to permit cross-examination of Foster D. Snell representatives.

In addition, the Office of Planning, Evaluation and Research of OSHA has prepared what might be considered a second part of the Economic Impact Survey entitled "An Economic Impact and Technological Feasibility Study for the Compounders, Processors and Fabricators of Polyvinyl Chloride Resins." Here too, copies of the Survey are available to interested parties; we are not including copies of either Study with this letter because of their great bulk.

A review of the latter Study shows that it draws no conclusions. Nevertheless, it clearly points out that exposure in processor's plants tend to be quite low and that the cost of compliance with a "non-detectable" requirement would tend to be quite high, although not readily quantifiable. We are attaching copies of two portions of this report referring to the Study's estimate of the magnitude of the problem, both from the point of view of exposure of workers and the difficulties of procuring whatever equipment may be required.

The VCM and PVC Producers Committee of The Society of the Plastics Industry met last Friday to consider both the Foster D. Snell report and OSHA's "Part Two." After the meeting we prepared Comments on the two reports and submitted the same today. A copy of our filing on behalf of SPI is enclosed herewith.

Our contacts at the Environmental Protection Agency have now indicated that the EPA's Task Force report "should be ready" to be submitted to the Administrator during the early part of the week of September 8. It seems reasonable, therefore, to conclude that EPA will take no formal action until the Administrator has had time to review the report so that our guess is that no EPA publicly announced action can be anticipated before the latter half of September.

With respect to the long anticipated proposed Interim Food Additive Regulation concerning polyvinyl chloride plastics for use in food contact applications, the Regulation has not yet been published in the Federal Register. A recent news release has ascribed some of the delay in promulgating

the Interim Food Additive Regulation to FDA's desire to "clear" it with other interested Agencies. This may well be involved, but it is expected to be published "within a week or two." Our contacts at the Food and Drug Administration can offer no better time estimate.

As we understand it, the delays appear to be the result of minor editorial changes and are not expected to have any substantive effect on the proposed Regulation. In other words, to the best of our present information, the proposed Regulation will still require that food contact polyvinyl chloride plastics contain less than 10 parts per million of residual monomer and that, when tested, the amount of vinyl chloride possibly migrating to food-simulating solvents may not exceed 50 parts per billion.

You may recall that FDA requested information regarding the residual monomer content of PVC packaging materials, and the possible migration of residual monomer to foods. FDA repeated this request in the preamble to a Notice concerning drugs and cosmetics published in the Federal Register on August 26, 1974. We are enclosing a copy of that notice to refresh your recollection.

The main reason we thought we would remind you about this matter is because we have reason to believe that, assuming FDA proceeds with its 10 ppm residual monomer in the food contact surface proposition, there could be special problems relative to so called "rigid films" of the type used for "bubble" packaging of food products. This being the case, it occurred to us that it might be worthwhile to remind you of the FDA request for data since we have reason to suspect that very little, if any, information has been supplied on either the residual monomer or extraction characteristics of this class of product. Although it is undoubtedly too late to supply data which might do anything to change the FDA proposal, the availability of such data could be most important as an influence on the final Interim Food Additive Regulation so receipt of the same by the Food and Drug Administration, and our office, would probably be most helpful.

A final FDA-related item relates to a meeting held by the Toxicology Task Group of the Plastic Bottle Institute, the Food, Drug and Cosmetic Packaging Materials Committee, and

the VCM and PVC Producers Committee to review work done by Food and Drug Research Laboratories (FDRL) as the initial phase of a study of the ingestion toxicity of vinyl chloride. The preliminary FDRL study was intended to evaluate possible methods of feeding vinyl chloride monomer in a controlled fashion to rats so that an appropriate feeding study could be conducted to demonstrate the safety of polyvinyl chloride as a food packaging material. A more complete protocol based upon the results of this preliminary study is being prepared for submission to the appropriate groups in the Society.

We will continue to keep you as fully informed as possible.

