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THE SOCIETY OF THE PLASTICS INDUSTRY, INC.
250 PARK AVENUE • NEW YORK, NEW YORK 10017 • 212/687-2675

MINUTES

MEETING OF SPI FOOD, DRUG AND COSMETIC
PACKAGING MATERIALS COMMITTEE

Shoreham Hotel
Washington, D. C.

March 15, 1972
9:20 a.m.

Present:

- Robert M. Miller, General Chairman, Hercules, Inc., Delaware Trust Building,
Wilmington, Delaware 19899
Watson B. Ackart, Union Carbide Corp., River Road, Bound Brook, New Jersey 08805
William Allen, American Cyanamid Co., Bound Brook, New Jersey 08885
Ronald R. Arnold, M & T Chemicals, Inc., Rahway, New Jersey 07065
Robert C. Asam, The Goodyear Tire & Rubber Co., 1485 E. Archwood Avenue,
Akron, Ohio 44316
W. C. Bachtel, B. F. Goodrich Co., 500 S. Main Street, Akron, Ohio 44318
Norman M. Bornstein, Cryovac, P. O. Box 464, Duncan, South Carolina 29334
Roger G. Boyer, Pantasote Corp. of New York City, 26 Jefferson Street,
Passaic, New Jersey 07055
Kenneth C. Conley, Marbon Division, Borg-Warner Corp., Washington, West
Virginia 26181
Paul F. Cundy, American Can Company, Box 702, Neenah, Wisconsin 54956
Richard A. Dannells, Dart Industries, Inc., P. O. Box 37, Paramus, New Jersey 07450
LaVerne J. DeCorte, Sinclair-Koppers Company, Frankfort Road, Monaca,
Pennsylvania 15061
Daniel S. Dixler, Keller and Heckman, 1150 17th Street, N.W., Washington, D.C. 20036
Dr. Ernest M. Dixon, Celanese Corporation, 522 5th Avenue, New York, New York 10036
Thomas J. Dolce, Celanese Plastics Co., Box 828, Greer, South Carolina 29651
George W. Ferner, The Goodyear Tire & Rubber Co., 1144 E. Market, Akron, Ohio 44316
Robert P. Fischer, Kerr Glass Manufacturing Corp., P. O. Box 4000, Lancaster,
Pennsylvania 17604
David H. Fishman, Celanese Plastics, Morris Court, Summit, New Jersey 07901
Gerhard H. Fuchs, Allied Chemical Corp., Box 1057R, Morristown, New Jersey
David R. Gaskill, Mobil Chemical Co., P. O. Box 240, Edison, New Jersey 08817
B. J. Garceau, ICI America Inc., 151 South Street, Stamford, Connecticut 06904
Max Goldfrank, Stein, Hall & Co., Inc. (Celanese), 605 Third Avenue, New York,
New York 10016
S. F. Goodheart, Levey Div. Cities Service Co., 630 Glendale-Milford Road,
Cincinnati, Ohio 45215
Charles H. Goodman, The Dow Chemical Company, 2030 Dow Center, Midland,
Michigan 48640

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Francis W. Greenough, Cryovac Division, W. E. Grace & Co., P. O. Box 464, Duncan,
South Carolina 29334
Taylor Hanavan, E. I. duPont de Nemours, Film Dept., 1007 Market Street,
Wilmington, Delaware 19898
G. Frederick Hanna, Marbon Division, Borg-Warner Corp., P. O. Box 68, Washington,
West Virginia 26181
Jerome H. Heckman, SPI General Counsel, 1150 17th Street, N.W., Washington, D.C. 20036
Michael Hirsch, B. F. Goodrich Chemical, 5100 Oak Tree Blvd. Cleveland, Ohio 44111
Karl A. Hochschwender, American Hoechst Corp., Route 202-206 North, Somerville,
New Jersey 08876
John F. Jones, The Standard Oil Co. (Sohio), Midland Bldg., Cleveland, Ohio
Otto S. Kauder, Argus Chemical Corp., 633 Court St., Brooklyn, New York 11231
Peter P. Klemchuk, CIBA-GEIGY Corp., Ardsley, New York 10502
Robert H. Knust, Celanese Plastics Co., Morris Court, Summit, New Jersey 07901
Jack L. Lawing, Eastman Chemical Products, Inc., Kingsport, Tennessee 37662
Clyde W. Leaf, BASF Wyandotte Corp., Biddle Avenue, Wyandotte, Michigan 48183
Jerome H. Ludwig, Synthetic Products Co., 1636 Wayside Road, Cleveland, Ohio 44112
Joel Markowitz, Dart Industries Inc., Chemical Group, W. 115 Century Road,
Paramus, New Jersey 07652
Peter Morison, Eastman Chemical Products Inc., Kingsport, Tennessee 37662
Peter M. Nemkov, Keller and Heckman, 1150 17th Street, N.W., Washington, D. C. 20036
Donald W. Pugh, U.S. Industrial Chem. Co., P. O. Box 218, Tuscola, Illinois 61953
Lorence Rapoport, Olin Corp., P. O. Box 200, Pisgah Forest, North Carolina 28768
George A. Richter, Rohm and Haas, Independence Mall West, Philadelphia,
Pennsylvania 19105
Robert E. Rutherford, Gulf Oil Corporation, 439 Seventh Ave., Pittsburgh,
Pennsylvania 15230
A. Merrill Schnitzer, Phillips Petroleum Co. 356 Research Building 1, Bartlesville,
Oklahoma 74004
W. W. Sederlund, National Starch & Chemical Corp., 1700 West Front Street,
Plainfield, New Jersey 07063
Dwight M. Sheets, Shell Chemical Company, One Shell Plaza, P. O. Box 2463,
Houston, Texas 77001
Matthew E. Smith, Owens-Illinois, 14th & Adams Sts., Toledo, Ohio 43606
Charles J. Spiegl, Continental Can Co., 7622 S. Racine Ave., Chicago, Illinois 60620
Don F. Thompson, Amoco Chemicals, Tech Center, Naperville, Illinois 60540
Judith A. Tins, Celanese Corporation, 522 5th Avenue, New York, New York 10036
Philip J. Vanderhorst, DuPont-Film Department, 1007 Market Street, Wilmington,
Delaware 19898
E. J. Vandermark, Northern Petrochemical Co., 2223 Dodge St., Omaha, Nebraska 68102
Willard M. Westveer, The Dow Chemical Co., 2040 Dow Center, Midland, Michigan 48640
George F. White, Jr., Reynolds Metals Co., 10th & Byrd Sts., Richmond, Virginia 23219
Ambrose G. Whitney, W. E. Grace & Co., Research Division, Clarksville, Maryland 21029
Ronald M. Wilson, Jr., Emery Industries, Inc., 4900 Este Ave., Cincinnati, Ohio 45231
L. W. Ziemiak, Foster Grant Co., Inc., 289 N. Main Street, Leominster, Massachusetts
C. L. Condit, Secretary, SPI, 250 Park Avenue, New York, New York 10017

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Under the Chairmanship of Robert M. Miller, Hercules, Inc., a regular meeting of the SPI Food, Drug and Cosmetic Packaging Materials Committee convened in the Shoreham Hotel, Washington, D. C. at 9:20 a.m. Mr. Miller commented on the outstanding attendance, noting that there were more present than the Secretary expected.

Further, Mr. Miller mentioned that it had been some time since the Committee conducted a so-called "closed" meeting since at the last few sessions, there have been FDA people on the program, and at times others not part of the Committee. He asked those present to feel free, at any time, to pose questions throughout the day's meeting.

Referring to the detailed Agenda, Mr. Miller then asked for the usual self-introductions.

Minutes of Last Meeting Approved

Indicating that the last meeting of the Committee was held at the Commodore Hotel, New York City, on June 3, 1971, Chairman Miller asked if there were any corrections or additions to the Minutes as developed and circulated by the Secretary. In the absence of comments, he declared the Minutes approved as circulated.

Preliminary Remarks by Mr. Miller

At this point Mr. Miller expressed pleasure that Charlie Stone, Eastman Chemical Products, Inc., and Vice Chairman of the Committee, as well as Chairman of the Lawyers' Advisory committee is reported to be coming along very nicely following a prolonged illness, and more recently, major surgery. Mr. Miller announced that Jack L. Lawing of Eastman Chemical Products, Inc. would represent Mr. Stone at the day's session, and, at the appropriate time, would deliver the report on the activities of the Lawyers' Advisory Subcommittee.

Comments by Chairman Miller on Activities and Scope of the SPI Public Affairs Council and European Developments

Chairman Miller then gave the following report, dealing with the SPI Public Affairs Council and European developments:

Report of Chairman Miller

SPI PUBLIC AFFAIRS COUNCIL

"SPI has formed a new operating division known as the Public Affairs Council. It formerly was designated as the Plastic/Packaging Council and Plastics Council and was initiated as the single focal point of the SPI environment program. It is now a division of SPI and will have representation on the SPI board. A draft of by-laws for the council has been prepared and is ready for adoption. It is composed of management representatives of many member companies and has the following objectives:

- a) Convince influential publics about the benefits of plastics.