Cordially yours,

Jerome H. Stockman

Enclosures

Excerpt from "An Economic Impact and Technological Feasibility Study for the Compounders, Processors and Fabricators of Polyvinyl Chloride Resins"

Of the three industry layers in question, the compounders have the most exposure. Processing has less exposure by virtue of the fact that it subjects PVC compounds, which still contain some small amounts of residual VCM to heat pressure. Fabricating, the fashioning of a finished product from an intermediate one made through processing, is the most removed from possible worker exposure to VCM.

Some reasons for the feasibly higher exposure levels at the compounding layer are:

(1) Compounders work with raw resin which still has much of the original residual VCM entrapped within it. This is especially true today due to the high market demand for PVC. Raw resin spends very little time in inventory between the time it is produced and the time it is compounded. The result is that the release of residual monomer, which naturally takes place over time, is limited.

(2) The mixing and blending operations accelerate the release of residual VCM by heating the resin. Even though venting is done above the mixers and mixer operators do not normally get near the top of an operating vessel, there is an inevitable release of residual into the ambient air of the workplace.

It can be argued, however, that processors, fabricators, and processors/fabricators really do not have an exposure problem at all. Referring back to our monitoring data, 81% of all readings from both the hearings and OSHA inspections taken at these layers indicate exposure levels of one ppm (TLV) or less. The evidence becomes even stronger if allowable exposure becomes defined as an eight hour time weighted average (TWA) which allows for excursions above one ppm and gives a better picture of the true exposure level.

Estimates for all of the above are not able to be made at this time. Although it would certainly be useful to be able to include these costs, particularly numbers 7 and 8, it is felt that they quite simply cannot be accurately estimated. In view of this, leaving them unanswered seems more constructive than answering them with possibly mistaken or erroneous information.

As alluded to in Section III, cost impact information at the compounder, processor and fabricator level is just not readily available. These industry layers seem to feel that they ought to be treated separately by any regulation and thus have not themselves examined the possible direct impact resulting from the proposed standard. The standard itself is viewed as having been written with the VCM and PVC producers in mind.

Unfortunately, there also exist no good estimates of engineering costs related to compliance with the proposed standard. Again, since almost all compounders, processors and fabricators are currently operating at exposure levels well below both the Emergency Temporary Standard and the VCM and PVC producers, and since it is generally believed that the permanent

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[6] Snell Preliminary Report, Appendix F.

[7] Ibid.

[8] Ibid.

standard will be less stringent than the proposed standard, possible engineering changes and the costs associated with them have not in most cases, been planned for. These three industry layers have adopted a "wait and see" attitude towards the whole question of control of vinyl chloride exposure. Most firms are doing nothing, with the possible exception of some personal monitoring. The are waiting to learn what they will be required to do.

Aside from the obvious difficulty this creates in trying to estimate cost impact, this situation may also produce real logistical problems once a permanent standard has been promulgated. The Department of Labor may be faced with 8,000 or more compounders, processors and fabricators all straining simultaneously to secure the same limited supply of equipment and technical expertise. The industries that provide these services and equipment will most certainly not be able to meet this sudden surge in demand, thus creating shortages and long lead times. This would be especially critical if deadlines are written into the permanent standard.

The upshot of this discussion is that a comprehensive picture of cost impact has not been able to be presented. Due to the scarcity of information necessary for making such estimates, the question of direct economic effect on the compounder, processor and fabricator level, is still an open one.

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 310—NEW DRUGS

Subpart E—Requirements for Specific New Drugs or Devices

SUBCHAPTER G—COSMETICS

PART 700—GENERAL

Subpart B—Requirements for Specific Cosmetic Products

Vinyl Chloride as an Ingredient of Drug and Cosmetic Aerosol Products

In the FEDERAL REGISTER of April 22, 1974 (39 FR 14215), the Commissioner of Food and Drugs issued a notice of proposed rule making regarding all drug and cosmetic aerosol products containing vinyl chloride as an ingredient, including propellant. The proposal was based on the Commissioner's determination that there are sufficient scientific data on which to base a decision that: (1) Vinyl chloride presents an unnecessary hazard to the public health when it is used as an ingredient in cosmetic aerosol products, and that such use should be banned; and (2) vinyl chloride, when used as an ingredient in drug aerosol products, is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, and requires an approved new drug application as a condition of marketing. Interested persons were invited to submit comments regarding the proposal on or before May 22, 1974.