- b) Convince our customers that not only do plastics represent good, modern design and material solutions, but also that plastics do not expose these customers to public relations problems.
- c) Respond quickly and accurately to public criticism of plastics.
- d) Counteract or repeal anti-plastics legislation.
- e) Demonstrate that the plastics industry has a genuine and constructive concern for improving our environment.

"To assist in reaching these objectives, the Council has obtained the services of Hill and Knowlton, one of the leading public relations firms. In addition, the Council has hired its initial legislative representative.

"From its inception in mid-July to the end of 1971, the Council operated on a budget of approximately \$391,000. Pledges totalled approximately \$340,000 and SPI pledged \$50,000 to make up the difference. The Public Affairs Council has a proposed 1972 budget of \$975,000. As of the middle of February, pledges have been received in excess of \$850,000 from 44 member companies. They hope to obtain pledges of at least \$1,000,000. If your company has not joined the Council, please check and see that they know about its activities and can become a member. This is a united plastics industry effort with which we all should be concerned.

"Three current 'hot areas' of immediate concern to the SPI Public Affairs Council are the states of Massachusetts, Vermont and New York. Bills pending in Massachusetts concern taxes on non-returnable and no deposit containers and perhaps some actual bans on certain items. Vermont has a bill to be passed momentarily which stipulates a 1 mil/container tax on all separate closed containers (bottles, jars, cans and cartons). We just have been informed that this Vermont bill was not passed but was returned to committee for further consideration. New York has a non-returnable container tax bill before the legislature, as well as one to ban PVC. The SPI PAC is actively engaged in following these actions.

"The Subcommittee on the Environment of the Senate Commerce Committee just concluded hearings (held on March 6, 10 and 13) concerning the environmental aspects (primarily of solid waste disposal) of containers of all types, Ralph Harding, Executive Vice President of SPI, made a statement to the subcommittee regarding the environmental characteristics of plastic containers.

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"We do not want to take time to discuss the details of these actions here, but if any of you is interested in them, we suggest you contact Mr. Sam Nuspliger at the SPI office.

INTERNATIONAL DEVELOPMENTS

"The Council of Europe is holding a second symposium on food packaging in Rome on March 23 and 24 as a follow-up on the 1971 symposium in the Netherlands, which I attended as a representative of SPI and reported on at the June 3 meeting. This symposium is being hosted by the Italian government, and, unfortunately, they decided not to invite any delegates from the U. S. Apparently they plan to continue discussion of 'global' migration and the philosophies of policing and regulating food packaging materials. We will have to receive our reports of their deliberations from our European contacts.

"We have received word that the Dutch have come up with a new approach to regulating packaging materials as an attempt to resolve the differences between the French and Italian philosophy and that of the Dutch and Germans so that uniform regulations can be established. We cannot see that this new approach will be of much help to us in our negotiations with FDA, but here is the Dutch proposal as we understand it:

"The old system was like that of West Germany in that positive lists of recommended or approved additives were given for each plastic or packaging material, with limitations on the quantity of many. The limitations resulted from toxicological considerations, self-limiting features or the amounts tested in each instance. This meant an analytical method was required for each additive in each plastic. The Dutch commission analyzed the list, deleting all additives where the limitation was not based on toxicological considerations and where the compounds did not give rise to toxicological problems. This resulted in deletion of 75% of the list. For the remaining 25%, it was decided to replace the maximum concentration in the plastic or other food packaging material with a maximum number of milligrams in food or a food simulating solvent. This number, when converted to ppm's in food, should not exceed the ADI (Acceptable Daily Intake) times 60. An assumption is made that the daily food intake is 1 kg/day. Since 1 kg of food is wrapped in an average of 6 sq. dm. of plastic, and the migration of plastics does not exceed 10-12 mg per sq. dm, this calculates to 60 mg/kg food or 60 ppm. This 60 ppm is an arbitrary number, but it was concluded that if the migration (or extraction) of a specific ingredient does not exceed the ADI times 60, it may be used in any quantity with no limitations or analytical tests required. Since it was established that the maximum migration of

a plastics component was 60 ppm, compounds with an ADI greater than one will meet these criteria.

"The ADI times 60 has been designated as the Packaging ADI (PADI). The ADI used for most of the calculations has been based on the results of 90-day animal feeding studies. If the migration exceeds the PADI, the specific migration of the additive must be determined, and a limitation for that ingredient will be in the regulations. Thus, an analytical method is required for those compounds. The PADI system supposedly incorporates the 'Frawley proposal' to 0.05 ppm, but we have no details on that as yet. Perhaps we will know more after the Rome symposium.

"The Dutch proposal was developed to attempt to resolve the differences noted at the Noordwijk symposium in 1971 between the Dutch and German approach versus that of the French and Italians. The former had positive lists with provisions for petitioning for new additives, while the French and Italians assumed that plastic packaging materials would offer no hazard to public health if the gross migration or extraction is less than 50-60 ppm when using a procedure similar to our end-use extraction test. The French and Italians desired to use this as a means of policing the law. The new Dutch PADI system supposedly combines the two approaches, which may satisfy the Council of Europe.

"The second item concerning international developments is the notice of a forthcoming seminar on the 'Migration of Additives from Plastics and Their Determination in Fat Simulants', sponsored by Unilever in Hamburg, West Germany."*/

Following Mr. Miller's report on European activities, Norman Bornstein, Cryovac Division, W. R. Grace & Company, suggested that in one manner or another it would be quite desirable to assemble a bibliography of foreign papers on extraction studies or methods which have either been delivered, or are to be delivered at some time in the future. Mr. Miller said that this could very well be considered by the Technical Information Subcommittee, and asked that the Subcommittee Chairman report on such matters from time to time to the extent that is possible to assemble such a list.

In closing his report, Mr. Miller noted that the international situation as regards the interests of the Committee's members are becoming more and more important and that, therefore, there is every reason for an adequate liaison to be maintained with the various countries abroad, if, for no other reason, than to try to steer them towards a better regulatory system than ours.

*/ Details are contained in the attached announcement, Appendix A.

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Nomination and Election of Officers

Chairman Miller reminded those present that, some time ago, he had appointed a Nominating Committee composed of Messrs. Matthew E. Smith, Chairman, Owens-Illinois; and members George W. Ingle, Monsanto Company; and Max Goldfrank, Stein, Hall & Co., Inc; asking that they propose a slate of proposed officers as well as Steering Committee members-at-large for the period beginning June 1, 1972 to June 1, 1974.

He then called upon Matt Smith to give the Nominating Committee report.

Mr. Smith named the following proposed officers: General Chairman Karl A. Hochschwender, American Hoechst Corporation; and Vice Chairman, Willard M. Westveer, The Dow Chemical Company. The appointment of the following members to the Steering Committee, Karl A. Hochschwender, Chairman, American Hoechst Corporation; W. B. Ackart, Union Carbide Corp.; Paul F. Cundy, American Can Company; Taylor W. Hanavan, E. I. duPont de Nemours & Co., Inc.; Robert M. Miller, Hercules, Inc.; George A. Richter, Jr., Rohm & Haas Company; and Willard M. Westveer, The Dow Chemical Company; was also recommended.

Chairman Miller asked if there were further nominations, and in the absence of any, Mr. Smith moved that the nominations be closed and that the Secretary cast a unanimous ballot for the slate as proposed. The motion was seconded and carried unanimously.

At this point, Chairman Miller expressed deep appreciation for the fine cooperation he has had from both the Steering Committee and the SPI office during his tenure of office, and expressed hope that some accomplishments were made during his Chairmanship.

Report of SPI General Counsel

Chairman Miller next introduced Jerome H. Heckman, Keller and Heckman, and General Counsel for SPI, to deliver his regular report on various regulatory activities relating to the interests of the industry.

[Please note: Attached hereto is a reproduction of Mr. Heckman's complete presentation at the day's session, including various attachments in the form of appendices mentioned by him.]

At the outset, Mr. Heckman asked that those present interrupt him at any time should they have questions to pose or, on the other hand, at any point where formal action was requested to be taken at the day's session regarding any one or more of the items he discussed.

In discussing the status of the USDA proposed amendments to meat inspection regulations, Mr. Heckman reminded those present that attached to his report (see attachment to these Minutes) was MPI Notice 69 while available for the

first time at the day's meeting of the Steering Committee was a document labeled MPI Notice 74.

It was requested by Mr. Heckman at the day's session that the Secretary place the MPI 74 Notice in the Minutes. It follows:

"UNITED STATES DEPARTMENT OF AGRICULTURE MPI NOTICE 74
Consumer and Marketing Service
Meat and Poultry Inspection Program
Washington, D. C. 20250

"INFORMATION FOR: All MPI Personnel, Owners, and Operators
of Official Establishments, and State
Officials

Section 302.3 in the Manual of Meat Inspection Procedures
and Section 81.95 of the Poultry Inspector's Handbook

"The above sections are being revised to permit the use of continuing letters of FDA guaranty.

"Please advise those who inquire, that such letters will be permitted whenever letters of FDA guaranty pertain in the instruction to be implemented April 1, 1972.

"An example follows:

'The articles listed herein comprising each shipment or other delivery hereafter made by (name of person or company giving guaranty) to, or on the order of (name and address of person or company to whom the guaranty is given) is hereby guaranteed as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act.'