Comments were received from the American Academy of Pediatrics, a municipal consumer affairs unit, and an individual. All the comments were in support of the Commissioner's proposal. Accordingly, the Commissioner concludes that the regulations should be adopted as proposed.

The notice of proposed rule making also requested data regarding the use of polyvinyl chloride in containers for food and cosmetics, and in devices. The Commissioner urgently requested that certain data be submitted on the extent of the usage of polyvinyl chloride containers, the rates of extraction of vinyl chloride monomer from these containers, and other matters that will pertain to the safety of these containers. The time limit for submission of data requested in the proposal was on or before June 21, 1974. However, to date, the Commissioner has received only a few responses and again requests that the pertinent information be sent to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, as soon as possible.

A companion notice in the same issue of the FEDERAL REGISTER (39 FR 14238) required each registrant under section 510 of the Federal Food, Drug, and Cosmetic Act to submit a list of all human drugs which are being manufactured, prepared, propagated, compounded, or processed for commercial distribution and which contain vinyl chloride as an ingredient or are packaged in polyvinyl chloride containers. The notice also requested registrants to furnish certain additional information relating to vinyl chloride and polyvinyl chloride.

Data being received by the Food and Drug Administration as a result of the FEDERAL REGISTER notices are being compiled and reviewed to determine whether any additional action by the Commissioner is needed to protect the public health.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 601(a), 701(a), 52 Stat. 1050–1055, as amended; 21 U.S.C. 352, 355, 361(a), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 310 and 700 are amended as follows:

1. By adding a new § 310.506 to Subpart E to read as follows:

§ 310.506 Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products.

(a) Vinyl chloride has been used as a propellant in aerosol drug preparations. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have been reported in animals. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Recently, vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride.

(b) The Commissioner finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of aerosol drug preparations containing vinyl chloride as an ingredient, including propellant. Therefore, any such product containing vinyl chloride is a new drug and a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD-1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that such preparations are safe and effective for the purposes intended.

(d) Any such drug within the jurisdiction of the act which is not in accord with this regulation is subject to regulatory action.

2. By adding a new § 700.14 to Subpart B to read as follows:

§ 700.14 Use of vinyl chloride as an ingredient, including propellant of cosmetic aerosol products.

(a) Vinyl chloride has been used as an ingredient in cosmetic aerosol products including hair sprays. Where such aerosol products are used in the confines of a small room, as is often the case, the level of vinyl chloride to which the individual may be exposed could be significantly in excess of the safe level established in connection with occupational exposure. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Furthermore, vinyl chloride has recently been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride. It is the view of the Commissioner that vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Any cosmetic aerosol product containing vinyl chloride as an ingredient shipped within the jurisdiction of the act is subject to regulatory action.

Effective date. This order shall be effective September 25, 1974.

(Secs. 502, 505, 601(a), 701(a), 52 Stat. 1050–1055, as amended; 21 U.S.C. 352, 355, 361(a), 371(a).)

Dated: August 20, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-19657 Filed 8-23-74;8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Exempt Chemical Preparations

The Administrator of the Drug Enforcement Administration has received applications pursuant § 1308.23 of Title 21 of the Code of Federal Regulations requesting that several chemical preparations containing controlled substances be granted the exemptions provided for in § 1308.24 of Title 21 of the Code of Federal Regulations.

The Administrator hereby finds that each of the following chemical preparations and mixtures is intended for laboratory, industrial, educational, or special research purposes, is not intended for general administration to a human being or other animal, and either (a) contains no narcotic controlled substances and is packaged in such a form or concentration that the package quantity does not present any significant potential for abuse, (b) contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration, that the preparation or mixture does not present any potential for abuse, or (c) the formulation of such preparation or mixture incorporates methods of denaturing or other means so that the controlled substance cannot in practice be removed, and therefore

Vinyl Chloride Link to Cancer Known in 1971, Report Says

By Bob Kuttner
Washington Post Staff Writer

Evidence existed as early as 1971 that low doses of vinyl chloride caused cancer in laboratory animals, according to an internal technical report by the World Health Organization's International Agency for Research on Cancer.

The researcher isn't identified, but several prominent U.S. cancer scientists believe he is Dr. P. L. Viola, the Italian researcher whose earlier work first alerted the chemical industry to the possible carcinogenic — cancer-causing —effects of high doses of vinyl chloride.

So far, 14 deaths from a rare liver cancer called angiosarcoma have been reported among U.S. chemical workers exposed to vinyl chloride gas, which is the base ingredient for one of the most common plastics, polyvinyl chloride.

The disclosure Jan. 22 by the B. F. Goodrich Co. that three workers in its Louisville, Ky., plant died of angiosarcoma led to a crash research program by several federal agencies, including the National Institute of Occupational Safety and Health and the Labor Department's Occupational Safety and Health Administration (OSHA).

Consequently, OSHA adopted an emergency standard lowering exposure limits to vinyl chloride workers from 500 parts per million to 50 parts per million, and NIOSH has recommended a permanent permissible level of zero.

In addition, dozens of consumer aerosol products containing vinyl chloride gas as a propellant have been withdrawn from the market.

In the wake of these findings, the chemical industry has been sharply criticized by cancer scientists for failing to fully inform either the government or its own plant physicians about the results of European studies showing links to cancer as early as 1971.

"If the latest report means what it seems to mean," said Dr. Irving Selikoff, director of the Environmental Sciences Laboratory at Mt. Sinai School of Medicine in New York," then we're nearly four years behind where we should be."

"You don't automatically assume that animal studies are conclusive, but the industry should have at least notified their own doctors," he added.

"It's inexcusable that they didn't tell the government," said Dr. Sidney Wolfe, director of the Nader-sponsored Health Research Group.

"It would have been appropriate for them to tell us about the European studies as soon as they knew," added a NIOSH scientist.

According to the Manufacturing Chemists Association, the principal industry trade association, the MCA invited Dr. Viola to discuss his study with U.S. industry representatives in May, 1971. The preliminary studies showed vinyl chloride was carcinogenic at levels of 30,000 parts per million.

By November, 1971, the MCA was aware that concentrations of 5,000 parts per million "and perhaps less" also could cause tumors in laboratory animals.

According to the latest World Health Organization report, which summarizes a meeting held last June, a laboratory in Italy during that period—presumably Dr. Viola's —was also finding that concentrations as low as 500 parts per million could cause tumors, including angiosarcomas of the liver. Those results have not yet been published.

Subsequently, the European chemical industry sponsored another series of experiments by a second Italian scientist, Dr. Caesare Maltoni. The U.S. Manufacturing Chemists Association learned of Dr. Maltoni's studies in late 1972. Those studies showed that animal tumors could be produced at concentrations as low as 250 parts per million, or half the permissible exposure levels for workers in the United States.

However, the MCA did not share the information with government agencies, having promised its European counterparts to keep the findings secret.

Instead, the MCA and several of its member companies contracted for new animal studies in the United States. It also arranged for an epidemiological survey, to study the health records of workers exposed to vinyl chloride.

In June, 1973, at a meeting with NIOSH officials, industry representatives are said to have down played the significance of the European findings.

Although the 1973 Maltoni research indicated that liver cancer could be caused at concentrations as low as 250 parts per million, NIOSH director Dr. Marcus Key told an Aug. 21 Senate hearing on vinyl chloride that at the meeting "no mention was made to us about liver cancer and no mention was made to us about the name of the Italian scientist."

Only after B. F. Goodrich reported that its Louisville plan physician, Dr. John Creech, independently discovered the cases of angiosarcoma did the trade association fully reveal the Maltoni findings to NIOSH officials. Even at that point, according to NIOSH sources, the MCA asked NIOSH to keep the findings secret.

Dr. Maurice Johnson, Goodrich's medical director, confirms that he knew about the Maltoni study but said that he saw no need to notify the company's plant physicians. "It was by no means a finished study," he said.

When Goodrich's Dr. Creech found the third case of angiosarcoma among plant workers, Dr. Johnson said, "that was the clincher."