(Signature of person with responsible
position in supplying firm--address)

/s/
Fred J. Fullerton, Director
Field Operations Division"

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There was a great deal of discussion at the day's session relating to Mr. Heckman's report on the negative-type publicity which has appeared on the use of phthalate plasticizers ever since the announcement of Dr. Rubin's findings on the PVC blood bags problem. Especially helpful in the course of this discussion was a report given by Peter Morison of Eastman Chemical Products, Inc. relative to a recent meeting of a special MCA Committee called to discuss the phthalates problem. Mr. Morison reported as follows:

Manufacturing Chemists Association Technical
Meeting on Phthalates - February 24, 1972

"Thirty-three member companies of MCA most intimately affected convened in Washington, D. C. on February 24, 1972 to discuss the significance of publicity on phthalate plasticizers used in bio-medical applications, particularly blood bags and medical tubing.

"It was agreed that some toxicological data on ingestion of phthalates has been published and substantially more information of value is believed to exist in company files. It would be helpful to pool existing unpublished data and appraise its applicability to the current problem.

"It was noted that a test program representing use of plasticized PVC in sensitive applications is under way at Stanford Research Institute and supported by representatives of industry. Results of this program are not expected to be available for some months.

"At the meeting, representatives of eight MCA member companies volunteered to create an Ad Hoc Planning Group on Phthalate Studies for the purpose of developing a program for further consideration which may include a meeting with Drs. Rubin (Johns Hopkins), Autian (University of Tennessee), and Guess (University of Texas), and other researchers in this field.

"The Ad Hoc Committee is composed of representatives of the following companies:

Baxter Laboratories	(Dr. Gesler)
Borden Chemical Co.	(Dr. Cummin)
Eastman Kodak Co.	(Dr. Raleigh)
Enjay Chemical Co.	(Dr. Livingston)
W. R. Grace & Co.	(Mr. Magram)
Monsanto Company	(Mr. Graham)*
Union Carbide Corp.	(To be named)
USS Chemicals	(Dr. Mackay)

*Temporary Chairman

"MCA will serve only as a vehicle reflecting the position of

its member companies. MCA sponsorship of any program must be approved in advance by its Board of Directors and funded by participating member companies."

Thereafter, Mr. Miller pointed out that the Steering Committee, in a meeting the previous evening, had expressed great concern about the phthalates problem and believes this whole matter should be brought to the special attention of the SPI Board of Directors. In this regard, Bill Westveer, a member of the Steering Committee, first proposed a motion whereby the full Committee would approve approaching the SPI Board of Directors to call a meeting of PVC and plasticizer producers in order to ascertain whether the time has come for a position paper to be prepared on the use of these materials if, for nothing else, than to protect the market where these materials are known to be advantageous and have favorable characteristics.

There was then a great deal of discussion about the matter, one question raised being whether the action proposed by the Steering Committee might result in the preparation of a position paper by SPI which could duplicate or conflict with the present work of MCA in this area. It was noted that at a recent special MCA meeting it was decided that it was premature from a technical point of view to prepare such a paper. In any case, it was reported that the MCA Committee is considering conducting a literature search, and has asked companies represented on the study committee of MCA to make a search of their own files in order to provide more input on the entire matter. The MCA group apparently has also asked various toxicologists to review the works of such researchers as Dr. Rubin and others; determine then, what further information is required; and, finally, recommend what future work should be undertaken, if any.

Mr. Bornstein urged that it would certainly seem more desirable to effect liaison with the MCA Committee, rather than duplicate its activities. Chairman Miller and others agreed that Mr. Bornstein's points were very well taken. He noted that, in the final analysis, the real intent of the motion proposed by the Steering Committee was to make certain the seriousness of the plasticizers matter is brought to the attention of the SPI Board of Directors since it is recognized that the SPI represents a segment of industry, principally fabricators and converters, which are not necessarily represented in MCA activities.

It was further noted that this Committee does believe the matter requires SPI Board of Directors consideration because of its marketing and public relations overtones. The present constitution of the SPI Food, Drug and Cosmetic Packaging Materials Committee would not appear to be of the type which would assure completely appropriate activity on the phthalates matter for this reason. Mr. Heckman noted that perhaps an entirely new Committee should be considered by SPI, and should include marketing people who recognize the problems as they relate to selling the products involved. Furthermore, Mr. Heckman said, call it a position paper or not, what actually is needed is a kind of response

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from the Society to answer inquiries which are beginning to be made at various levels, including ones he is receiving from Capitol Hill.