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September 9, 1974

Mr. Julius Jimeno
Attn: OSH-36
Occupational Safety and Health
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U.S. Department of Labor
Room 200
1726 M Street, N.W.
Washington, D. C. 20210

Re: In The Matter of: PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE

Dear Mr. Jimeno:

On behalf of our client, The Society of the Plastics Industry, Inc. (SPI), we are herewith transmitting five copies of the statement entitled "Post-Hearing Memorandum of The Society of the Plastics Industry, Inc. re Economic Impact Studies." It is our intent, of course, that this Memorandum be incorporated as a part of the official Record in the above-referenced matter.

Should any questions arise with regard to any matter contained in the SPI filing, please do not hesitate to contact us.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

By Jerome H. Heckman
Jerome H. Heckman
General Counsel

By Joseph E. Hadley
Joseph E. Hadley

cc: Messrs. Boyd, Lassiter and Regad

bcc: VCM/PVC Resin Producers Committee
Messrs. Harding, McGrath and Lawrence

UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

In the Matter of:	
PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE	DOCKET: OSH-36

POST-HEARING MEMORANDUM OF
THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

ECONOMIC IMPACT STUDIES

The Society of the Plastics Industry, Inc. (SPI)[1/], by its attorneys, hereby respectfully submits its Comments with respect to the Foster D. Snell Preliminary Report entitled "Economic Impact Studies of the Effects of Proposed OSHA Standards for Vinyl Chloride" commissioned by the Occupational Safety and Health Administration (OSHA) in connection with the above-referenced proceeding. These Comments are being submitted in accordance with the Notice concerning the

1/ The interests, composition and extent of participation of SPI in these proceedings is by now well known to the Department of Labor. A complete discussion of the interests of the Society is specifically detailed in its "Post-Hearing Memorandum of The Society of the Plastics Industry, Inc.--Proposed Findings of Fact and Conclusions Supported by the Record," dated August 23, 1974.

economic impact study, published in the Federal Register on August 26, 1974 (39 Fed. Reg. 30844). Simultaneously, although we are aware of no formal notice published regarding the document prepared by the OSHA Staff (Evaluation and Research Division) entitled "An Economic Impact and Technological Feasibility Study For The Compounders, Processors and Fabricators of Polyvinyl Chloride Resins," included in the Record as Exhibit 172, this opportunity is being taken to comment briefly on that document as well. This would appear appropriate since the OSHA Staff document is internally characterized as constituting "Part II" of the overall, OSHA-ordered economic and technological feasibility review.

I

INTRODUCTORY STATEMENT

It should be recognized that commenting on the referenced preliminary reports presents some very unique problems. As will be noted hereinafter, there are a few rather easily identifiable portions of the Snell and OSHA reports which, it is submitted, contain significantly erroneous information or interpretations. The major problem presented, however, is that it is most difficult to submit pointed comments because neither of the preliminary reports actually set forth conclusions or recommendations. The right

to comment on any conclusions or recommendations ultimately included in the reports should be afforded all interested parties; thus, the right to comment in this area is hereby explicitly reserved.

Aside from this basic issue, the following observations are submitted with respect to the reports, it being urged that the documents in question be modified accordingly.

II

PRELIMINARY REPORT OF FOSTER D. SNELL, INC.

A. Specific Comments

1. At page V-6 the Preliminary Report states that "Firestone was the only PVC producer reporting the ability to meet a 'no detectable' VCM standard primarily using engineering controls." This statement is amplified by extrapolations set forth in Exhibits V-10(1) and (2) of the Preliminary Report. Furthermore, other data and information which we submit is based on this erroneous interpretation of the Firestone position has been woven into the report at several other places, as will be discussed below.

2. The Society hereby respectfully submits that the ability of Firestone to eliminate occupational exposure to vinyl chloride, reportedly based on both Foster D. Snell and Firestone data, comports with neither the information

presented orally by Firestone at the Hearings in this matter nor in any of its written submissions. In fact, Firestone has repeatedly stated, to the contrary, i.e. that it is of the opinion that it cannot achieve a no detectable level of vinyl chloride in the work place. (Tr. 1602, 1682, 1695-99, 1754 and 1822) Thus, since in point of fact Firestone has denied an ability to meet a no detectable standard, it is urged that all pertinent parts of the Preliminary Report must be altered to reflect the position actually articulated by Firestone, that is, that it is technologically infeasible to attain a non-detectable exposure level of vinyl chloride in the work place.

3. If the basic Firestone position were correctly stated in the Preliminary Report, other information contained therein and based on the Firestone statement at the Hearings and the studies it presented to OSHA, should be reflective of the information as presented. To accomplish this, consistency would demand that the following changes be made:

a. Exhibits V-10(1) and (2), both entitled "Estimated Cost for the Firestone Tire and Rubber Company to Achieve a 'No Detectable' VCM Level," should be deleted in their entirety;

b. Exhibit V-12: the figures presented in the chart under the headings "Information on the Direct Cost of Compliance," "Cost to Make Up for Loss of Productivity," "Total Costs," and "Compliance Period Required For Engineering Controls" and aligned across from the heading "No Detectable" should be deleted and replaced by the term "Not Applicable"; and

c. Exhibits V-14(1) and (2): the last column on the right in each of these tables entitled "1 ppm Ceiling-1 ppm TWA" should be deleted due to lack of factual support for the same contained in the study.

The items listed and any others based on the interpretation of the information concerning the Firestone position should be deleted or altered to accord with the actual Firestone position.

4. It is respectfully submitted that the changes suggested above with regard to information concerning Firestone are justified by the information in the Record, the studies and analyses made by Firestone notwithstanding. The fact of the matter is that each of the vinyl chloride

and polyvinyl chloride resin producers conducted some type of study in an attempt to determine how a "no detectable" occupational exposure level to vinyl chloride could be achieved. All of these studies, including that made by Firestone, concluded that attaining such an exposure level was technologically infeasible. The only difference is that Firestone put a price tag on every action it contemplated. Nevertheless, Firestone was unable to define a means for achieving the "no detectable" occupational exposure level set in the Proposed Permanent Standard. (Tr. 1725, 1749, 1750 and 1819) The Firestone Study is, therefore, not an answer to the economics of achieving a no detectable exposure level. On the contrary, the costs shown reveal that compliance with the proposal cannot be achieved despite the projected capital expenditures.

5. Also included in the Preliminary Report are two references to the reported ability of a VCM producer to operate its vinyl chloride monomer plants at a 1 ppm ceiling and a 1 ppm TWA. This could only be based on information supplied by Dow Chemical U.S.A. which, we believe, has been misinterpreted. The first reference is in Note (2) to Exhibit V-6. The second is in Note (2) to Exhibit V-13.

6. It is respectfully submitted that the Record does not support these statements. Even though Dow indicated

that it could achieve low levels of occupational exposure to vinyl chloride in its monomer plants, it stated unequivocally at the Hearings that it was infeasible to operate within the parameters of the Proposed Permanent Standard. (Tr. 884-901) Accordingly, it is suggested that the two referenced Notes be deleted from the Report inasmuch as they reflect an inaccurate interpretation of the Dow position.

B. General Comments

7. The Proposed Permanent Standard raises a central question regarding the technological feasibility of compliance. The vinyl chloride and polyvinyl chloride resin producers are unanimous in their view that the achievement of a no detectable level of vinyl chloride in existing and planned manufacturing facilities is technologically infeasible. Consequently, the Society is not prepared to discuss the specific costs of achieving a no detectable or 1 ppm occupational exposure level because the technology required to reach this goal is unknown to the Society and its members and, therefore, the costs related to this technology are obviously incalculable.

8. Nevertheless, a few general, but nonetheless important, observations are in order concerning the costs associated with taking certain actions and/or achieving

specific goals as set out in the Preliminary Report. Although these comments are being made without the benefit of particular knowledge about the methodology employed by Foster D. Snell to arrive at the figures tabulated throughout the Report, cost estimates for accomplishing certain objectives and/or for the achievement of set levels of occupational exposure to vinyl chloride are substantially understated.