Finally, after much discussion on the composition of a motion which would direct the whole problem in one form or another to the attention of the SPI Board of Directors, the following motion was carried with one negative vote:

"The SPI Food, Drug and Cosmetic Packaging Materials Committee orders its Chairman to suggest to the SPI Board of Directors that it consider calling a meeting of PVC and plasticizer producers, as well as users, in order to ascertain what course of action should best be taken to clarify the present phthalate plasticizer situation for the industry, and when necessary, for inquirers on the subject."

Chairman Miller agreed that, for the present at least, there should be liaison between SPI and the MCA Committee on the matter of phthalates, PVC, etc. At this point he asked Norm Bornstein to accept this liaison position and Mr. Bornstein agreed to do so.

At another point in his presentation, Mr. Heckman asked for direction as to whether it is feasible and possible for a small amount of barium compound to be added to plastics generally so that x-rays could more readily detect a swallowed substance.

In dealing with this matter in detail in his report, Mr. Heckman also discussed at the day's meeting the various attachments to his presentation to illustrate that a Dr. William P. Slover, Hartford Radiology Group, Hartford, Connecticut, points out that as a radiologist he is called upon from time to time to find a foreign body which a child has ingested or inhaled, and that he wonders, in the case of plastics, whether it would be possible to impregnate an object with barium; which is readily detected on an x-ray.

Essentially, Mr. Heckman asked for general guidance at the day's session as to how he might answer this inquiry.

Several opinions were offered, such as the fact that a study would have to be made as to how much barium can safely be added to the various molding compounds as they relate to compatibility for one thing, and how such compounding would affect properties such as impact. It was suggested during the discussion that if the designation "barium compound" could be avoided, thus allowing for other materials of this nature to be used, it might be desirable and that care must be taken to assure that the system is not construed as a diagnostic drug.

It was revealed at the day's meeting that the barium compounds have been introduced effectively in polystyrene.

By way of summary, Mr. Heckman said that it would appear that introducing a barium system into plastics does not pose a major problem but, on the other hand, it is not without its problems which would have to be investigated and considered in the context of specific applications. On the other hand, Mr. Heckman noted that this whole matter is also being taken up with the toy manufacturers by FDA in order to resolve any problems which might exist.

During a discussion of the PCB problem, it was noted that in the March 13 edition of Food Chemical News there was an article on the polychlorinated biphenyls.

Speaking on the subject of updated methodology to provide PCB-free "certificates" to customers, Mr. Heckman pointed out that W. B. Papageorge of Monsanto has supplied such a method to many inquirers. The question arose at the day's meeting, however, as to whether Mr. Papageorge has updated his procedure since last summer, or whether it is otherwise adequate for plastics. Dan Dixler, Keller and Heckman, said that his information is recent and that apparently Mr. Papageorge's test method does not include recent updating but, on the other hand, he was not too certain of this.

The question then arose as to whether the Committee should organize a task force to either develop procedures or at least determine whether more specific procedures are actually needed at this time. For instance, it was opined that the paper people, more involved apparently with this problem, may be developing all of the type methodology that is needed, thus making it unnecessary for the SPI Committee to get involved at all. Also brought out was the fact that there is in ASTM a Committee known as F-2 dealing with flexible materials that has considered this matter to some extent. Finally it was decided that Mr. Miller would assign this whole problem to the Technical Information Subcommittee for full investigation and, if necessary, test method development.

At this point, Mr. Norm Bornstein, W. R. Grace & Company, volunteered to work on the project, and Mr. Westveer, Chairman of the Technical Information Subcommittee, asked that others advise him should they care to help on the PCB matter. Watt Ackart also noted that a Union Carbide paper on the subject would appear in the March issue of Modern Packaging Magazine.

At the end of his discussion, Mr. Heckman dealt at some length with devices legislation, and, in this connection, asked the Committee whether it wished to take a position on the FDA sponsored bill on devices, (see Mr. Heckman's attached report) in view of the fact that there may soon be a time when the preparation of testimony is called for either for the legislation, against it, for it in part, against it in part, etc.

On a more specific point, Mr. Heckman said that, as his report indicates, he would like to have the Committee's instructions about the invitation received from the Food and Drug Administration to supply it with information about an SPI Subcommittee which can be called upon to work with the Division of Standards

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of the Office of Medical Devices with a view towards development of future device standards, where needed. Mr. Heckman felt that a permanent Subcommittee on "medical devices" is quite in order at this time.

Taylor Hanavan, E. I. duPont de Nemours & Co., Inc. moved that the Chairman appoint and organize a standing Subcommittee on Devices. The motion was seconded and carried unanimously.

Chairman Miller then appointed George Richter, Rohm & Haas Company as Chairman, and the following individuals volunteered to serve on the Subcommittee: Philip J. Vanderhorst, E. I. duPont de Nemours & Co., Inc. (Film Department); Ernest M. Dixon, Celanese Corporation; E. J. Vandermark, Northern Petrochemical Company; Peter Morison, Eastman Chemical Products; Leo Ziemlak, Foster-Grant; and, finally, Daniel S. Dixler, Keller and Heckman, who will serve as Subcommittee Secretary.

Reports on Liaison with Other Organizations

Mr. Miller then called for the regular reports on activities of other organizations relating to the interests of the Committee.

Pharmaceutical Manufacturers Association
and U. S. Pharmacopeia--Drug
Packaging Materials Subcommittee

W. B. Ackart, Union Carbide Corporation gave the following report:

"The June 3, 1971 report of this Subcommittee included the details of its expanded sphere of interest, name change, and personnel changes which have taken place. We also reported at that time that our report on 'Methodology for Testing Polyolefin Containers for Tablets, Capsules, Oral Powders, and Granules' had been accepted by the Quality Control section of the Pharmaceutical Manufacturers Association who in turn had submitted it to the U. S. Pharmacopeia for publication. Some uncertainty regarding which draft had reached the PMA was satisfactorily resolved through a meeting with the appropriate PMA people.

"Last November, we were contacted by Dr. Jules Pinsky, a charter member of this Subcommittee who is now associated with The Mearl Corporation. Dr. Pinsky told us that the draft of the Methodology had come from Mr. John Ruggiero of the PMA staff to Mr. George Schneller, Chairman of the U. S. Pharmacopeia Advisory Panel on Containers and Packaging who in turn referred it to Jules as chairman of their Task Group on Plastic Containers.

"Dr. Pinsky suggested some modifications in the procedure which were circulated to this Committee and shortly thereafter a

telephone conference call was arranged between Dr. Pinsky and three of us at which agreement was reached regarding the changes. These included (1) the complete removal of the biological test, (2) a narrowing of the density limits from 0.020 g per cc to 0.005 g per cc where one polyolefin resin may be substituted for another in a packaging situation, and (3) a change in the form of the formula for water vapor permeability.

"Dr. Pinsky has circulated the revised method to members of his task force and has received no adverse comments. The parent Advisory Panel was also circulated and Dr. Pinsky feels that the Methodology can be cleared for publication this year. When this is accomplished, it is our intent to approach Food and Drug to seek changes in their regulations to permit the interchangeability in dry drug packaging of a polyolefin resin with any other manufacturer's generic counterpart where the basic specifications are the same as determined by the published methodology."

In closing his report, Mr. Ackart said that he had just received some proposed definitions and procedures for a forthcoming edition of the U. S. Pharmacopeia. He said that he would circulate this information to members of his task force.

Manufacturers' Chemists Association

Taylor W. Hanavan, E. I. duPont de Nemours & Co., Inc., reporting on MCA's Food, Drug and Cosmetics Chemical Committee activities, first advised that he considers it one major achievement of the MCA group that George W. Ingle, Monsanto Company, was elected Vice Chairman so that he will soon be the incoming Chairman.

Mr. Hanavan next reported that Dr. Dodgen of National Academy of Sciences, who is working on the FDA GRAS survey and Food Chemicals Codex, has recently been sitting in on discussions with the MCA Committee so that the GRAS survey form now being circulated embodies the MCA suggestions and comments. Continuing, Mr. Hanavan noted that the MCA Committee had provided testimony on the Toxic Substances Control Act of 1971; and has issued 40,000 copies of a new booklet entitled "Food Additives--What they Are and How They are Used." In conclusion, Mr. Hanavan made mention of the recent meeting of the Society of Toxicology and the symposium on mutagenicity studies since this has been the subject of FDA-MCA controversy, just as such work was viewed critically at the Toxicologists' meeting the previous week.

Can Manufacturers' Institute

Charles J. Spiegel, Continental Can Company, Inc. indicated there was nothing new to report in this area.

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SPI Market Development Committee of
The Plastic Bottle Division

Matthew E. Smith, Owens-Illinois, presented the following report:

"I wish to point out to some of you that the Food and Drug Bottling Committee of the Plastic Bottle Division is now called the Market Development Committee of the Plastic Bottle Division. This change in name was made to reflect more closely the objectives and plans of our Committee.

"As previously mentioned, members of the Bottle group worked closely with Jerry to help prepare SPI's report to ATFD which they used very favorably in writing their initial Environmental Impact Statement. For obvious reasons, we are following this very closely.

"At our last meeting on February 29 in New York, we discussed the possibility of holding another seminar late in '72 or early in '73. The details are not finalized as yet."

American Paper Institute

Chairman Miller called upon Paul Cundy, American Can Company to report on activities of the American Paper Institute knowing of the concern which the API has presently as regards the PCB problem.