9. Firstly, many cost factors requisite to this type of analysis have not been made or even referenced. The Preliminary Report does not address, for instance, the costs to some companies of reducing the residual monomer content in the various types of resins. Similarly, the economic impact of the inevitable United States Environmental Protection Agency Regulations for the control of vinyl chloride emissions have not been estimated or even noted as a potential cost that should be expected to at least "affect" cost and price considerations. The potential effects of actual plant closings expected to occur should OSHA's Permanent Standard ultimately set a very stringent level of occupational exposure to vinyl chloride are also not detailed, even though such would certainly be expected to alter the supply-demand outlook.

10. Additionally, the Foster D. Snell Preliminary Report finds fewer companies stating that they can reach the SPI recommended exposure levels. This should be noted as actually bolstering the industry position with regard to the technological infeasibility of the Proposed Permanent Standard. Individual company confidence in being able to attain compliance with even the SPI recommendations has been eroding as lead times for attaining equipment expand, as capital costs rise rapidly, and as the prospects for financing these projects becomes dimmer. The demands for equipment and money are out-pacing supply and the net effects of this situation must also be costed out, that is, if the goals remain within the realm of feasibility. For example, delivery times for equipment have risen from the 16-18 months indicated by Snell to about 28 months at present; new plant construction time is also up from 30-36 months to 42-48 months.

11. Finally, the price tags attached to compliance with varying exposure levels are stated in absolute terms. Considering the continuing variation in prices for raw materials, it is suggested that the approach in the Preliminary Report of using calculations in absolute figures is not meaningful. For example, the price quotations for the cost of vinyl chloride monomer were already out of date when the Preliminary Report was made available. It is

respectfully submitted that, instead of employing absolute terms, the costs should be calculated in terms of their variance from a given constant. That is, given a base, known cost factor, the other costs and prices could be more intelligibly stated in terms of the percentage or actual cost change from the base figure. Such calculation methodology would obviate confusion and misunderstanding about compliance costs posited in terms of absolute values.

12. A final important point to be made with regard to the Preliminary Report is that, although the Report contains other mechanical errors which will undoubtedly be corrected, there is one very important typographical correction that must be made. In Exhibit III-17, the current residual vinyl chloride monomer level for exemplary general purpose suspension-type resin is stated as 50 ppm. That figure is in error and should be changed to read 500 ppm.

III

OSHA STAFF REPORT ENTITLED "AN ECONOMIC IMPACT AND TECHNOLOGICAL FEASIBILITY STUDY FOR THE COMPOUNDERS, PROCESSORS AND FABRICATORS OF POLYVINYL CHLORIDE RESINS"

13. It should first be noted that the typographical error in the Snell Preliminary Report which showed general purpose suspension resin with a residual monomer level of 50 ppm rather than 500 ppm has been carried over into this

Report in Subsection 5.4. The OSHA Staff should also correct its Report as indicated above.

14. In Section II on the background and research for the Proposed Standard, this Report contains subsections on medical research and ongoing studies concerning the effects of exposure to vinyl chloride. The Report regretably fails to include several significant elements of available research. Specifically, the Report does not give the details of or even list the human experience data submitted to OSHA by Air Products, Diamond Shamrock, Dow and Union Carbide. These submissions include extensive epidemiological data and, in the case of the Dow studies, considerable information about actual human exposure to known concentrations of vinyl chloride. Although the details of these studies are contained in the Record, none are listed in this Report as "major pieces of bio-statistical evidence." A correction in this respect is clearly in order.

15. Finally, this Report's Subsection 5.5 details extensive compliance costs for medical surveillance, monitoring and personal protective equipment but finds that compliance cost information for compounders, processors and fabricators is not readily available. The Society is of the view that such is not the case. The issue here, detailed at length in the Record, is two-fold. First, the Proposed Permanent

Standard is not applicable to the situation as it exists in this portion of the industry. Second, because of this inapplicability, the compliance mechanics are, on both the physical and economic planes, unduly burdensome. Therefore, the Society respectfully submits that compliance costs for compounders, processors and fabricators can be estimated and that such estimates illustrate that the requirements of the Proposal are physically and economically infeasible for this segment of the industry.

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All the foregoing considered, it is respectfully urged by The Society of the Plastics Industry on behalf of the entire industry that the recommendations made be considered and that the two Reports be modified accordingly.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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