Dr. Cundy reported that API has sponsored research work now being conducted at Hazelton Laboratories to define the scope and significance of the "PCB in paper" problem. The research attempts to answer two questions: an analysis of a broad spectrum of paper, paperboard, and pulp to determine how much PCB may actually be found in such products; and migration tests using paper packaging material with known added quantities of PCB to determine exactly how much PCB could be expected to migrate into foods from paper which contained PCB. In connection with this latter investigation, three different barrier materials are also being evaluated. These are polyethylene, saran coated paper and glassine.

Although the study is not yet completed, Dr. Cundy reported, the 30 day results show that migration even from heavily "spiked" paper is considerably less than was originally believed to be true. When the study is completed, the API hopes that the results will provide firm scientific background to justify limiting the PCB content in food rather than in containers or other packaging materials.

Report of Technical Information Subcommittee

Chairman Miller called upon Willard M. Westveer, The Dow Chemical Company and Chairman of the Technical Information Subcommittee to make his usual report.

In the first place, Mr. Westveer referred to the PCB problem, indicating his Subcommittee would undertake a study of this matter; attempt to determine the relevance and extent of what other groups are doing; gather all of this information; and then make a recommendation on how the Technical Information Subcommittee should proceed. He therefore urged that all present send him any information they have on these matters.

Mr. Westveer then turned the Committee's attention to a listing of recently promulgated food additive regulations, and related regulatory actions. In so doing, he highlighted some of the items in the listing which he felt should be brought to the Committee's attention.

[Please note, attached hereto as an exhibit, dated March 13, 1972, is the regular listing of "Recently Issued Food Additive Regulations"].

Report of Lawyers' Advisory Committee

On behalf of M. C. Stone, Chairman of the Lawyers' Advisory Subcommittee, Jack L. Lawing of that company presented a detailed report. [Please note: This report dated March 15, 1972 is attached as an exhibit]

In concluding his report, Mr. Lawing asked those present to join him in wishing Charlie Stone a quick recovery.

At this point, before the subject of new business was introduced, the matter of the Toxic Substances Act was discussed. William Allen, American Cyanamid Company noted that the Toxic Substances Control Act could be a "Frankenstein monster" although it is generally understood that passage of the legislation in this Session of Congress is unlikely. During the subsequent discussion, it was noted that some customers are asking for impossible guarantees and information about the more than 12,000 substances on the first Government list of toxic substances but this is because of erroneous impressions of Occupational Safety and Health Act responsibilities, not because the Toxic Substances Act has been passed.

New Business

Under the subject New Business, Karl Hochschwender, incoming General Chairman of the Committee, cited two items which he felt would be of interest. One deals with those importing products subject to FDA procedures and regulations. He noted special briefings on this subject are being held in view of the fact that, evidently, FDA is stepping up its inspection program and there is to be more careful screening of certain products under its jurisdiction as they come across the USA borders. Dr. Hochschwender indicated he would be attending one of the briefings to be held on March 16 and would be glad to give a report on the same to the Committee at its next meeting, or perhaps by means of a written report which could be circulated sooner.

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Secondly, Dr. Hochschwender said that the U. S. Tariff Commission is investigating on behalf of the Senate Finance Committee non-tariff barriers and that originally the deadline for comments was March 16 but that he has learned that the Tariff Commission has extended this deadline date to April 11. Essentially, the Tariff Commission is looking for information from those who have encountered difficulties in this area so anyone with such information should consider supplying it to the Tariff Commission which will treat it confidentially. The type restrictions referred to by Dr. Hochschwender are those such as unreasonable food additive regulations and similar official policies of foreign governments that hinder the international exchange of goods.

William Allen, American Cyanamid Company, again brought up the subject of the Occupational Safety and Health Administration and the Act that it administers indicating that his company is beginning to be deluged with requests for information from customers for labeling information, especially on how much is used of a substance that is "so-called 'toxic'". Mr. Heckman acquainted the Committee with the fact that SPI is strongly involved in this whole matter of OSHA through its Safety and Loss Prevention Committee headed up by a staff man, Jerry Carroll, at the SPI office in New York. Mr. Carroll and his Committee are beginning to issue regular bulletins outlining the impact of OSHA on the plastics industry and most certainly Mr. Carroll or Mr. Shaye (in Mr. Heckman's office) would be receptive to hearing from anyone encountering problems of a nature where some assistance or clarification can be given.

Next Meeting

Mr. Miller announced that the time and site of the next overall meeting of the Committee will be left up to the Steering Committee and the new officers, as is customary.

There being no further business, the meeting was adjourned at 2:45 p.m.

Respectfully submitted,

Charles L. Condit, Secretary